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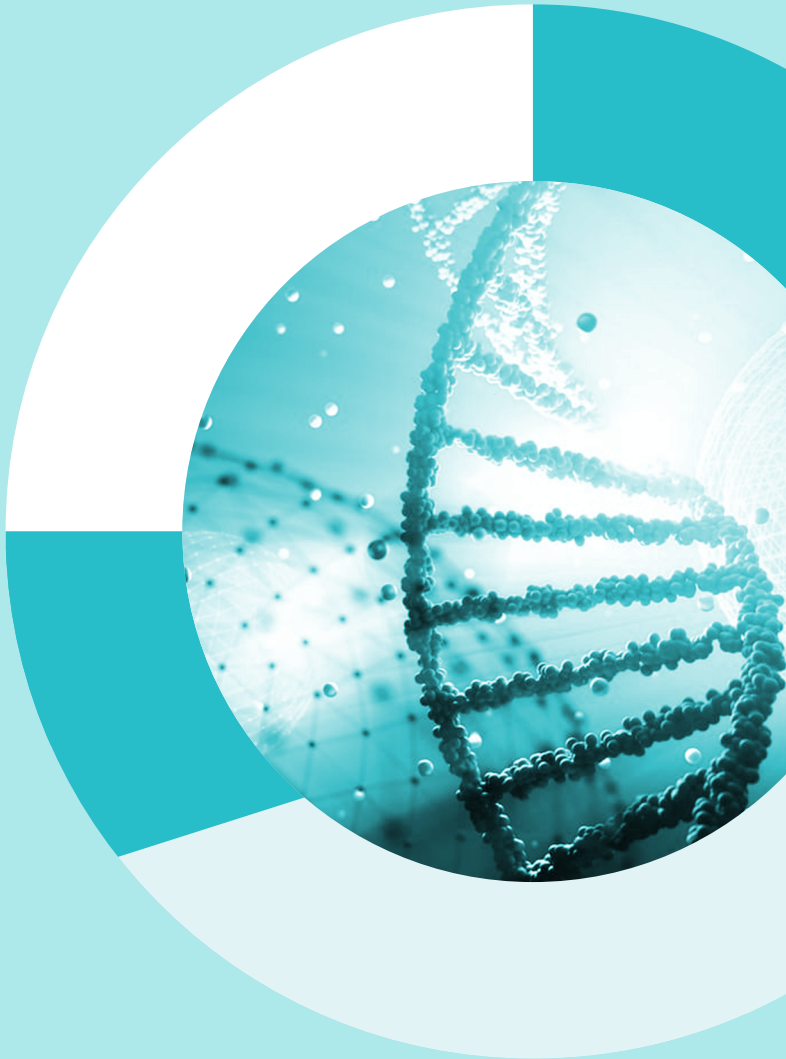

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RESEARCH ARTICLE

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Design, Manufacture and Characterization of a Liver-Chip Model: A Platform for Disease Modeling and Toxicity Screening

Buket Baddal[1,2], **Emil Mammadov**[2,3]

[1]Department of Medical Microbiology and Clinical Microbiology, Near East University Faculty of Medicine, Nicosia, North Cyprus
[2]Microfluidic Systems Research Group, Near East University, DESAM Research Institute, Nicosia, North Cyprus
[3]Department of Pediatric Surgery, Dr. Burhan Nalbantoglu State Hospital, Nicosia, North Cyprus

Abstract

BACKGROUND/AIMS: Drug research and development processes often fail in human clinical trials due to the inability of current *in vitro* cell culture and *in vivo* experimentation platforms to accurately predict toxicity and drug efficacy. There is an increasing need for human relevant systems which will enable studies on target tissue models prior to clinical trials. Drug-induced liver injury (DILI) is an important cause of acute liver failure. Species differences in liver toxicity and the limited predictability of traditional models represent a primary barrier to drug development for DILI. The aim of this study was to establish and characterize a dynamic microfluidic liver-chip with a physiological secretion function, continuous flow and compatibility with monitoring toxicity reactions.

MATERIALS AND METHODS: A biocompatible polymer-based prototype liver chip was designed using 3D stereolithography printing, CNC milling technology and molding. The chip with two microchannels, an upper channel for hepatocytes, and a lower microvascular channel for endothelium was produced by 3D bioprinting. The liver chips, pre-coated with collagen type I, were seeded with HepG2 cells and cell proliferation was monitored via microscopy. Toxicity was measured using a lactate dehydrogenase (LDH) assay. Albumin, alpha-fetoprotein (AFP), alanine transaminase (ALT) and aspartate aminotransferase (AST) secretion were also investigated.

RESULTS: LDH readings demonstrated that the designed microfluidic chip was non-toxic to human hepatocytes. Albumin, AFP, ALT and AST secretions were detected in cellular secretions at physiologically-relevant levels.

CONCLUSION: Overall, this study demonstrated the design and manufacture of a physiologically-relevant microfluidic liver chip model, which can be used in drug-monitoring and toxicity studies.

Keywords: Microfluidic system, 3D bioprinting, organ chip, drug monitoring, personalized medicine

INTRODUCTION

Drug development and disease simulation studies include both *in vitro* and *in vivo* stages. During these stages, multiple repetitions are performed in order to obtain the desired accurate results, leading to the consumption of large amounts of consumables and experimental animals. As a major drawback, incompatibilities between the two stages may occur. A disease model or a treatment which can be simulated at the cellular level can sometimes not be replicated in the animal model.[1] Therefore, scientists have sought models which can be studied both on a cellular level basis and closely represent the model organism. In the search for this model, organ-on-a-chip (OOAC) technology has

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ORCID IDs of the authors: B.B. 0000-0003-3319-2179; E.M. 0000-0001-8143-1643.

Address for Correspondence: Emil Mammadov
E-mail: dremilmammadov@gmail.com
ORCID ID: orcid.org/0000-0001-8143-1643

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recently come into use. OOAC systems contain engineered or natural human-relevant miniature tissues grown inside microfluidic chips. To better mimic human physiology, these chips are designed to control cell microenvironments and maintain tissue-specific functions.[2] It is a promising technology for effective drug discovery and drug screening for precision medicine. OOAC systems have made a significant advancement over the last 10 years. The OOAC was initiated with a lung chip, and has subsequently evolved into systems in which many different organs can be simulated.[3-7] The OOAC technology combines both cell culture and microfluidic systems. The most important distinguishing feature of these systems is that the cell culture medium is not static; it is stimulated with a continuous dynamic fluid flow and mechanical stimuli can be given if required. These mechanical stimuli can be in the form of stretching, which mimics the human organs, such as the simulation of the human respiratory movements via the stretching in a lung chip or peristalsis in a gut-chip. In addition, the dynamic flow of the culture medium in the OOAC eliminates the need for daily medium changes by the researchers, and the amount of consumables is considerably reduced due to the small size of the microfluidic channel.[8]

The liver is the largest internal organ of the human body, with its complex microarchitecture and function which plays a critical role in drug metabolism. Hepatotoxicity and drug-induced liver injury (DILI) are the main causes of drug failures.[9] Moreover, liver diseases are among the leading causes of death in the world, with new cases occurring each year. Although animal models have been traditionally used to investigate human drug metabolism and toxicity prior to clinical trials, rat and dog models have been reported to predict only 71% of the drug toxicities observed in humans.[10]

The aim of the current study was to design a three-dimensional (3D) microfluidic liver chip model which would reflect the characteristics of human liver physiology and pathophysiology; recapitulate the sinusoidal structure of the liver, maintain high cell viability and cellular phenotypes, and mimic natural liver functions. The designed liver chip would allow for the simulation of different disease phenotypes and aid in the development of safer and more efficient personalized treatments.

MATERIALS AND METHODS

Chip Design, Production and Assembly

For the mold design, a two-piece mold system which enabled the production of six chips was designed using the Fusion 360 (Autodesk Inc, USA) software. The production of the molds was accomplished both by using biocompatible resin in a Prusa SL-1 (Prusa Research, CZ) SLA 3D printer and CNC machining of aluminum. Quality control of the molds and canal diameter verification were performed via DinoLite (DinoLite Inc, USA) digital microscopy. The mold surfaces were cleaned with alcohol and distilled water. PDMS (Sylgard 184, Dowsil, USA) and a curing agent were mixed at a ratio of 10:1 and placed in a vacuum desiccator device for 30 minutes to remove air bubbles. This mixture was then poured into the molds and was incubated in an oven at 100 °C for 30 minutes. The two halves of the chip were then removed from the mold after cooldown and stored in dust-proof sealed boxes. Corning Transwell polyester membrane (10-micron thickness, 0.4-micron pore width) (Sigma-Aldrich, St. Louis, MO, USA) was used as the separating membrane between the chip channels. The membrane was cut from the Transwell wells with a scalpel to form strips which coincided with the middle channel of the chip. Two pieces separated from the molds and the previously prepared membrane in the form of upper part-membrane-lower part were applied to all surfaces with the Plasmatreat FG5001 (Plasmatreat GmbH) plasma activator device (IL, USA). As an alternative method, the surfaces of the upper part and the lower part were treated with uncured PDMS to adhere to each other and then cured in an oven at 60 °C for 12 hours. Subsequently, each chip was connected to the Syringe Two (Elveflow, FR) micro-perfusion pump and checked for watertightness. Cross-sectional controls of the first chips were also performed via DinoLite (DinoLite Inc, USA) digital microscopy.

Cell Culture

For cell culture, the HepG2 hepatocellular carcinoma cell line (catalog no: HB-8065, ATCC, Virginia, USA) was used. Vials containing 1 mL of frozen cell suspension at passage 10 were removed from a liquid nitrogen tank, thawed in a 37 °C water bath and added to 14 mL of cell culture medium (DMEM, 10% FBS, and 1% penicillin-streptomycin) (Invitrogen, USA). The cell suspension was centrifuged at 1,500 rpm for 5 minutes. After the centrifugation, the supernatant was gently decanted without disturbing the cell pellet. The cells were resuspended in 5 mL culture medium, and transferred into a 75 cm^2 flask (VWR, USA) containing 15 mL culture medium. After 24 hours of incubation at 37 °C with 5% CO_2, the medium was refreshed and placed in an incubator. The cells were observed daily under an Olympus IX53 inverted microscope and until 80% confluency was reached. Then, the culture medium was removed and the cells were washed with phosphate buffered saline (PBS) (Sigma-Aldrich, St. Louis, MO, USA). Three mL of 0.05% 1 x trypsin-EDTA solution (Thermo Fisher Scientific, MA, USA) were added to the culture dish and this was incubated at 37 °C for 10 minutes. After incubation, the cells were suspended in 10 mL of DMEM with 10% FBS and centrifuged at 1,500 rpm for 5 minutes. The cell pellet was resuspended in 10 mL of cell culture medium in a new cell culture dish and transferred to a 37 °C incubator with 5% CO_2. This procedure was repeated twice per week in order to ensure the continuity of the cell line.

Chip Loading with HepG2

Hydrogen peroxide gas plasma sterilization was performed for all of the chips manufactured. The chip channels were treated with 1 mg/mL Sulfo-SANPAH (sulfosuccinimidyl 6-(4'-azido-2' nitrophenylamino) hexanoate) solution (Thermo Fisher Scientific, MA, USA) with 50 µL in the upper channel and 30 µL in the lower channel. Activation was performed using 365 nm UV light for 20 minutes. Post activation, Sulfo-SANPAH was removed and the channels were washed first with 200 µL of sterile H_2O, and later with 200 µL of 70% ethyl alcohol. The channels were washed 3 times with 200 µL of sterile PBS in order to avoid ethyl alcohol residues. Subsequently, the upper and lower channels of the chips were coated with ~30 µL of 1 mg/mL collagen type I (Sigma-Aldrich, St. Louis, MO, USA) previously prepared with 0.25% acetic acid, and kept at 4 °C overnight. At the end of the incubation period, the collagen in the channels was removed, the channels were washed once with 200 µL of HepG2 culture medium and equilibrated for cell culture.

When 80% confluency was reached, the HepG2 cells were removed from the culture medium and washed with 5 mL of PBS. Then, 3 mL of 0.05% 1 x trypsin-EDTA solution was added to the culture dish and, after shaking gently, the culture dish was incubated at 37 °C for 10 minutes. After incubation, the cells were suspended in 10 mL of DMEM with 10% FBS and centrifuged at 1,500 rpm for 5 minutes. Then, the cells were resuspended in 300 µL of DMEM medium with 10% FBS and they

were stained with 10 µL of 0.4% trypan blue (Sigma) and counted on a Neubauer chamber. The cells were seeded at a concentration of $3x10^6$/mL cells (~30 µL) into the upper channel of a chip previously coated with type I collagen. In order for the cells to adhere to the chip, the chips were placed in an incubator at 37 °C with 5% CO_2 and incubated for 2 hours. After the incubation, the chips were examined with an inverted microscope. The chips were consequently connected to the syringe pump and the flow rate was set to 30 µL/hr. The input reservoir containing 10 mL culture medium and the empty waste output reservoir, chips and perfusion pump were placed into the incubator at 37 °C with 5% CO_2 for the duration of the experiment (Figure 1).

Chip Characterization

The HepG2 cells were examined with an inverted microscope at different incubation times including 6, 24, 36, 48 and 72 hours in order to monitor cell proliferation. Lactate dehydrogenase (LDH) measurements were performed using a colorimetric assay (Sigma-Aldrich, St. Louis, MO, USA) to test for cellular cytotoxicity. The culture medium containing cell secretions collected in the output reservoir was used for the LDH assay. In addition, the albumin, alpha-fetoprotein (AFP), alanine transaminase (ALT) and aspartate aminotransferase (AST) levels in the output culture medium were measured using an ARCHITECT ci4100 Analyzer (Laboratories, Abbott Park, IL, USA) and compared with a DMEM culture medium without cells.

Statistical Analysis

No statistical analysis was required for this study.

RESULTS

Primarily, two mold designs were investigated in this study. It was determined that the first design caused an air bubble problem which prevented the flow of the culture medium, and therefore the study proceeded with design number two (Figure 2). The molds produced from resin by SLA 3D printing prevented complete curing of the PDMS thus leading to the adhesion of PDMS to the mold surface post curing. In order to solve this issue with the resin, the molds were subjected to both heat (60 °C) for 12 hours and a second UV (365 nm) treatment for 30 minutes. After this treatment, the PDMS was easily released from the mold. However, it was noted that the PDMS partially lost its transparency feature. However, PDMS chips which were cured at 100 °C for 30 minutes using an aluminum mold were easily released and showed proper transparency. Another failure was encountered during the air plasma activation of the chip halves to induce adhesion. The parts did not adhere after air plasma treatment, and therefore this method was discarded in this study. Instead, the chip halves were treated with a thin layer of uncured PDMS on the inner surfaces, a polyester membrane was placed in between, and the chips were assembled and cured at 60 °C for 12 hours. With this method, it was noticed that the two surfaces adhered to each other in a watertight manner (Figure 3).

The results indicate that, during the liver-chip culture, HepG2 cells were able to adhere to the upper channel of the liver chip at 1-hour post seeding as shown in Figure 4. Monolayer formation was examined under the microscope on the 3rd, 4th and 6th days post seeding (Figure 5). Culture medium containing cell secretions were collected in the output reservoir for LDH cell cytotoxicity measurements. The levels of LDH in the liver chips were found to be comparable with the DMEM culture medium without cells (Table 1). The cells, which formed a monolayer in the chip, were found to secrete albumin, ALT and AST. In addition, the AFP level in cells was found to be high and concordant with regenerating hepatic cellular physiology.

Figure 1. Incubator setup (chip, chip tray, perfusion pump, connectors, and output vials).

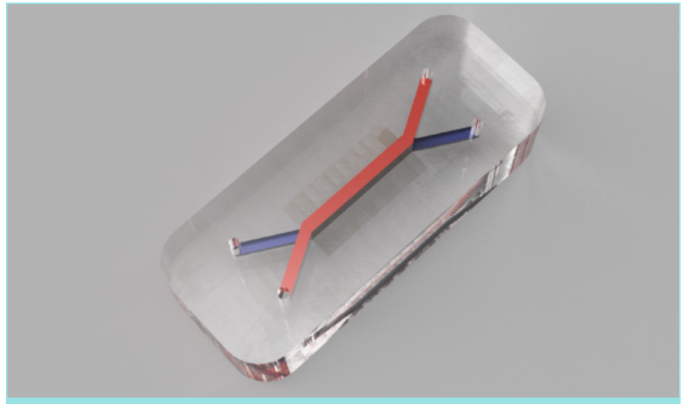

Figure 2. Chip design which was selected for this study (rendered in Autodesk Fusion360 [Autodesk Inc, USA)].

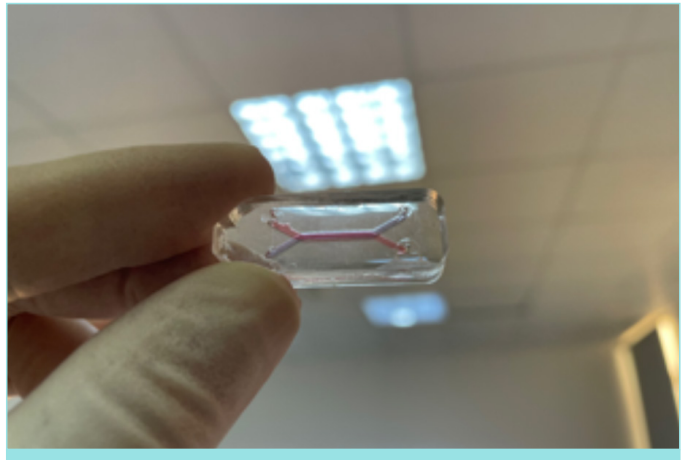

Figure 3. Assembled chip after water-tightness test (different dye colors indicate separate channels).

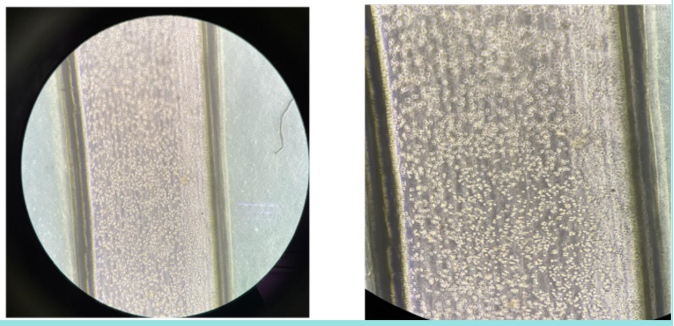

Figure 4. HepG2 cells attached to the chip upper channel 1-hour post seeding [(A) 10x magnification, (B) 20x magnification].

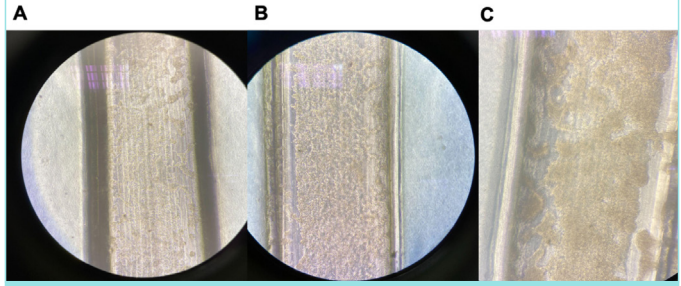

Figure 5. Proliferation of HepG2 cells on the liver chip and monolayer on (A) day 3, (B) day 4 and (C) day 6 (10x magnification).

Table 1. Comparison of the HepG2 liver chip and DMEM culture medium for cellular secretions

	Liver chip	DMEM without cells
LDH	45 U/L	37 U/L
Albumin	15 mg/L	7.41 mg/L
AFP	978 ng/mL	0
ALT	<6 U/L	ND
AST	3 U/L	ND

ND: Not detected, DMEM: Dulbecco's modified Eagle's medium, LDH: Lactate dehydrogenase, AFP: Alpha-fetoprotein, ALT: Alanine transaminase, AST: Aspartate aminotransferase.

DISCUSSION

Time and cost are two significant parameters for the R&D of new drugs. The development of a new drug takes about 12 to 15 years and costs about 800 million US dollars. In the R&D process, which consists of four phases, namely discovery and research, preclinical studies, clinical studies and treatment approval, 10 of approximately 10,000 compounds taken into animal testing reach clinical trials and only 1 is approved by the pharmaceutical agencies.[11] In this approach, only the preliminary physiological and pathological effects and toxicity results of the tested drug in tissue culture models can be observed. If the *in vitro* results are promising, the effects of the compounds developed are further investigated using animal models. However, these two models have significant disadvantages. For example, *in vitro* models cannot fully represent the complex cell-cell and cell-matrix interactions, and this incomplete interaction may lead to erroneous study results.[12] Drugs compounds shown to be effective *in vitro* may be ineffective during *in vivo* studies. Therefore, unexpected toxicity and low efficacy not detected during *in vitro* studies represent one of the most common and important causes of drug development failures. In addition, the highest rate of failure in drug development occurs in the second and third phases of clinical trials conducted in the final stages. For this reason, critical studies performed in the earlier stages significantly reduce costs and time spent in the process. The main reasons for the failure of new drug candidates can be attributed to the ineffectiveness of the existing *in vivo* and *in vitro* models, and the inability to detect serious side effects through these models.[13]

Although the current market size of OOAC technology is not as much as its potential, it was 7.5 million USD worldwide in 2016. According to some estimates, this market size will increase rapidly and may reach 163 million USD by 2023 with the completion of the existing R&D projects and an increase in the acceptance rates of organ chips in pharmacology.[14] Considering the use of the animals as well as the high costs, there is an increasing need for innovative alternative research processes which can achieve success in a shorter time, and which can be investigated using target tissue models before starting clinical studies, thus increasing the reliability of the R&D process. Recently developed bioengineered devices which mimic human organs or tissues have emerged as OOAC technology in the literature.[15] OOAC is an *in vitro* technique in which the mechanical and physiological responses of human tissues and organs are recreated and simulated by 3D microfluidic and other micro-scale supported structures.[16,17] Cell and tissue cultures made with standard cell culture flasks, petri dishes and well plates have many disadvantages such as being static, lacking extracellular matrix, and having deficiencies in modeling human tissue physiology, pathophysiology and microstructure. Microfluidic organ-chips enable 3D cell cultures in designed microchannels, and by better modeling complex tissues with multi-cell cultures, enable assays which cannot normally be performed with the existing experimental methods to be performed.[18] When previous studies on OOAC are examined, it can be observed that the importance of OOACs which can mimic the functions of various living organs, including the kidney, liver, lung, brain, skin, bone marrow and intestine has increased in recent years.[19-22] If the liver is taken as an example, the role of both new drug candidates and chemicals such as food additives in liver metabolism should be examined before human use. It is not possible to fully understand human liver tissue cells through animal models. Since *in vitro* cell lines proliferate on a single surface, they cannot be successfully simulated with liver tissue. With the OOAC design, it is possible to place hepatocytes, endothelium, Kupfer, stellate and iPSC cells into the microchannel in order to enable the physical simulation of the liver, or it is possible to create a spheroid, which is a 3D cell culture form from hepatocytes, and model 3D liver tissue within microchannels via these spheroids.[23,24]

With the current study, the first organ-chip study was established in our region, and although it was only a pilot organ-chip study, the results obtained were promising. In this study, it was observed microscopically that HepG2 cells continued their physiological development on the OOAC platform created, and the cells were observed to secrete proteins physiologically. Although HepG2 cells are hepatic carcinoma cells and are more disadvantageous compared to normal hepatocytes due to their proximity to the fetal liver, they represent a good model for proof-of-concept studies. During this study, significant potential advantages of microfluidic systems over conventional methods were observed. The most important of these is that the cells do not need intermittent media replacements due to the dynamic flow, and the positive effects of dynamic flow on cell physiology compared to static environment. The flow of dynamic DMEM or other culture media solutions in the chip channel has been proven to mimic the physiological blood or extracellular fluid flow of cells, and has also been shown to trigger growth. Although not included in the results, an increase in AFP secretion was observed within days in our study. It is also likely that risks of deterioration of the sterile environment will be reduced as this method requires less intervention. However, the most important advantage of microfluidic systems can be stated as being the use of very limited amounts of biomaterial. This allows a higher number of experiments to be performed with the same amount of material consumption compared to conventional methods.

In the context of the recent literature, a plethora of studies have been performed in order to demonstrate the superiority of microfluidic liver-on-a-chip systems over conventional cell culture methods in terms of their similarities to the physiology, mechanisms, and functionalities of liver cells in an *in vitro* environment. In particular, the use of primary hepatocytes obtained from liver biopsies or non-transplantable livers has been stated as being the gold standard for the development of human-relevant *in vitro* liver models, yet human induced pluripotent stem cells (hiPSCs), non-parenchymal cells and hepatic cell lines, which was the choice of cell source in the current study, are also being used as alternatives. In addition to monolayer cultures, matrix-free spheroids/organoids-on-chip, scaffold/hydrogel-based 3D liver OOACs and 3D liver OOACs using bioprinting are being considered as the emerging models for liver chips.[25] Furthermore, models such as the PhysioMimix liver-on-a-chip have recently been proposed and their utility has been shown to be effective for the exploration of multiple drug metabolism applications.[26] A hybrid polymer-based microfluidic platform, including cyclic olefin copolymer and PDMS, has also been developed for culturing hepatocytes and it has been demonstrated to retain the functionality and metabolic activity of perfusion culture as assessed by the secretion rates of albumin, urea, and cell viability visualization. This hybrid platform has been shown to produce comparable biomarker levels similar to published studies on other *in vitro* models.[27] More recently, a customizable microfluidic origami liver-on-a-chip model which simplifies the laboratory-scale fabrication of organ-on-chip models and hence speeds up chip development and optimization without reducing structural and functional features has been proposed.[28]

In the current study, the levels of albumin, AFP, ALT and AST values of HepG2 cells were also measured. Butterfield et al.[29] previously demonstrated that HepG2 cells cultured in 24-well plates produced AFP at 606 ng/mL/10^6 cells at 24 h. In our study, the amount of AFP secretion was found to be 978 ng/mL, which was comparably higher in the liver chip. Similarly, albumin secretion by HepG2 cells in tissue culture has been reported to be between 1.7-2 µg/mL, which is lower than the albumin values obtained in the liver chip (15 µg/mL).[30,31] Additionally, ALT and AST levels secreted by HepG2 cells in dishes or multi-well plates have been reported to be 3 IU/L and ~5 IU/L in the literature, respectively.[32] While these results are not superior to the cells in dishes, our results still demonstrated the presence of these secretions, which are important for physiological relevance.

Study Limitations

Under current conditions, experiments can be concurrently performed on four chips with a single channel or two chips with two channels. However, more equipment is required to perform experiments with higher numbers of chips. The liver chip secretions were only compared against cell culture medium without cells and not with secretions from cells grown without the chip. Another limitation of our study was the lack of immunostaining. This limitation did not pose a major problem as we biochemically and microscopically demonstrated that cell viability was preserved.

CONCLUSION

The liver chip model established in this study successfully demonstrated the viability of hepatocytes and physiologically-relevant secretions under constant flow. It is predicted that, in the near future, the OOAC models developed will replace experimentation on animal models and offer cheaper and faster potential new diagnosis and treatment methods. Therefore, future studies to improve and develop this technology are of paramount importance in order to advance this line of research.

MAIN POINTS

- There is an increasing demand for human-relevant micro-physiological systems which can accurately model and predict human diseases and aid in drug development processes.
- A microfluidic human liver-chip for modeling DILI was developed using 3D stereolithography printing, CNC milling technology and molding.
- The liver-chip model was non-toxic to human hepatocytes. The HepG2 cells secreted albumin, ALT and AST at physiologically-relevant levels. The AFP level in the cells was found to be high and concordant with regenerating hepatic cellular physiology.
- The model developed represents an advancement in drug-monitoring and toxicity studies.

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ETHICS

Ethics Committee Approval: Ethics committee form was not required. The study followed the principles of the Declaration of Helsinki.

Informed Consent: Informed consent form was not required.

Authorship Contributions

Surgical and Medical Practices: E.M., Concept: B.B., E.M., Design: B.B., E.M., Data Collection and/or Processing: B.B., E.M., Analysis and/or Interpretation: B.B., E.M., Literature Search: B.B., E.M., Writing: B.B., E.M.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study had received no financial support.

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RESEARCH ARTICLE

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Living with Stroke in North Cyprus: Which ICF-Based Biopsychosocial Factors are Related to Community Participation?

Utku Kurtaran[1], Beliz Belgen Kaygısız[2], Nazemin Gilanlıoğulları[2], Ferda Selçuk Muhtaroğlu[2]

[1]Clinic of Physical Medicine and Rehabilitation, Near East University Hospital, Nicosia, North Cyprus
[2]Department of Physiotherapy and Rehabilitation, Faculty of Health Sciences, European University of Lefke, Nicosia, North Cyprus

Abstract

BACKGROUND/AIMS: Improved treatment and rehabilitation care opportunities are resulting in increasing numbers of stroke survivors. Accordingly, the active community participation of stroke survivors is becoming more important in order to maintain a person's psychological and social status and so to improve their quality of life. This study aimed to investigate the relationships among the sociodemographic characteristics, clinical characteristics, International Classification of Functioning, Disability and Health (ICF)-based biopsychosocial factors, and community participation of stroke survivors living in North Cyprus.

MATERIALS AND METHODS: This cross-sectional study recruited 43 participants. The sociodemographic and clinical characteristics of the participants were recorded. Functional Independence Measure (FIM), Stroke Impact Scale 3.0 (SIS), Fall Efficacy Scale (FES), Fatigue Severity Scale (FSS), Beck Depression Inventory (BDI), Measure of Quality of the Environment-Short Form (MQE-SF), and the Community Integration Questionnaire (CIQ) were used to collect the data.

RESULTS: Those participants who did not use assistive devices had higher community participation ($p<0.05$). Additionally, gender, lesion type, and the affected body side did not have any relationship with community participation ($p>0.05$). As the Brunnstrom stages (Upper extremity: $r=0.455$, $p=0.002$; Lower extremity: $r=0.608$, $p=0.001$) of the participants and their scores in FIM ($r=0.809$, $p=0.001$), SIS ($r=0.766$, $p=0.001$), and MQE-SF ($r=0.467$, $p=0.002$) increased, so did their CIQ scores ($p<0.05$). However, as the age of the participants ($r=-0.413$, $p=0.006$) and their FES ($r=-0.752$, $p=0.001$), FSS ($r=-0.479$, $p=0.001$), and BDI ($r=-0.783$, $p=0.001$) scores increased, their CIQ scores decreased ($p<0.05$).

CONCLUSION: To increase their community participation, stroke survivors need to be assessed holistically by considering all factors of the ICF model and they require multidisciplinary rehabilitation, which will lead to better rehabilitation outcomes. The community participation levels of stroke survivors living in North Cyprus were related to the factors of the ICF base biopsychosocial level.

Keywords: Stroke, community participation, ICF

INTRODUCTION

Disease-related limitations in the biological system affect psychological and social aspects negatively, which in turn limits community participation among stroke survivors. Recently improved treatment and rehabilitation care opportunities have resulted in increasing numbers of stroke survivors.[1] Therefore, it is important for this population not to be isolated from society, so that they can continue to participate actively in their community, as their activity and participation levels are related to their quality of life.[2]

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ORCID IDs of the authors: U.K. 0000-0002-6134-2077; B.B.K. 0000-0003-4801-0884; N.G. 0000-0003-1945-1701; F.S.M. 0000-0002-2170-4061.

Address for Correspondence: Beliz Belgen Kaygısız
E-mail: bkaygisiz@eul.edu.tr
ORCID ID: orcid.org/0000-0003-4801-0884

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The International Classification of Functioning, Disability and Health (ICF) is a classification system which is based on biopsychosocial factors and it aims to improve health-related issues.[3] It examines body structure, functions, activity and participation, the capacity of individuals to perform their functions, and their communication with their environment.[4] As described by the ICF, environmental factors constitute the physical and social context in which people live and maintain their lives. Personal factors include those in an individual's life which are not a part of their health status. Contextual factors can have positive or negative effects on an individual's bodily functions and physiology, behaviours or capacity to perform tasks, and their community participation.[5] Therefore, it is important to understand the community participation levels of stroke survivors in order to increase their quality of life.

Studies on community participation in stroke survivors have mostly been conducted in developed countries such as the United States, Northern Ireland, and Australia.[6-9] It is also important to identify the ICF-based biopsychosocial factors which are related to the community participation of stroke survivors in socioeconomically diverse countries such as North Cyprus.

Aims

It was aimed to determine the levels of relationships of sociodemographic and ICF-based biopsychosocial factors with the community participation of stroke survivors living in North Cyprus. The results of this study aimed to shed light on the development of appropriate strategies for improved participation and the introduction of mechanisms to facilitate the community participation of this population. This research may also help to understand if the concepts of ICF are relevant for those stroke survivors who live in North Cyprus, namely to understand if culture has any impact on ICF-based biopsychosocial factors related to the community of stroke survivors in North Cyprus.

MATERIALS AND METHODS

Design

This was a cross-sectional analytical study conducted between January, 2020 and May, 2020 with stroke survivors in a private rehabilitation centre in North Cyprus, after obtaining ethical from the Ethics Committee of European University of Lefke (approval number: ÜEK/50/01/02/1920/10, date: 11.02.2020). The population of this study included individuals who presented to the neurology inpatient clinics of a public hospital and a private hospital over the previous five years. Those people who met the inclusion criteria were informed about this study, and written consent was obtained from those who agreed to participate.

Participants

Fifty-three stroke survivors were invited to take part in this study by a systematic sampling method. The registration numbers at hospitals were listed and the sixth person was chosen randomly, followed by every subsequent sixth person. All chosen individuals were invited to enrol (n=53). Some individuals (n=10) were not included because they either did not want to participate (n=8) or could not spare time to be evaluated (n=2). As a result, 43 participants were included (Flowchart 1).

Inclusion/Exclusion Criteria

The inclusion criteria were as follows; living in North Cyprus, being able to speak and write in Turkish, being diagnosed with stroke for the first time by a neurologist, being 45-80 years old, having had a stroke at least three months prior, and being cooperative and agreeing to participate in this study (mini-mental test ≥24). The exclusion criteria were determined as having other neurological disorders or other diseases affecting the musculoskeletal system.

Data Collection Tools

The sociodemographic and clinical characteristics of the participants were recorded on personal information and clinical information forms. The sociodemographic data of the participants included their age, sex, smoking status, alcohol intake, and educational status, while the clinical information form included the affected side of the body, the duration since the stroke, their walking aid usage status, and lesion type.

The data collection instruments included the Functional Independence Measure (FIM) to determine functional levels in activities, the Brunnstrom Stage Assessment to assess the stage of recovery, the Stroke Impact Scale (SIS) to assess disease status and limitations in daily activities, the Falls Efficacy Scale (FES) to assess self-efficacy related to falls, the Fatigue Severity Scale (FSS) to determine fatigue levels, the Beck Depression Inventory (BDI) to assess depression, the Measure of Quality of the Environment-Short Form (MQE-SF) to determine environmental factors, and the Community Integration Questionnaire (CIQ) to assess community participation. The previously validated Turkish language versions of all measures were used.

Data collection was performed by the primary investigator, who worked as a physiotherapist and each assessment took 45-50 minutes according to the participant. However, breaks for 10 minutes took place during the assessments if requested by the participant.

Stage of Motor Recovery

The Brunnstrom Stage Assessment was used to assess the stage of recovery for the upper and lower extremities. It is an approach developed by Brunnstrom[10] in the 1960s which has six stages to understand how motor control can be restored to gain functionality after a stroke. Higher scores indicate more improvement. It is a valid, reliable, and responsive stroke-specific and commonly used tool which helps classify the motor levels of stroke survivors.[11-13]

Functional Level in Activities

The FIM is an 18-item scale which evaluates both the physical (13 items) and cognitive (5 items) functions of an individual to evaluate them in terms of personal care, sphincter control, transfer, mobility, communication, and social-cognitive status.[14] The validity and reliability study of this scale in Turkish was carried out by Küçükdeveci et al.[15]

Community Participation

The CIQ consists of 18 items and evaluates three variables consisting of home participation, community participation, and productivity and work/school activity.[16] The validity and reliability of this scale in Turkish were tested by Akyurek et al.[17]

Limitations in Activities of Daily Living

The SIS version 3 was specifically developed for stroke survivors. It is a scale developed by Duncan et al.[18] to evaluate the quality of life of people who experience loss of mental and physical function after a stroke, depending on the extent of the impact of the stroke. In this scale, which consists of eight domains and 59 items, each item is evaluated by scoring difficulties experienced over the prior seven days on a 5-point Likert-type scale. The validity and reliability study of this scale in Turkish stroke survivors was performed by Hantal et al.[19]

Self-Efficacy Related to Falls

The FES was developed by Tinetti et al.[20] It aims to investigate the self-efficacy of stroke survivors regarding falls they experience while fulfilling the ADL. This scale consists of 10 items which determine their self-efficacy while performing activities, such as how confident they are that they can dress and undress without falling.[20] Higher scores indicate higher self-efficacy levels. The Turkish language validity and reliability study of this scale was conducted by Ulus et al.[21]

Level of Fatigue

The FSS was developed by Krupp et al.[22] It is a 7-point Likert-type scale (1=strongly disagree, 7=strongly agree) consisting of nine items, and the total score of the scale is found by averaging the scores of all nine items. Getting a score of four or higher indicates the presence of pathologic fatigue. The Turkish validity and reliability study of this scale was conducted by Armutlu et al.[23]

Level of Depression

The BDI was developed by Beck et al.[24] The purpose of this scale is to objectively measure the level of depression symptoms possessed by an individual. It determines the behavioural pattern which is specific to depression and includes 21 evaluation statements with four options each. The Turkish validity and reliability study of this scale was conducted by Hisli.[25]

Environmental Factors

The MQE-SF was tested for reliability by Boschen.[26] This scale is a modified ICF format measure created specifically for people with different degrees and types of disability. The five dimensions of this scale include 26 items aiming to assess the impact of the environment on the success of a person's daily activities by considering their abilities and limitations. The respondent scores whether their daily activities are facilitated or obstructed by environmental factors. The validity study of MQE-SF in Turkish was conducted by Akyurek and Bumin.[27]

Statistical Analysis

The SPSS 25.0 program was used for the statistical analyses of the data collected. Percentage, mean and standard deviation values were calculated for the sociodemographic and clinical data. Based on the Shapiro-Wilk test which was conducted in this study, the FIM, CIQ, SIS, FES, FSS, BDI, and MQE-SF scores of the participants were not normally distributed. Accordingly, the Mann-Whitney U test was used to compare the CIQ scores of the participants based on their gender, use of walking aids, affected body side, and lesion type. The relationships between the participants' FIM, SIS, FES, FSS, BDI, and MQE-SF scores and their CIQ scores were examined via Spearman's correlation test. The degree of correlation was defined as low if the coefficient was lower than 0.3, moderate if it was between 0.3 and 0.5, and strong if it was greater than 0.5. The level of statistical significance was determined as $p<0.05$. As a result of power analysis, the sample size was determined as being 43 participants in order to provide 80% power with a 95% confidence interval.

RESULTS

Forty-three individuals participated in this study (13 female, 30 male, mean age: 70.67±8.22 years). Table 1 shows the sociodemographic and clinical characteristics of the participants. Descriptive statistics were calculated regarding the stroke-related scores of the participants and their scores on the Brunnstrom Stage Assessment (upper/lower extremity), FIM, SIS, FES, FSS, BDI, MQE-SF, and overall CIQ (Table 2).

A statistically significant difference was determined in the participants' CIQ scores based on their walking aid usage status ($p<0.05$). However, there was no statistically significant relationship between the CIQ

Table 1. Sociodemographic and clinical characteristics of the participants (n=43)

	Frequency (n)	Mean ± SD
Age (years)	43	70.67±8.22
BMI (kg/m²)	43	25.69±4.18
Age (years)		Percentage (%)
55-64	11	25.58
65-74	14	32.56
75-84	18	41.86
Gender		
Male	30	69.77
Female	13	30.23
Smoking status		
Smoker	9	20.93
Non-smoker	34	79.07
Alcohol use status		
Non-drinker	43	100.00
Drinker	0	0.00
Educational status		
High school	30	69.77
University	13	30.23
Duration since stroke ($\bar{x}$=51.19±45.54 months)		
36 months or shorter	19	44.18
37-60 months	14	32.56
61 months or longer	10	23.26
Affected body side		
Right	22	51.16
Left	21	48.84
Status of using walking aids		
Using	22	51.16
Not using	21	48.84
Lesion type		
Haemorrhagic stroke	19	44.19
Ischemic stroke	24	55.81

SD: Standard deviation, BMI: Body mass index.

Table 2. Results of the stroke-related tools examining the biopsychosocial dimension of the participants (n=43)

	Mean ± SD	Min.	Max.
Brunnstrom stage (upper extremity)	5.37±0.87	3.00	6.00
Brunnstrom stage (lower extremity)	5.63±0.49	5.00	6.00
CIQ overall score	6.70±4.75	0.00	18.00
Home participation sub-score	1.05±1.46	0.00	7.00
Community participation sub-score	4.77±2.72	0.00	10.00
Work/school sub-score	0.88±1.33	0.00	5.00
FIM	93.30±17.08	45.00	118.00
SIS	195.81±36.23	107.00	281.00
FES	47.72±22.69	10.00	85.00
FSS	5.51±1.02	2.55	6.77
BDI	19.51±9.06	5.00	44.00
MQE-SF	41.12±5.83	30.00	54.00

SD: Standard deviation, Min. Minimum, Max. Maximum, CIQ: Community Integration Questionnaire, FIM: Functional Independence Measure, SIS: Stroke Impact Scale, FES: Falls Efficacy Scale, FSS: Fatigue Severity Scale, BDI: Beck Depression Inventory, MQE-SF: Measure of Quality of the Environment-Short Form.

scores of the participants and their affected body side or lesion type (p>0.05). The results of the comparisons between the participants' overall CIQ scores based on their sociodemographic and disease-related characteristics are presented in Table 3.

A statistically significant relationship was found between the participants' age, Brunnstrom stages, and their scores in FIM, SIS, FES, FSS, BDI, and MQE-SF with their CIQ scores (p<0.05). Table 4 shows the correlations between the independent variables of the participants and their CIQ scores.

DISCUSSION

Strokes result in physical and psychological impairments which have a negative relationship with the community participation of individuals. The qualifiers for activity and participation components are performance and capacity.[5] The performance qualifier is the qualitative and quantitative definition of the behaviour or abilities shown for the action performed in the environmental conditions of the individual. Capacity defines how much an individual can perform a task or an action. This construct argues that individuals perform an activity with the maximum efficiency while performing an action.[5] Therefore, this study aimed to

Table 3. Comparison of the clinical characteristics of the participants and their overall Community Integration Questionnaire scores (n=43)

			Frequency, (n)	Mean ± SD	p-value
Community Integration Questionnaire Overall Score	Lesion type	Haemorrhagic	19	6.47±5.10	0.623
		Ischemic	24	6.88±4.56	
	Walking aid	Using	22	4.09±3.19	0.001*
		Not using	21	9.43±4.63	
	Affected body side	Right	22	6.91±5.14	0.742
		Left	21	6.48±4.43	
	Gender	Male	30	7.33±4.52	0.108
		Female	13	5.23±5.13	

Statistically significant: *p<0.05, Mann-Whitney U test.

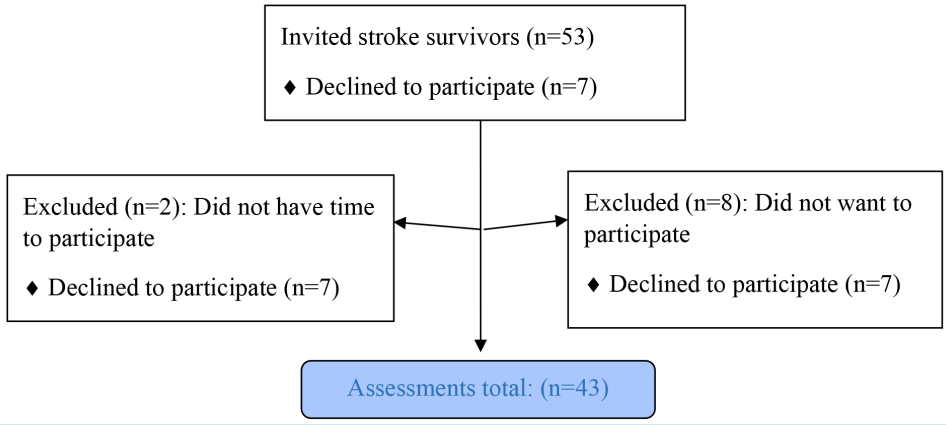
Table 4. Correlations between age, duration since stroke, education status and stroke-related tools and the Community Integration Questionnaire scores of the participants (n=43)

Variables		Community Integration Questionnaire Overall Score	Home participation	Society participation	Work-school
Age	r	-0.413	-0.354	-0.339	-0.317
	p	0.006*	0.020*	0.026*	0.038*
Duration since stroke	r	-0.170	-0.011	-0.175	-0.179
	p	0.275	0.942	0.261	0.251
Education status - (high school)	r	0.456	0.235	0.765	0.645
	p	0.227	0.975	0.199	0.083
Education status - (university)	r	0.346	0855	0.003	0.217
	p	0.446	0.434	0.256	0.134
Brunnstrom stage (upper extremity)	r	0.455	0.383	0.411	0.452
	p	0.002*	0.011*	0.006*	0.002*
Brunnstrom stage (lower extremity)	R	0.608	0.546	0.527	0.564
	p	0.000*	0.000*	0.000*	0.000*
FIM	r	0.809	0.747	0.743	0.660
	p	0.000*	0.000*	0.000*	0.000*
SIS	r	0.766	0.649	0.744	0.576
	p	0.001*	0.001*	0.001*	0.001*

Table 4. Continued

Variables		Community Integration Questionnaire Overall Score	Home participation	Society participation	Work-school
FES	r	-0.752	-0.643	-0.714	-0.604
	p	0.001*	0.001*	0.001*	0.001*
FSS	r	-0.479	-0.433	-0.490	-0.344
	p	0.001*	0.004*	0.001*	0.024*
BDI	r	-0.783	-0.638	-0.798	-0.543
	p	0.001*	0.001*	0.001*	0.001*
MQE-SF	r	0.467	0.442	0.427	0.287
	p	0.002*	0.003*	0.004*	0.062

Statistically significant: *p<0.05, Spearman's correlation, FIM: Functional Independence Measure, SIS: Stroke Impact Scale, FES: Falls Efficacy Scale, FSS: Fatigue Severity Scale, BDI: Beck Depression Inventory, MQE-SF: Measure of Quality of the Environment-Short Form.



Flowchart 1. Diagram of recruitment of participants.

determine whether ICF-based biopsychosocial factors are related to the community participation levels of stroke survivors living in North Cyprus. It was hypothesised that ICF-based biopsychosocial factors are correlated with the community lives of stroke survivors living in North Cyprus to different degrees, and the results of this study confirmed this hypothesis.

We analysed participation not only as an overall community integration score, but also from the aspects of social, home and work/school participation. The community participation levels of our sample were low, while participation was highest in the social participation subscale. It was expected for the participants to report low in-home participation subscale scores, as they could have support from family members. It was also predicted for the participants to score low in work/school integration as many studies in the literature have supported this expectation.[28,29]

We found a significant relationship between the sociodemographic characteristics and community participation levels of the stroke survivors. Those participants who used walking aids had lower community participation than those who did not use walking aids. Tyson and Rogerson[30] reported that walking aids are an environmental facilitator for stroke survivors, which may increase community participation, suggesting that supportive equipment can be beneficial in increasing the participation of those individuals who have had a stroke. However, the results of our study did not align with the study conducted by Tyson and Rogerson.[30] This may be because of both physical infrastructure and psychological factors. As a physical infrastructure obstacle, the inadequacy of urban design in North Cyprus was identified as a limiting factor for participation.[31] At the same time, it was reported that depression seen in individuals after a stroke causes individuals to feel as if they were being watched in their environment.[32] Therefore, besides urban accessibility barriers, the use of walking aids by the participants who had had a stroke limited their participation, due to their perception of psychological pressure on them.

It is known that getting older restricts community participation due to physiological or biopsychosocial reasons.[33-35] Our results were similar to those in the literature because it was found that community participation decreased with increasing age. It was expected for our sample to have low community participation rates as 74.42% of the participants were 65 years or older. On the other hand, the duration of living with a stroke was not found to be related to community participation, which was a parallel result to that reported by D'Alisa et al.[29] This may be because stroke survivors may have learnt how to live with their limitations and developed coping strategies. This shows that there is a need for further follow-up of stroke survivors in order to understand the degrees of their limitations over time.

We found that each ICF factor including body structure, functions, activities, participation, environmental factors, and personal factors had a different relationship with the community participation levels of the participants. The functional independence levels of the participants were found to be the most significantly related factor to

their community participation. "Function is a process, and the vector of change in function through time is, in part, determined by the unique interaction of an individual's genome with their environment, diet, and lifestyle".[36,37] A previous study revealed that functional disability is the most significant variable which explains restriction in the community participation rates of stroke survivors.[29] Moreover, it was found that the current levels of the activities of daily living (ADL) of the participants of this study and their mobility stages were moderately correlated with their community participation levels. Mikołajewska[37] reported that especially the gait parameters, hand functions, and functional levels of stroke survivors were related to community participation among individuals with limited ADL. Other than ADL limitations, psychological factors and functional status, there are further factors which may have a negative impact on community participation among stroke survivors, such as comorbidities, coordination in exercise, family support, and the physical and social environment.[38-40] Many studies have investigated the factors affecting community participation and return to society after a stroke.[41,42] In our study, which is in line with the literature, it was found that the community participation levels of stroke survivors were affected by not only physical function, but also by personal and environmental factors. Therefore, it is important to think holistically and consider all aspects which can cause obstacles to participation in order to improve the rehabilitation outcomes of stroke survivors.

Our results also showed that the community integration of our participants was moderately obstructed by environmental factors. Although the relationship of community participation with environmental factors has not been evaluated as much as functionality, activity, or depression in the literature, it is known that environmental factors including the social and attitudinal aspects of one's environment have a high impact on the community participation levels of stroke survivors.[43] Due to the diversity of outcome measures in this area, one recent systematic review suggested the need for a core set of outcome measures to assess the long-term participation of stroke survivors in life situations.[41] Although the tools which we used help to measure the quality of the environment in different aspects, we think that the use of a stroke-specific tool to measure the interaction between these variables and changes in community participation could give us a better view of the relationships with environmental factors.

Additionally, personal factors such as fatigue, depression, and self-efficacy related to falls were all found to have moderate relationships with community participation. Stroke survivors with functional limitations develop some compensatory movements while performing activities, and extra energy consumption was found to cause early fatigue and the subsequent development of withdrawal from activities.[44] Our participants' depression levels were at the borderline of clinical depression. This may be due to the participants having difficulty in performing activities which they found easy before their stroke. It has also been documented that the attitudes of people around hemiplegic people result in anxiety, a lack of respect and they affect the social roles of stroke survivors, which have negative relationships with their community participation.[44,45] Stroke survivors with a history of falling are afraid of falling and have lower self-efficacy related to falls,[46] and it has been reported that individuals with poor participation have a greater fear of falling.[47,48] Our results led to the conclusion that the fear of falling in stroke survivors can be due to their belief that, in the event of a possible fall, their health status may deteriorate, so they avoided community participation. Our results highlighted that it is important to work with a multidisciplinary team in cases with long-term limitations as they are restricted in terms of different biopsychosocial factors.

Study Limitations

Our study had some limitations. Firstly, most of our participants were living close to the private centre where this study was conducted which is located in the central area of North Cyprus. This factor may affect the ability to generalise our results. Secondly, the assessments were performed by the same physiotherapist who was not blinded to the community integration levels of the participants. Lastly, as this was a cross-sectional study, our results do not indicate a causal relationship. Further studies with different methodologies to explore the causes of community participation are recommended.

CONCLUSION

This study revealed that the community participation levels of stroke survivors living in North Cyprus were related to the factors of the ICF-based biopsychosocial model. Therefore, in order to increase the community participation levels of stroke survivors, these individuals need to be assessed holistically by considering all factors of the ICF model, which will lead to better rehabilitation outcomes, and multidisciplinary rehabilitation approaches in this process are needed.

MAIN POINTS

- Holistic assessment is required in order to increase the community participation levels of stroke survivors.
- All factors of the ICF model had an impact on the community participation of stroke survivors.
- Multidisciplinary rehabilitation will result in better rehabilitation outcomes.

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ETHICS

Ethics Committee Approval: This study was approved by the Ethics Committee of European University of Lefke (approval number: ÜEK/50/01/02/1920/10, date: 11.02.2020).

Informed Consent: Written consent was obtained from those who agreed to participate.

Authorship Contributions

Concept: U.K., B.B.K., F.S.M., Design: U.K., B.B.K., F.S.M., Data Collection and/or Processing: U.K., B.B.K., N.G., F.S.M., Analysis and/or Interpretation: U.K., B.B.K., N.G., Literature Search: U.K., N.G., Writing: U.K., B.B.K., F.S.M.

DISCLOSURES

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RESEARCH ARTICLE

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The Association Between Red Cell Distribution Width and Blood Pressure Variability in Hypertensive Patients

Mehmet Ali Mendi

Department of Cardiology, Near East University Faculty of Medicine, Nicosia, North Cyprus

Abstract

BACKGROUND/AIMS: The relation between blood pressure (BP) variability and inflammation has been demonstrated in numerous types of research. Red cell distribution width (RDW) is independently related to worse cardiovascular consequences. An increased RDW in the circulation may project continuing systemic and vascular inflammatory processes and contribute to the development of hypertension. We aimed to investigate the correlation between RDW and BP variability in hypertensive patients.

MATERIALS AND METHODS: Our research included 210 participants with essential hypertension. The hypertensive participants were identified according to the current guidelines. Twenty-four-hour ambulatory blood pressure monitoring (24-hABPM) was performed for each participant. Since variability values were in a standard deviation distribution, statistical analysis was carried out accordingly. Routine biochemistry analyses and complete blood count were also performed. The contribution of independent variables on BP variability was analyzed by stepwise multivariable linear regression analysis.

RESULTS: A positive statistical correlation was found between RDW levels and daytime systolic blood pressure (SBP) variability, and also diastolic blood pressure (DBP) variability (r=0.198, p=0.002 and r=0.101, p=0.004 respectively). Similarly, positive correlations were found between the variables of gender, DM, and smoking (r=0.202, p=0.002; r=0.130, p=0.042; r=0.181, p=0.004 respectively) both for daytime SBP and DBP variability (r=0.186, p=0.005; r=0.192, p=0.004; r=0.191, p=0.004 respectively). Although a strong positive statistical correlation (p<0.001) was found between age and daytime SBP, no correlation was detected between age and daytime DBP variability.

CONCLUSION: Elevated RDW values predict daytime BP variability in hypertensive patients. This relationship may depend on the underlying inflammation. Further research is needed in order to investigate the influences of strict BP control on adverse cardiovascular events via inflammation and BP variability.

Keywords: Blood pressure variability, inflammation, red cell distribution width, ambulatory blood pressure monitoring

INTRODUCTION

Red cell distribution width (RDW) is a numerical value of versatility in the volume and dimension of red blood cells, and it is in the routine blood cell count which shows anisocytosis.[1] In addition, RDW can be a guide in the differentiation of types of anemia, as well as predicting morbidity and survival rates for many other conditions.[2] RDW has been reported as a predictor of adverse outcomes and mortality in many cardiovascular diseases (CVD) such as stable coronary artery disease,[2,3] heart insufficiency,[1,4] stroke,[5] myocardial infarction,[6] limb atherosclerosis[7] and also in those patients with myocardial infarction.[8] The pathophysiological rationale between the inflammatory process and RDW is based on the hypothesis that chronic systemic inflammation

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ORCID IDs of the authors: M.A.M. 0000-0003-4948-1645.

Address for Correspondence: Mehmet Ali Mendi
E-mail: mendimehmetali@gmail.com
ORCID ID: orcid.org/0000-0003-4948-1645

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in CVD may cause anisocytosis.[9] The RDW value is elevated in hypertensive patients with normotensives[10] and it is raised in non-dipping hypertensive patients with dipper hypertensives[11] as well. A high level of circulating RDW may project continuing vascular inflammatory processes and play a part in the mechanism of hypertension.[12] Elevated blood pressure (BP) aggravates the vascular inflammatory process, leading to endothelial damage and eventually atherosclerosis.[13]

Recent trials have added to the emphasis on 24-hour blood pressure variability (24-hBPV). Hypertensives in those with low 24-hBPV have a lower prevalence and severity of end-organ damage than in those with high 24-hBPV.[14,15]

Based on our hypothesis that there is a positive correlation between BP variability and RDW in hypertensive patients, which has not been investigated before to the best of our knowledge, we aimed to investigate this relationship.

MATERIALS AND METHODS

Our study included 210 consequent patients with high BP who had applied to the outpatient department of a cardiology clinic. Hypertension was defined as BP ≥140/90 mmHg in-office measurements for at least two repeated readings.[16] Twenty-four-hour ambulatory blood pressure monitoring (24-hABPM) was carried out for all hypertensive participants. Patients with secondary hypertension, hematological system disorders (anemia, leukemia, etc.), renal or hepatic dysfunction, malignancy, or connective tissue diseases were not included in this research. The demographic characteristics of the participants, such as their age, gender, smoking status, and diabetes mellitus (DM) were noted. In addition, fasting serum lipid panels including high-density lipoprotein, triglyceride, low-density lipoprotein, total cholesterol, fasting blood glucose, and creatinine values were also recorded. The Ethics Committee of Ankara Yüksek İhtisas Training and Research Hospital authorized the research protocol (approval number: 2962, date: 16.09.2013) and informed consent was taken from all participants. Lipid profile, glucose and creatinine were designated by standard methods. Hemoglobin, total white blood cell counts, platelet counts, and RDW were calculated using a self-acting blood cell counter (ADVIA 2120i Hematology System, Siemens, USA).

A 24-hABPM device (Stolberg, Mobilograph, Germany) was used on all participants. The device was worn to measure 24 h BP in 15-min periods during the daytime and each 30-min during the nighttime. It was placed on the non-dominant arm. We analyzed the recordings with interactive software. 24-hABPM was repeated if 20% or more of the measurements could not be taken. The daytime, nighttime, and 24-h averages of systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean BP were obtained from all participants based on the hourly averages of the ambulatory BP recordings.

Statistical Analysis

Since the variability values were in standard deviation distribution, statistical analysis was performed accordingly. Statistical analysis was implemented by SPSS 17.0 statistical software (SPSS Inc., Chicago, IL, USA). The Kolmogorov-Smirnov test was performed to establish the distribution of all data. According to the test results, the analysis of normally distributed variables was performed with mean ± standard deviation, and the analyses of non-normally distributed variables were performed with medians. The contributions of independent variables on BP variability were analyzed by stepwise multivariable linear regression analysis. Statistical significance was set at $p<0.05$.

RESULTS

A total of 210 individuals with primary hypertension took part in our research, and the baseline characteristics of these individuals are outlined in Table 1. Office BP measurements and 24-hABPM results are given in Table 2.

A positive statistical correlation was found between RDW levels and daytime SBP variability, and also daytime DBP variability. Similarly, positive correlations were found between the other variables (female gender, DM, smoking) both for daytime SBP and DBP variability. Although a strong positive statistical correlation ($p<0.001$) was found between age and daytime SBP, no correlation was detected between age and daytime DBP variability. Although a positive correlation was found between nighttime SBP standard deviation with type-2 DM alone, a positive correlation was found between nighttime DBP standard deviation with type-2 DM as well as female gender (Table 3).

Table 1. Baseline characteristics

Variable	n (%)/mean or median ± SD
Age	55.1±12.3
Gender (male)	124 (59%)
Type-2 DM	65 (31%)
Smoking	43 (20.5%)
RDW (%)	13.9±1.4
Hgb (g/dL)	14.5±1.5
WBC (10^3/mm^3)	7.5±1.8
Plt (10^3/mm^3)	258 (219-295)
Fasting glucose (mg/dL)	101 (93-128.2)
Creatinine (mg/dL)	0.9±0.2
HDL-cholesterol (mg/dL)	45.1±13.1
LDL-cholesterol (mg/dL)	123.1±32.9
Triglycerides (mg/dL)	138 (113-198)

SD: Standard deviation, DM: Diabetes mellitus, RDW: Red cell distribution width, Hgb: Hemoglobin, WBC: Wight blood cell, Plt: Platelet, HDL: High-density lipoprotein, LDL: Low density lipoprotein.

Table 2. Office and 24-h blood pressure mean and awake and asleep standard deviation values

Variable	Mean ± SD (mmHg)
Office SBP	172.1±21.4
Office DBP	99.3±16.5
24-h mean SBP	142.5±13.7
24-h mean DBP	89.1±10.1
Awake mean SBP	145.3±14.2
Awake mean DBP	94.7±10.5
Asleep mean SBP	133.1±17.1
Asleep mean DBP	80.6±11.6
Awake SBP SD	15.2±4.1
Awake DBP SD	11.1±2.9
Asleep SBP SD	17.1±3.1
Asleep DBP SD	12.4±2.4

SD: Standard deviation, SBP: Systolic blood pressure, DBP: Diastolic blood pressure.

Table 3. Stepwise multivariable linear regression analysis

	Awake SBP SD		Awake DBP SD		Asleep SBP SD		Asleep DBP SD	
	r^2=0.469		r^2=0.387		r^2=0.176		r^2=0.156	
	r	p	r	p	r	p	r	p
Age	0.265	<0.001						
Female	0.202	0.002	0.186	0.005			0.154	0.025
RDW	0.198	0.002	0.101	0.004				
Smoking	0.181	0.004	0.191	0.004				
Type-2 DM	0.130	0.042	0.192	0.004	0.176	0.011	0.162	0.03

SD: Standard deviation, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, RDW: Red cell distribution width, DM: Diabetes mellitus.

DISCUSSION

Our research revealed that RDW was positively correlated with daytime BP variability but no correlation was found between nighttime BP variability and RDW.

Hypertension has been reported as one of the major causes of coronary artery disease, cerebrovascular events, and renal insufficiency.[17] With the increasing availability of 24-hABPM, it has become possible not only to measure the BP during 24 h, but also 24-hABPM can contribute to more information about BP, such as the average level, fluctuations, and the circadian rhythm of BP.[18]

The effects of BP variability on adverse cardiovascular outcomes have been demonstrated by recent research. Suchy-Dicey et al.[19] put forward that SBP variability is independently associated with high mortality ratios and myocardial infarctions. In addition, BP variability is related to increased end-organ damage.[12] The association between BP variability and inflammation has been demonstrated in many types of research using different inflammatory biomarkers, such as high sensitive-C-reactive protein, sE-selectin, and IL-6.[13,20,21]

The clinical importance of RDW in hypertension has been defined in various trials. Tanindi et al.[10] demonstrated a strong correlation between high levels of RDW and high SBP and DBP levels. It has been reported that increased RDW levels were associated with higher BP levels in two major community-based cohorts.[3,22] In this study, we attempted to establish whether there was any possible association between BP variability and RDW levels in current essential hypertension. Our results indicate that RDW is associated with daytime BP variability in essential hypertension.

Increased RDW shows a strong and independent association with poor cardiovascular outcomes in CVD and so it is suggested as a new predictor of mortality.[1,7] The association between RDW and CVD may be based on underlying inflammations.[2,23,24] According to our results, increased RDW levels in patients with high BP variability may suggest a greater inflammatory load. There was no correlation between nighttime BP variability and RDW and this may be explained by a decrease in sympathetic activity at nighttime. An elevated RDW level may be a marker which demonstrates increased BP variability in hypertensive patients.

Study Limitations

One of the main limitations of our study was that it was single-centered and did not include normotensive individuals. In addition, the results cannot be generalized to the entire hypertensive population due to the lack of black origin among the participants. Also, morning BP fluctuation was not evaluated. Body mass index and waist circumference were not measured. Other biomarkers which have been proven to be associated with inflammation were not included in this study. Despite these limitations, this was the first study to draw attention to the association of BP variability with RDW.

CONCLUSION

Elevated RDW value predicts daytime BP variability in hypertensive patients. This relation may depend on the underlying inflammation. Further research is needed to investigate the influences of strict BP control on adverse cardiovascular events via inflammation and BP variability.

MAIN POINTS

- Elevated RDW values predict blood pressure variability.
- Blood pressure variability is associated with a raised inflammatory process.
- The inflammatory process takes part in the setting of worse cardiovascular outcomes.

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ETHICS

Ethics Committee Approval: The Ethics Committee of Ankara Yüksek İhtisas Training and Research Hospital authorized the research protocol (approval number: 2962, date: 16.09.2013).

Informed Consent: Informed consent was taken from all participants.

DISCLOSURES

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RESEARCH ARTICLE

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Examination of Sleep Disturbance and Sleep-Related Problems in Children with Type 1 Diabetes

Zekiye Küpçü[1], Funda Kardaş Özdemir[2], Dilek Çiftçi Baykal[3], Gülçimen Güney[4], Canan Kara[5], Servet Yel[1]

[1]Department of Pediatric Endocrinology, University of Health Sciences Türkiye, Van Training and Research Hospital, Van, Türkiye
[2]Department of Child Health and Diseases Nursing, Kafkas University Faculty of Health Sciences, Kars, Türkiye
[3]Department of Child Health and Diseases, Van Yüzüncü Yıl University, Van Vocational School of Health Services, Van, Türkiye
[4]Department of Nursing, University of Health Sciences Türkiye, Van Training and Research Hospital, Van, Türkiye
[5]Department of Nutrition and Dietetics, University of Health Sciences Türkiye, Van Training and Research Hospital, Van, Türkiye

Abstract

BACKGROUND/AIMS: This research aimed to investigate the sleep disorders and sleep problems of children with type 1 diabetes (T1D).

MATERIALS AND METHODS: This research was descriptive and cross-sectional. This research was conducted with 105 parents of children with T1D who were admitted to a training and research hospital between June and August 2022. In the collection of the research data, the "Introductory Information Form" and the "Sleep Disorder Scale for Children (SDSC)" were used.

RESULTS: As a result of our research, the average total score of SDSC was found to be 47.60±12.740. According to this result, the level of sleep disorders of the children participating in this study was below the average score. Significant differences were found in the sub-dimensions of Wakefulness Reactions Disorders, Sleep-Wakefulness Transition Disorders, and Excessive Sleepiness Disorders.

CONCLUSION: The parents participating in this study evaluated their children's sleep disorder levels as being below the average score. Since the sleep disorders of children with T1D are affected by familial characteristics and factors related to the disease, it is recommended to conduct further studies in order to identify sleep disorders and influencing factors so as to improve these conditions, and also to provide educational and counselling services to parents on these issues.

Keywords: Type 1 diabetes, children, sleep

INTRODUCTION

Type 1 diabetes (T1D) disease occurs as a result of the autoimmune destruction of insulin-producing β-cells in the pancreas. Although its exact cause is not known, genetic and environmental factors are effective in accelerating this disease.[1] T1D is an important subtype of diabetes which occurs mostly in childhood.[2] The incidence of T1D in childhood is increasing globally.[3] Although it is often diagnosed during adolescence, the highest increase occurs in young children[4] and about 15-20% of new cases are diagnosed in children aged five years old or younger.[5]

Sleep health has been defined as "a multidimensional sleep-wake model that supports physical and mental well-being, adapted to individual, social and environmental influences." Healthy sleep is characterized by an adequate sleep duration, sleep efficiency, the subjective feeling of satisfaction, proper timing and constant alertness during the waking hours.[6] Children with chronic diseases, including T1D, have a higher

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ORCID IDs of the authors: Z.K. 0000-0001-7979-5456; F.K.Ö. 0000-0002-0164-0304; D.Ç.B. 0000-0001-7937-5646; G.G. 0000-0001-5731-8990; C.K. 0000-0002-8433-3202; S.Y. 0000-0001-6889-4504.

Address for Correspondence: Dilek Çiftçi Baykal
E-mail: dilekbaykal@yyu.edu.tr
ORCID ID: orcid.org/0000-0001-7937-5646

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risk of showing sleep-related problems such as insufficient sleep and daytime sleepiness than healthy children. Children with T1D are susceptible to sleep disturbances due to the effects of glucose and insulin on their central nervous system and an increased response to bodily stress.[7]

The interactions between sleep and T1D are reciprocal; disrupted sleep negatively affects glycaemic control, while uncontrolled blood sugar can also affect sleep.[8,9] In addition, nocturnal hypoglycaemia and the need for intervention can affect the amount of time spent in bed and the duration of sleep.[10] Nocturnal hypoglycaemia is one of the most feared conditions and it psychologically negatively affects the child and parent and leads to impaired sleep.[11] Since parents often wake up their children at night to prevent nocturnal hypoglycaemia, it is inevitable that children with T1D will have sleep problems and their parents will experience various difficulties in this regard.[12] Young people with T1D experience more sleep disturbance and a shorter sleep duration than their healthy peers.[9,13] Poor sleep quality also negatively affects diabetes management skills and overall well-being.[14,15]

This study aimed to determine the sleep disturbance and sleep-related problems of children with T1D.

MATERIALS AND METHODS

This research was conducted as a descriptive and cross-sectional study. This research was conducted with the parents of children with T1D who were admitted to a training and research hospital for routine check-ups between June and August 2022. The G*power 3.1.9.4 analysis program was used to calculate the sample size of this study. It was determined that at least 97 parents should participate in the sample of this study with an effect size of 0.30, a margin of error of 0.05%, df= 96 and 90% power. In total, one hundred and five parents participated in this study.

This study was approved by the University of Health Sciences Türkiye, Van Training and Research Hospital Ethics Committee (approval number: 2022/14-05, date: 24.06.2022).

Data Collection Tools

The "Introductory Information Form" and the "Sleep Disturbance Scale for Children" were used as the data collection tools in this research. The "Introductory Information Form" contains questions regarding demographics, illness, the living environment and sleep. This form was prepared by the researchers within the scope of the literature.[16,17] The "Sleep Disturbance Scale for Children" was developed by Bruni et al.[18] Its validity and reliability studies have been conducted in many languages. The validity and reliability study of the scale in Turkish was conducted by Agadayi et al.[19] This scale is a Likert type scale which investigates sleep disturbance. In this scale, the child's sleep disturbance is questioned in 26 items with 6 sub-dimensions. These sub-dimensions are Initiation and Persistence of Sleep Disturbance (UBSB; items 1, 2, 3, 4, 5, 10 and 11), Respiratory Disturbance during Sleep (RDDS) (USB; items 13, 14 and 15), Reactions and Alertness Disturbance (URB; items 17, 20 and 21), Sleep-Wake Transition Disturbance (SWTD) (UUGB; items 6, 7, 8, 12, 18 and 19), Disturbance of Excessive Sleepiness (DES) (AUB; items 22, 23, 24, 25 and 26) and Excessive Sweating during Sleep (UAT; items 9 and 16). The answers to the questions were between never (1 point) and always (5 points). A minimum score of 26 and a maximum score of 130 could be obtained from this scale. High scores are interpreted as indicating the presence of sleep disturbance. The Cronbach's alpha value of this scale was 0.79.[19] In this study, it was found to be 0.84.

Data Collection

The research data were collected by interviewing the parents who visited a training and research hospital. After the parents were informed about the purpose and content of this research, the data collection forms were filled out using a face-to-face interview method with those parents who agreed to participate in this research. The completion time of the data collection forms was about 20 minutes.

Statistical Analysis

The data obtained from this study were evaluated using the SPSS 20 statistical software package. In the analysis of the data, number, percentage, average, standard deviation and minimum and maximum values were used. The conformity of continuous variables to a normal distribution was evaluated using Kolmogorov-Smirnov normality analysis. The Mann-Whitney U test was used in binary groups to determine differences between variables, the Kruskal-Wallis H test was used in groups of three or more, and Spearman's Rank correlation analysis was used to determine relationship status.

RESULTS

Table 1 shows the demographic characteristics of the parents who participated in this study. According to the table, 72.4% of the participants in this study were mothers and 27.6% were fathers. 86.7% of the participants were married, 55.3% were primary school graduates and 57.1% were working. The proportion of participants whose income was less than their expenses was 61%.

The duration since the diagnosis of diabetes in 31.4% of their children was between 1 and 3 years. 43.8% of the participants lived in the province where the study was conducted. 63.8% of the participants had a nuclear family structure and 65.7% of their children had more than two siblings. The average age of the parents who participated in this study was 39.32 years and the average age of their children was 10.95 years (Table 1).

Table 2 shows the distribution of characteristics related to diabetes and sleep. According to this table, 57.1% of the children slept with their siblings in separate rooms. 52.4% of the children consumed liquids before going to sleep. 17.1% of the children slept during the day, while 41% did not sleep and 41.9% slept sometimes in the daytime. 84.8% of the children had a digital device (phone, tablet, computer, etc.) which they used and 65.7% of them went to bed after 10 p.m. at night. 88.6% of the parents gave insulin to their children before going to sleep, 60% of the children took blood sugar drops during sleep and 61.9% of the children had a snack before going to sleep. Finally, 51.4% of the parents believed that diabetes had an effect on sleep (Table 2).

Table 3 shows the descriptive statistics of the individuals participating in this study according to the "Sleep Disturbance Scale for Children" and its sub-dimensions. According to the analysis, the average total score of the SDSC was 47.60±12.740. When reviewing the sub-dimensions of this scale, "Sleep Initiation and Persistence Issues" had an average score of 14.27±4.156, "RDDS" had an average score of 4.29±1.911, "Vigilance Reactions" had an average score of 4.09±1.522, "SWTD" had an average score of 10.75±3.965, "DES" had an average score of 9.75±4.300 and "Excessive Daytime Sleepiness" had an average score of 4.43±2.507 (Table 3).

Table 1. Distribution of demographic characteristics of the individuals participating in the study

Variables		n	%
Parent	Mother	76	72.4
	Father	29	27.6
Marital status	Married	91	86.7
	Single	14	13.3
Education level	Primary	58	55.3
	High school	27	25.7
	Bachelor	20	19.0
Employment status	Employed	60	57.1
	Unemployed	45	42.9
Income status	Less income than expenses	64	61.0
	Income equal to expenses	33	31.4
	Income more than expenses	8	7.6
Duration since child's diagnosis	Less than 1 year	31	29.5
	1-3 years	33	31.4
	4-6 years	17	16.2
	More than 6 years	24	22.9
Place of residence	Village/town	24	22.9
	District	35	33.3
	City	46	43.8
Type of family	Nuclear family	67	63.8
	Extended family	38	36.2
Number of siblings	No siblings	4	3.9
	One sibling	16	15.2
	Two siblings	16	15.2
	More than 2 siblings	69	65.7
Parent age		39.32±7.388	
Child age		10.95±4.128	
Total		**105**	**100.0**

Table 2. Distribution of the child's characteristics related to illness and sleep

Variables		n	%
The child's sleeping place	In the same bed with the parent	3	2.9
	Same room with parents, separate bed	25	23.8
	Alone in a separate room	17	16.2
	In a separate room with siblings	60	57.1
Fluid consumption before sleep	Yes	55	52.4
	No	50	47.6
Daytime sleeping condition	Yes	18	17.1
	No	43	41.0
	Sometimes	44	41.9
Spending time with digital devices before sleep	Yes	89	84.8
	No	16	15.2
Child's sleep time	Between 8 p.m. and 10 p.m.	36	34.3
	After 10 p.m.	69	65.7
The way of taking insulin at night	Before sleeping	93	88.6
	Waking up	9	8.6
	Pump	3	2.8
Snacking before sleep	Yes	65	61.9
	No	40	38.1
Blood sugar drop during sleep	Yes	63	60.0
	No	42	40.0
The effect of diabetes on sleep status	Yes	54	51.4
	No	51	48.6
Total		**105**	**100.0**

Table 4 shows the results of the analysis conducted to compare the average scores of the "Sleep Disturbance Scale for Children" and its sub-dimensions according to the demographic characteristics of the parents who participated in this study. According to the results of the analysis, a significant difference was found in the total of the "Sleep Disturbance Scale for Children" according to the income status variable of the parents ($p<0.05$). According to this significant difference, the average score of those parents whose income was more than their expenses was lower than the average score of the parents whose income was less than or equal to their expenses.

A significant difference was found in the "Sleep Initiation and Maintenance Problems (SIMP)" sub-dimension according to the parents' educational status ($p<0.05$). According to this significant difference, the average score of those parents with a bachelor's degree was lower than the average score of the parents with only elementary or high school education.

A significant difference was found in the "SWTD" sub-dimension according to the parents' income status ($p<0.05$). According to this significant difference, the average score of those parents whose income was more than their expenses was lower than the average score of the parents whose income was less than or equal to their expenses.

A positive and statistically significant relationship was found between the "Excessive Sleepiness Disturbance (ESD)" sub-dimension and the age of the children. In other words, as the age of the children increased, ESD also increased (Table 4).

Table 5 shows the results of the analysis conducted to compare the average scores of the "Sleep Disturbance Scale for Children" and its sub-dimensions according to the information about the disease and sleep. According to the results of the analysis, a significant difference was found in the sum of the "Sleep Disturbance Scale for Children" according to the variables of the child's daytime sleeping status, their state of blood sugar drop during sleep and the negative effect of diabetes on their sleep ($p<0.05$). According to these significant differences, the average score for those parents whose child/children slept during the day was higher than the average score of the parents whose child did not sleep during the day. The mean scores of those parents who stated that blood sugar negatively affected sleep in their children were higher than the average scores of those parents who stated that blood sugar did not negatively affect sleep in their children.

Table 3. Minimum, maximum, average and standard deviation values obtained from the sleep disturbance scale and its sub-dimensions for children

	Min.	Max.	Mean	SD
Problems with Sleep Initiation and Maintenance	8.00	28.00	14.27	4.156
Respiratory Disturbance During Sleep	3.00	13.00	4.29	1.911
Wakefulness reactions	3.00	11.00	4.09	1.522
Sleep Wakefulness Transition Disturbance	6.00	26.00	10.75	3.965
Excessive Sleepiness Disturbance	5.00	24.00	9.75	4.300
Excessive Sweating During Sleep	2.00	10.00	4.43	2.507
The Sum of the Scale	29.00	85.00	47.60	12.740

Min.: Minimum, Max.: Maximum, SD: Standard deviation.

Table 4. Comparison of the average scores of the Sleep Disturbance Scale and sub-dimensions for children according to the descriptive characteristics of the individuals participating in the study

Variable	PSIM	RDDS	WR	SWTD	ESD	ESDS	Sum scale
	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD
Parent							
Mother	14.56±4.45	4.44±2.00	4.09±1.44	10.69±4.04	10.02±4.34	4.38±2.47	48.21±13.44
Father	13.51±3.19	3.89±1.61	4.10±1.73	10.89±3.81	9.03±4.16	4.58±2.62	46.03±10.72
Test	U=984.5 p>0.05	U=911.5 p>0.05	U=1080.0 p>0.05	U=1047.5 p>0.05	U=938.5 p>0.05	U=1041.5 p>0.05	U=1054.5 p>0.05
Marital status							
Married	14.16±4.11	4.34±2.00	4.06±1.54	10.80±4.10	9.61±4.13	4.47±2.54	47.46±12.54
Single	15.00±4.52	4.00±1.10	4.28±1.38	10.42±3.03	10.64±5.34	4.21±2.32	48.57±14.41
Test	U=562.5 p>0.05	U=631.5 p>0.05	U=540.5 p>0.05	U=635.5 p>0.05	U=586.5 p>0.05	U=613.5 p>0.05	U=630.0 p>0.05
Education level							
Primary	14.43±4.52	4.62±2.29	4.24±1.53	11.36±4.54	10.08±4.44	4.56±2.62	49.31±14.56
High school	15.51±3.65	3.81±1.38	4.22±1.78	9.96±3.05	9.92±4.77	4.44±2.57	47.88±11.14
Bachelor	12.15±2.81	4.00±0.91	3.50±0.88	10.05±2.98	8.55±2.99	4.05±2.08	42.30±6.56
Test	**KW=10,247** **p<0.05** **1>3** **2>3**	KW=3,042 p>0.05	KW=4,010 p>0.05	KW=1,471 p>0.05	KW=1,365 p>0.05	KW=0.251 p>0.05	KW=2,486 p>0.05
Employment status							
Employed	14.10±4.02	4.18±1.79	3.90±1.44	10.85±3.90	9.20±0.02	4.58±2.46	46.81±12.00
Unemployed	14.51±4.36	4.44±2.06	4.35±1.59	10.62±4.09	10.48±4.58	4.24±2.57	48.66±13.72
Test	U=1284.5 p>0.05	U=1256.0 p>0.05	U=1123.0 p>0.05	U=1294.0 p>0.05	U=1110.5 p>0.05	U=1187.5 p>0.05	U=1262.0 p>0.05
Income status							
Less income than expenses	14.73±4.39	4.54±2.21	4.17±1.57	11.26±3.60	10.31±4.70	4.75±2.58	49.78±13.19
Income equal to the expenses	13.63±3.79	3.87±1.31	4.12±1.55	10.27±4.69	9.06±3.60	4.03±2.36	45.00±12.23
Income more than expenses	13.25±3.49	4.00±0.75	3.37±0.51	8.62±2.66	8.12±2.85	3.62±2.32	41.00±5.87
Test	KW=1,186 p>0.05	KW=1,877 p>0.05	KW=1,569 p>0.05	**KW=6,108** **p<0.05** **1>3** **2>3**	KW=2,665 p>0.05	KW=3,522 p>0.05	**KW=5,961** **p<0.05** **1>3** **2>3**
Duration since diagnosis							
Less than 1 year	13.90±4.12	4.06±1.36	4.22±1.74	10.48±3.31	8.45±3.60	4.32±2.53	45.45±10.75

Table 4. Continued

Variable	PSIM	RDDS	WR	SWTD	ESD	ESDS	Sum scale
	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD
1-3 years	14.18±3.81	4.30±2.31	4.03±1.42	11.00±4.38	10.27±3.95	4.66±2.68	48.45±11.84
4-6 years	14.76±4.61	5.05±2.41	4.17±1.38	11.64±4.15	10.35±4.52	4.17±2.27	50.17±14.44
More than 6 years	14.54±4.52	4.04±1.42	3.95±1.51	10.12±4.11	10.29±5.23	4.45±2.50	47.41±15.18
Test	KW=0.554 p>0.05	KW=3,301 p>0.05	KW=1,026 p>0.05	KW=2,015 p>0.05	KW=5,070 p>0.05	KW=0.325 p>0.05	KW=1,674 p>0.05
Place of residence							
Village/town	13.33±3.37	4.33±1.78	4.00±1.28	10.00±3.81	9.45±4.19	4.20±2.51	45.33±11.88
District	14.54±4.53	4.51±2.42	3.91±1.31	10.60±3.54	10.17±4.55	4.80±2.81	48.54±13.25
City	14.56±4.24	4.10±1.50	4.28±1.77	11.26±4.33	9.58±4.22	4.28±2.26	48.08±12.90
Test	KW=1,346 p>0.05	KW=0.428 p>0.05	KW=0.792 p>0.05	KW=1,547 p>0.05	KW=0.617 p>0.05	KW=0.558 p>0.05	KW=1,313 p>0.05
Type of family							
Nuclear family	14.20±4.15	4.14±1.76	4.05±1.57	10.76±3.44	9.52±4.51	4.50±2.57	47.20±12.35
Extended family	14.39±4.22	4.55±2.13	4.15±1.44	10.73±4.79	10.15±3.91	4.31±2.40	48.31±13.53
Test	U=1236.5 p>0.05	U=1111.0 p>0.05	U=1175.0 p>0.05	U=1156.5 p>0.05	U=1081.0 p>0.05	U=1236.0 p>0.05	U=1227.0 p>0.05
Number of siblings							
(1) No	11.50±2.38	3.50±0.57	5.00±4.00	11.00±2.16	7.00±1.41	3.75±0.95	41.75±6.60
(2) One	14.87±4.78	4.62±2.15	4.00±1.21	11.93±3.29	9.25±3.10	5.00±2.94	49.68±11.90
(3) Two	15.25±4.21	4.37±2.70	4.06±1.34	10.81±3.39	11.37±6.10	4.68±2.77	50.56±13.98
(4) More than two	14.07±4.04	4.24±1.69	4.07±1.43	10.44±4.29	9.65±4.08	4.28±2.41	46.78±12.89
Test	KW=3,288 p>0.05	KW=1,604 p>0.05	KW=0.255 p>0.05	KW=4,132 p>0.05	KW=2,533 p>0.05	KW=0.816 p>0.05	KW=3,067 p>0.05
Parent age^{r}	-0.004	-0.027	-0.050	-0.070	0.032	-0.017	-0.028
Child age^{r}	0.073	0.106	0.067	-0.026	0.218*	-0.085	0.050

*p<0.05, ^{r}: Spearman's rank correlation, Kw: Kruskal-Wallis H test, U: Mann-Whitney U test, PSIM: Problems with Sleep Initiation and Maintenance, RDDS: Respiratory Disturbance During Sleep, WR: Wakefulness reactions, SWTD: Sleep-Wake Transition Disturbance, ESD: Excessive Sleepiness Disturbance, ESDS: Excessive Sweating During Sleep, SD: Standard deviation.

A significant difference was found in the "Wakefulness Reactions Disturbance (WRD)" sub-dimension according to daytime sleeping status and snacking before going to sleep (p<0.05). According to these significant differences, the average score of those parents whose child slept during the day and those whose child sometimes slept was higher than the average score of the parents whose child did not sleep during the day. The average score of the parents of those children who snacked before going to sleep was lower than the average score of the parents of children who did not snack before going to sleep.

A significant difference was found in the "SWTD" sub-dimension according to the variables of daytime sleepiness, blood sugar drop during sleep, and the negative effect of diabetes on sleep (p<0.05). According to these significant differences, the average score of those parents whose child slept during the day and those whose child sometimes slept was higher than the average score of the parents whose child did not sleep during the day. The average score of those parents whose child's blood sugar dropped during sleep was higher than the average score of those whose child's blood sugar did not drop during sleep. The average score of those parents who indicated that blood sugar had a negative effect on sleep was higher than the average score of those who indicated that blood sugar had no negative effect on sleep. A significant difference was found in the "ESD" sub-dimension according to the variables of daytime sleepiness, spending time with a digital device before sleep, blood sugar drop during sleep and the negative effect of diabetes on sleep (p<0.05). According to these significant differences, the average score of those parents whose child slept during the day was higher than the average score of those whose child did not sleep during the day. The average score of those parents whose child spent time with a digital device before sleep was higher than the average score of those whose child did not spend time with a digital device before sleep. The average score of those parents whose child's blood sugar dropped during sleep was higher than the average score of those whose child's blood sugar did not drop during sleep. The average score of those parents who indicated that blood sugar had a negative effect on sleep was higher than the average score of those who indicated that blood sugar had no negative effect on sleep (Table 5).

Table 6 shows the distributions of the children's sleeping times at night and how quickly they fell asleep after going to bed. According to this table, 33.3% of the children slept between 8 and 9 hours per night. In addition, 39% of the children fell asleep within 15 to 30 minutes after going to bed (Table 6).

Table 5. Comparison of the score averages of the Sleep Disturbance Scale and sub-dimensions for children according to information about illness and sleep

Variables	PSIM	RDDS	WR	SWTD	ESD	ESDS	Sum Scale
	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD
In the same bed with parent	13.33±1.15	4.00±1.00	3.33±0.57	11.00±2.00	8.33±2.30	3.33±0.57	43.33±2.30
Same room with parents, separate bed	14.12±4.42	4.60±2.46	4.12±1.36	11.56±4.44	9.00±4.41	5.24±3.01	48.64±14.06
Alone in a separate room	13.94±5.04	3.70±0.91	4.41±2.23	9.64±2.99	10.35±5.18	4.35±2.69	46.41±13.62
In a separate room with sibling	14.48±3.92	4.35±1.88	4.03±1.37	10.71±4.05	9.96±4.08	4.18±2.23	47.73±12.38
Test	KW=0.883 p>0.05	KW=1.294 p>0.05	KW=0.909 p>0.05	KW=2,091 p>0.05	KW=2,802 p>0.05	KW=2,476 p>0.05	KW=0.680 p>0.05
Fluid consumption before sleep							
Yes	14.52±4.43	4.36±1.89	4.27±1.71	11.25±4.11	10.18±4.59	4.76±2.65	49.36±13.74
No	14.00±3.85	4.22±1.94	3.90±1.26	10.20±3.75	9.28±3.93	4.08±2.30	45.68±11.35
Test	U=1298.5 p>0.05	U=1295.5 p>0.05	U=1249.5 p>0.05	U=1180.5 p>0.05	U=1224.5 p>0.05	U=1162.5 p>0.05	U=1189.0 p>0.05
Daytime sleeping condition							
(1) Yes	14.88±5.42	4.61±2.68	4.94±2.26	11.88±4.61	11.33±6.13	5.44±3.31	53.11±17.09
(2) No	13.65±3.44	4.23±1.92	3.58±0.87	9.46±3.07	8.55±3.81	4.39±2.44	43.88±9.98
(3) Sometimes	14.63±4.22	4.22±1.52	4.25±1.49	11.54±4.18	10.27±3.59	4.06±2.11	49.00±12.29
Test	KW=0.850 p>0.05	KW=0.262 p>0.05	**KW=6,637 p<0.05 2<1 2<3**	**KW=6,860 p<0.05 2<1 2<3**	**KW=6,709 p<0.05 2<1**	**KW=1,611 p>0.05**	**KW=6,183 p<0.05 2<1**
Spending time with digital devices before sleep							
Yes	14.46±4.30	4.26±1.76	4.10±1.42	11.03±4.04	10.10±4.36	4.43±2.50	48.40±12.92
No	13.25±3.08	4.43±2.65	4.06±2.04	9.18±3.18	7.81±3.44	4.43±2.60	43.18±10.98
Test	U=609.5 p>0.05	U=658.0 p>0.05	U=648.5 p>0.05	U=508.5 p>0.05	**U=455.00 p<0.05**	U=711.0 p>0.05	U=508.5 p>0.05
Child's sleep time							
Between 8 p.m. and 10 p.m.	14.27±3.97	4.27±2.03	4.22±1.75	10.91±3.57	9.16±3.98	4.44±2.48	47.30±11.66
After 10 p.m.	14.27±4.27	4.30±1.85	4.02±1.39	10.66±4.17	10.05±4.45	4.43±2.53	47.76±13.34
Test	U=1220.0 p>0.05	U=1220.5 p>0.05	U=1199.0 p>0.05	U=1144.5 p>0.05	U=1082.5 p>0.05	U=1215.0 p>0.05	U=1197.5 p>0.05
The way of taking insulin at night							
Before sleeping	14.19±4.22	4.26±1.88	4.11±1.53	10.69±3.84	9.95±4.34	4.49±2.46	47.73±12.53
Waking up	15.44±4.06	5.00±2.34	4.11±1.69	12.22±5.28	8.55±4.12	4.33±3.31	49.66±16.05
Pump	13.33±2.30	3.00±0.00	3.33±0.57	8.00±1.73	7.00±2.00	3.00±1.00	37.66±3.51
Test	KW=0.995 p>0.05	KW=5,499 p>0.05	KW=0.721 p>0.05	KW=2.399 p>0.05	KW=3.302 p>0.05	KW=1,457 p>0.05	KW=2,866 p>0.05
Snacking before sleep							
Yes	14.13±4.19	4.26±1.97	3.83±1.23	10.86±4.10	10.03±4.33	4.63±2.57	47.75±12.80
No	14.50±4.13	4.35±1.81	4.52±1.83	10.57±3.76	9.30±4.26	4.12±2.39	47.37±12.79
Test	U=1235.5 p>0.05	U=1221.0 p>0.05	U=1024.5 p<0.05	U=1281.0 p>0.05	**U=1144.0 p>0.05**	U=1125.0 p>0.05	U=1232.0 p>0.05
Blood sugar drop during sleep							
Yes	14.66±4.45	4.63±2.22	4.25±1.70	11.63±4.10	10.96±4.75	4.71±2.59	50.87±13.92
No	13.69±3.63	3.78±1.15	3.85±1.18	9.42±3.38	7.92±2.64	4.02±2.34	42.71±8.81
Test	U=1167.0 p>0.05	**U=1033.5 p<0.05**	U=1181.0 p>0.05	**U=872.5 p<0.05**	**U=782.5 p<0.05**	U=1107.5 p>0.05	**U=846.5 p<0.05**
The effect of diabetes on sleep status							
Yes	14.70±4.78	4.59±2.20	4.09±1.44	11.59±4.23	11.12±5.08	4.94±2.80	51.05±14.70
No	13.82±3.35	3.98±1.50	4.09±1.61	9.86±3.48	8.29±2.61	3.90±2.04	43.96±9.05

Table 5. Continued

Variables	PSIM	RDDS	WR	SWTD	ESD	ESDS	Sum Scale
	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD	X ± SD
Test	U=1287.0 p>0.05	U=1175.5 p>0.05	U=1358.0 p>0.05	**U=1036.5 p<0.05**	**U=930.0 p<0.05**	U=1110.5 p>0.05	**U=999.0 p<0.05**

Kw: Kruskal-Wallis H test, U: Mann-Whitney U test, PSIM: Problems with Sleep Initiation and Maintenance, RDDS: Respiratory Disturbance During Sleep, WR: Wakefulness reactions, SWTD: Sleep-Wake Transition Disturbance, ESD: Excessive Sleepiness Disturbance, ESDS: Excessive Sweating During Sleep, SD: Standard deviation.

Table 6. Distributions of night sleeping time and falling asleep time of the children participating in this study

Questions		n	%
How many hours does your child sleep most nights?	9-11 hours	30	28.6
	8-9 hours	35	33.3
	7-8 hours	32	30.4
	5-7 hours	7	6.7
	Less than 5 hours	1	1.0
How quickly does your child usually fall asleep after going to bed?	Less than 15 minutes	39	37.1
	Between 15-30 minutes	41	39.0
	Between 30-45 minutes	8	7.6
	Between 45-60 minutes	7	6.7
	More than 60 minutes	10	9.5
Total		**105**	**100.0**

DISCUSSION

Sleep greatly affects people's health and their quality of life. Sleep is a concept with social, psychological and physiological dimensions.[20] Sleep in children and adolescents with T1D can often be disrupted due to hypoglycaemia, hyperglycaemia and their parents' diabetes care behaviours.[15] Sleep disturbance can negatively affect the progression of this disease and cause the development of complications.[17]

As a result of this research, the average total score of the SDSC was 47.60±12.740. According to this result, the level of sleep disturbance of the children who participated in this study was below the average score. In other words, the children who participated in this study had a low level of sleep disturbance. In the study of Agadayi et al.[19] the average total score of the SDSC answered by mothers was 40.9±10.1, while the total score average of the scale answered by fathers was 40.2±10.3. The results of the present research are in parallel with the literature. Six sub-dimensions of the SDSC were used within the scope of the research. According to the demographic characteristics of the surveyed parents with regards to the "Sleep Disturbance Scale for Children", when we look at the "SWTD" sub-dimension, a significant difference was detected in terms of the parents' income status ($p<0.05$). The average score of those parents whose income was more than their expenses was lower than the average score of those whose income was less than or equal to their expenses. A significant difference was found in the "SIMP" sub-dimension according to the parents' educational status ($p<0.05$). According to the results of this research, the average score of those parents who graduated with a bachelor's degree was lower than the average score of those who only graduated from elementary or high school. From the literature, a study conducted with the parents of 299 primary school students in Türkiye found significant differences between the family's income status, education status, bedtime resistance and sleep duration.[21] In the present research, a significant relationship was found between age and the "ESD" sub-dimension. In other words, as the age of the children increased, the ESD also increased. From a study found in the literature, according to the parent group having SDSC sleep problems, the average score of the subscale with the highest UUGB SWTD during the day was in elementary school.[17] A significant difference was found in the "WRD" sub-dimension according to daytime sleep status and snacking before going to sleep ($p<0.05$). A significant difference was found in the "ESD" sub-dimension according to the variables of the child's daytime sleeping status, spending time with a digital device before sleep, blood sugar drop during sleep and the negative impact of diabetes on sleep ($p<0.05$). According to these significant differences, the average score of those parents whose child slept during the day was higher than the average score of those whose child did not sleep during the day. The average score of those parents whose child spent time with a digital device before sleep was higher than the average score of those whose child did not spend time with a digital device before sleep. Sleep problems are affected by television, bedtime resistance, delays in starting to sleep and anxiety during sleep and thus they lead to shortened sleep durations.[22] From the literature, total sleep time and total duration of TV viewing were investigated in one study. 51% of respondents reported to having a TV set in the child's bedroom. For those children with a TV in the room, "night terrors", "nightmares", "sleep talking" and "being tired at wake-up" responses were seen to have significantly higher scores.[23]

Children with T1D may be especially vulnerable to sleep disturbances as parents may delay bedtime if their blood sugar levels are outside the target range and they often wake their children up during the night to monitor their blood sugar and treat episodes of hypoglycaemia or hyperglycaemia.[24] In the present research, the average score of those parents whose child's blood sugar dropped during sleep was higher than the average score of those whose child's blood sugar did not drop during sleep. The average score of those parents who indicated that blood sugar had a negative effect on sleep was higher than the

average score of those who indicated that blood sugar had no negative effect on sleep. In another study consisting of 75 children with T1D and 49 controls, 65.3% of all participants in both groups had sleep problems; children with T1D slept less and experienced more daytime sleepiness problems compared to the controls.[25] In the present study, a significant difference was found in the "SWTD" sub-dimension of the SDSC according to the variables of daytime sleepiness, blood sugar drop during sleep and the negative effect of diabetes on sleep ($p<0.05$). In another study, the SWTD was the subscale with the highest average score.[17] The results of the present research are similar to the literature. In the present research, 33.3% of the children slept between 8 and 9 hours per night. In addition, 39% of the children fell asleep between 15 and 30 minutes after going to bed. In a study conducted with 111 participants with T1D, which is similar to the sample of the present study, the children slept less than the recommended amount of sleep for this age group of children of approximately nine hours and were found to be in poor glycaemic control, which showed that less sleep is associated with poor management and glycaemic control. In the same study, it was reported that especially later bedtimes and a greater social jetlag were associated with poor glycaemic control.[26] In another study, 60 people formed the control group with 60 T1D patients. In that study, significantly more adolescents with 60 T1D delay starting to sleep, non-REM sleep and sleep efficiency, and arousal index significantly lower compared to the controls to have sleep rapid eye activity are stated.[27] In addition to the direct physiological effects of sleep on glycaemic control, insufficient or poor-quality sleep have an indirect behavioural effect on diabetes management. Sleep disturbance, including bedtime resistance and night-time waking, have been associated with greater behavioural problems in school-age children.[28] In the present research, most children also slept late. According to Monzon et al.[13], as sleep duration decreases due to increased frequencies of waking up at night, parental stress due to night care, anxiety about the illness, and constant monitoring, cortisol levels rise and glycaemic control is poor. In Farabi's[17] study with 130 people, it was reported by parents that 45.1% of their children's sleep duration was 8-9 hours per night. The results of this research are in line with the literature.

Study Limitations

Our research had some limitations. Our research sample size was small and our findings cannot be generalized to the larger child population.

CONCLUSION

As a result of this research, the parents who participated in this study evaluated the level of sleep disturbance of their children as being below the average score. The SDSC was affected in the dimensions of WRD, SWTD, and ESD, with significant differences being found in these sub-dimensions. When the sources of the sleep problems of children with T1D were examined, it was seen that the sleep of these children was affected by their condition. Since the sleep disturbances of those children with T1D are affected by familial characteristics and factors related to their disease, it is recommended to conduct further studies in order to identify sleep disturbance and influencing factors so as to improve these conditions, and to provide educational and counselling services to their parents on these issues.

MAIN POINTS

- Diabetes has a negative effect on sleep.
- The sleep problems of those children with chronic diseases are affected by familial characteristics.
- Parental education is important for the sleep health of children with diabetes.

ETHICS

Ethics Committee Approval: This study was approved by the University of Health Sciences Türkiye, Van Training and Research Hospital Ethics Committee (approval number: 2022/14-05, date: 24.06.2022).

Informed Consent: It wasn't obtained.

Authorship Contributions

Concept: Z.K., F.K.Ö., D.Ç.B., Design: Z.K., F.K.Ö., D.Ç.B., Data Collection and/or Processing: Z.K., G.G., C.K., S.Y., Analysis and/or Interpretation: F.K.Ö., D.Ç.B., Literature Search: F.K.Ö., D.Ç.B., Writing: F.K.Ö., D.Ç.B.

DISCLOSURES

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RESEARCH ARTICLE

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Evaluation of the Color Stability and Surface Roughness of a Novel Single-Shade Composite Resin: A Smart Chromatic Technology

Alper Cumhur[1], Begüm Büşra Cevval Özkoçak[2]

[1]Department of Restorative Dentistry, Bolu Abant İzzet Baysal University Faculty of Dentistry, Bolu, Türkiye
[2]Department of Restorative Dentistry, İstanbul Medeniyet University Faculty of Dentistry, İstanbul, Türkiye

Abstract

BACKGROUND/AIMS: This study aimed to assess the color stability and surface roughness of a newly developed single-shade resin-based composite (RBC) utilizing smart chromatic technology in comparison to nanohybrid and nanoceramic RBCs.

MATERIALS AND METHODS: A total of 120 specimens of RBC discs were prepared on a round metal mold (diameter 6 mm, thickness 2 mm). Distilled water was used as a control. Three different RBCs; harmonize (n=40), omnichroma (OM) (n=40), and zenit (n=40), were immersed into three staining beverages, namely orange juice, cola, and coffee, respectively, as the test groups. Prior to the immersion, the initial roughness and color values were recorded using a profilometer and CIE L* a* b*, respectively. The color changes and surface roughness values were determined again after one week. The normality test of numerical variables were analysed by means of Kolmogorov-Smirnov and Shapiro-Wilk tests ($p \leq 0.05$).

RESULTS: There was no significant difference between the initial surface roughness values (Ra) among the groups. However, a significant increase was observed in the roughness values of harmonize immersed in coffee ($p=0.024$) and OM immersed in cola ($p=0.021$). The color stability of RBC was significantly affected by the immersion period, and coffee caused the highest discoloration ($p<0.001$).

CONCLUSION: The new generation monochrome smart composite resin with spherical filler (OM) is clinically recommended as it shows acceptable values in terms of color stability and roughness. Therefore, OM may be preferred as an alternative to multi-shade composites as it simplifies color selection.

Keywords: Discoloration, single-shade composite resin, smart chromatic technology, spherical filler, surface roughness

INTRODUCTION

Color stability and surface texture are the most important characteristics of esthetic restorative materials aiming to provide a personalized smile.[1] The maintenance of color throughout the functional lifetime of restorations plays a significant role in the durability of the treatment. However, this characteristic is not constant among dental materials.[2,3] Various inorganic particles with different components, such as silica, alumina, zirconia, silicate glass, quartz, and ceramics, have been employed in the resin matrix of dental resin-based composites (RBC) as reinforcing filler phases. In addition to the composition of fillers, other properties, such as the filler particle content, size, size distribution, shape, morphology, porosity, and surface characteristics, play a critical role in the development of dental RBCs for specific applications and purposes.[4]

Since composite restorations have different shades and technical sensitivities, success is highly dependent on the skill of the dentist and the choice of shade. This complex process causes the physician to

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ORCID IDs of the authors: A.C. 0000-0003-3664-3545; B.B.C.Ö. 0000-0002-6371-5420.

Address for Correspondence: Begüm Büşra Cevval Özkoçak
E-mail: busra_cevval@hotmail.com
ORCID ID: orcid.org/0000-0002-6371-5420

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employ a trial-and-error method and increases the time spent in the dental chair. Therefore, the researchers aimed to simplify and reduce the number of shadows based on color interactions. The chameleon or blending effect is the ability of dental materials to adapt to the color of the surrounding dental hard tissue so that color mismatches are compensated to some extent.[5] These materials, which have the properties of imitating natural tooth structures such as enamel and dentine, support the remaining tooth structure. They employ "smart chromatic technology". However, they can be changed by factors such as temperature, humidity, pH, and stress.[6] RBCs have undergone many changes over the years in order to provide positive properties. For this purpose, many composite resin types are available on the market with changes in both their monomers forming the organic polymer matrix phase and their inorganic filler particles.[4]

Recently, a newly developed monochrome RBC [omnichroma; (OM), Tokuyama Dental, Tokyo, Japan] was introduced to shorten treatment time and reduce the clinician's difficulty in matching colors. The manufacturer claims that the structural color in the OM can mimic the color of the surrounding tooth, regardless of its shade.[7] Homogenized spherical filler particles with a size of 260 nm were used via the "sol-gel method" to obtain uniform filler particles with reflectivity. OM fillers change the light transmitted through the red-yellow area of the color spectrum, allowing it to match the color of the patient's neighboring teeth. OM's wide color matching ability minimizes the waste of unused composite hues by reducing the time spent on color selection and the time spent in the chair by the patient.[7,8] However, to date, there has not been enough research on the physical properties and color adjustment of these composite resins produced with this technology.

This study aimed to evaluate the surface roughness and color stability of OM, a newly developed single-shade composite resin containing spherical particles, by comparing it with nanohybrid and nanoceramic RBCs. The null hypothesis of the present study was that the surface roughness and color change of smart chromatic composite resins immersed in different beverages (distilled water, coffee, cola, and orange juice) were not significantly different from certain multi-shade RBCs with various contents.

MATERIALS AND METHODS

Preparation of Sample

A total of 120 samples were obtained in this study, with 40 samples for each RBC. A cylindrical metal mold of diameter 6 mm, thickness 2 mm was used for composite samples. Mylar strip (Kerr Corp. Orange CA, USA) and cement glass were placed on it in order to obtain a smooth surface. Based on the manufacturer's instructions, the light emitting diode light device Monitex Bluex, GT1200, (Monitex Industrial Co., Taiwan) was applied for 20 seconds in full power mode, M1 mode, at 1,200 mW/cm^2, with a glass coverslip and light device in contact. Following the polymerization process, the samples were kept in distilled water at 37 °C for 24 hours. They were then polished under a water spray (new discs were used for every five samples) by applying a unidirectional rotation motion with light pressure from coarse to fine grain with 4-stage OptiDisc (Kerr Corp. Orange CA, USA) containing aluminum oxide abrasive. The composite resin materials used in this study are listed in Table 1.

Roughness Evaluation

In this study, the initial roughness measurements were made with the Perthometer M2 (Mahr, Gottingen, Germany) profilometer device. Afterwards, the samples were kept in four different beverages (distilled water, coffee, cola, and orange juice) in an oven at 37 °C for one week, and the beverages were renewed every other day. At the end of this staining process, the final roughness measurements were evaluated. Three measurements were made in the center of the samples with the same device, and Ra values were recorded by calculating the average of these values.[9,10] A calibration process was performed after every five measurements.

Evaluation of Color Changes

The Minolta Chromascop colorimeter device (Chroma Me-ter CR 321, Minolta, Osaka, Japan) was used to evaluate color changes. It detects the reflected colors of surfaces using compact tristimulus color analysis. The measurement area was 3 mm and had 45° environmental illumination, and the viewing angle was 0°. Measurements are given as L* a* b*. During the measurements of the samples, the calibration of the instrument was checked before each color measurement step by using a standard white background. Measurements were repeated three times for each sample, and the average of the values was determined.

Table 1. Compositions of the resin-based composites in the present study

Material	Classification	Organic content	Inorganic content	Lot
Omnichroma Tokuyama dental, Tokyo, Japan	Supra-nano spherical resin-based composite	UDMA, TEGDMA, mequinol, Dibutyl hydroxyl toluene, UV absorber	Spherical silica-zirconia, average particle size: 0.3 µm Weight: 79% Volume: 68%	018EY9
Zenit President dental, Germany	Nanoceramic Resin-based composite	UDMA, BDDMA, BisGMA	Glass filler (0.7 µm) Pyrogenic silica (12 µm) Agglomerated nano-particles (0.6 micron) Weight: 83% Volume: 70%	2019012264
Harmonize Kerr Corp., Orange CA, USA	Nanohybride Resin-based composite	BisGMA, BisEMA, TEGDMA	Spherical silica (30 nm)-zirconia (5 nm) filler particles, barium glass particles (5-400 µ) Weight: 81% Volume: 64%	7253850

BDDMA: Butanediol dimethacrylate, BisGMA: Bisphenol-A-glycidyl methacrylate, BisEMA: Bisphenol-A-polyethylene glycol diether methacrylate, TEGDMA: Triethylene glycol dimethacrylate, UDMA: Urethane Di Methacrylate.

The amount of color change is expressed as ΔE and calculated as follows;

$\Delta E = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$

$\Delta L = L2^* - L1^*$

$\Delta a = a2^* - a1^*$

$\Delta b = b2^* - b1^*$

After the initial color measurements were taken and recorded, the samples (n=10) were kept in four different types of beverages (distilled water, coffee, cola, and orange juice) at 37 °C for one week. The beverages were renewed daily, the samples were kept in the beverages throughout the day, and final measurements were taken and recorded at the end of one week. For standardization, the same immersion period was applied in all beverages.

Statistical Analysis

The data obtained from this study were summarized, and descriptive statistics were tabulated as mean ± standard deviation and median and minimum-maximum for continuous variables depending on their distribution. Categorical variables were summarized as numbers and percentages. The normality test of numerical variables was verified by means of the Kolmogorov-Smirnov and Shapiro-Wilk tests. The paired t-test was used to examine whether the roughness value changed before and after the procedure. In comparisons of more than two independent groups, the Kruskal-Wallis H test was used when numerical variables did not show normal distribution. Differences among the groups in non-parametric tests were evaluated by the Dwass-Steel-Critchlow-Fligner test. Statistical analyses were performed using the IBM SPSS Statistics for Windows (version 20.0) program, and the significance level was defined as 0.05 (p-value).

RESULTS

Roughness

In regard to the staining beverages, when the roughness of each composite filling material was evaluated before staining, there was no significant difference among the harmonize, OM, and zenit groups (p=0.738, p=0.969, and p=0.940, respectively) (Figure 1-3). Similarly, no statistically significant difference was observed among the post-treatment roughness of each composite resin (p=0.843, p=0.229, and p=0.745, respectively). A significant increase in roughness was observed in harmonize immersed in the coffee solution (p=0.024) and OM immersed in the cola solution and water (p=0.021, p=0.038, respectively) (Table 2).

Color Changes

The overall color change (ΔE*) mean values of the RBCs for all staining beverages are shown in Table 3. When the RBCs were compared with each other in regard to the color change in distilled water, coffee, and cola solutions, there was no significant difference between the ΔE* values. The color change of harmonize and OM composite resins after immersion in distilled water, orange juice, and cola was found to be significantly lower than the ΔE* value obtained after immersion in coffee (p<0.001).

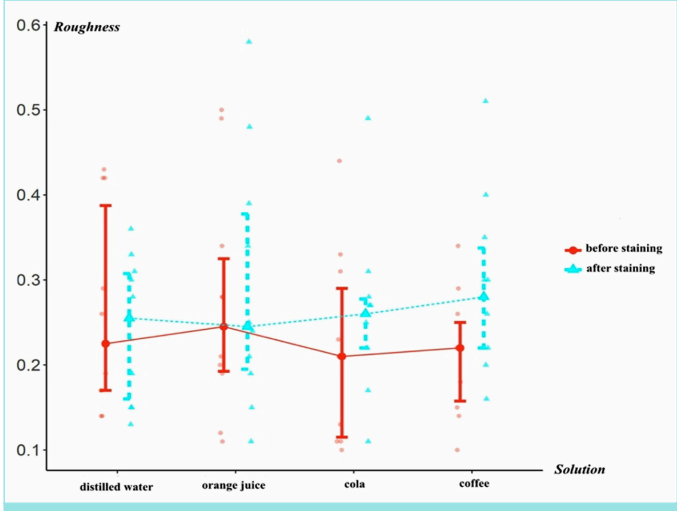

Figure 1. Roughness-solution graph of harmonize resin-based composite.

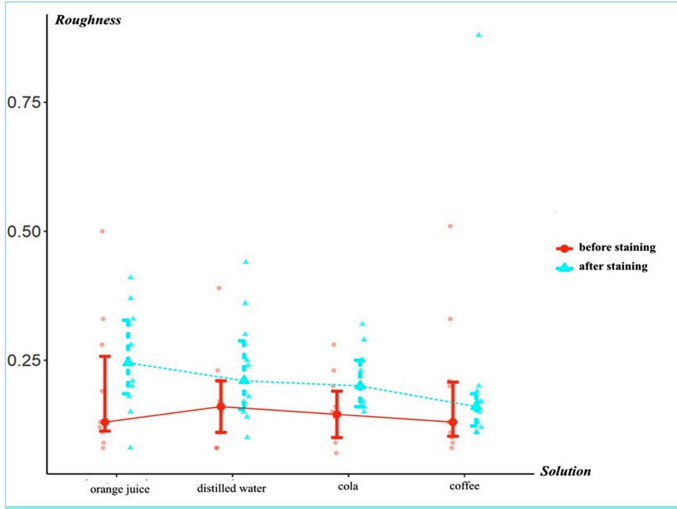

Figure 2. Roughness-solution graph of omnichroma resin-based composite.

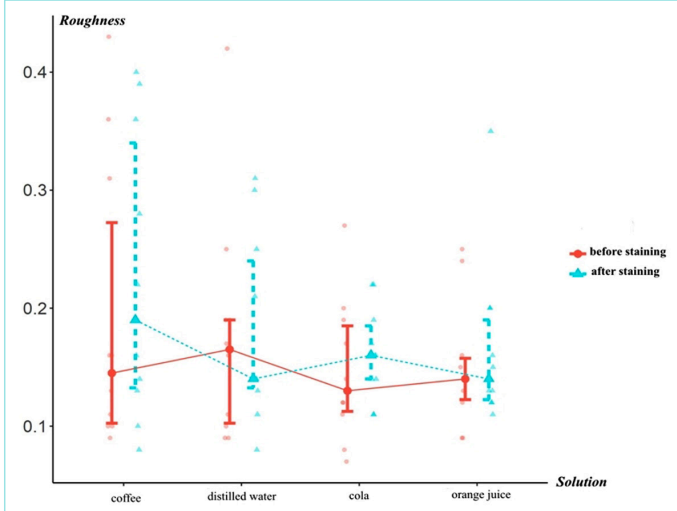

Figure 3. Roughness-solution graph of zenit resin-based composite.

Table 2. The values of the surface roughness (R_a) of the resin-based composites

	Beverages	Mean ± SD (before staining)	Mean ± SD (after staining)	p*
Harmonize	Distilled water	0.26±0.12	0.24±0.08	**0.798**
	Coffee	0.21±0.07	0.29±0.11	**0.024**
	Cola	0.22±0.11	0.26±0.1	**0.414**
	Orange juice	0.27±0.14	0.29±0.15	**0.683**
	p**	**0.738**	**0.843**	
Omnichroma	Distilled water	0.17±0.09	0.23±0.11	**0.038**
	Coffee	0.19±0.14	0.22±0.23	**0.878**
	Cola	0.15±0.07	0.21±0.06	**0.021**
	Orange juice	0.20±0.14	0.25±0.11	**0.236**
	p**	**0.969**	**0.229**	
Zenit	Distilled water	0.18±0.1	0.18±0.08	**0.906**
	Coffee	0.20±0.12	0.23±0.12	**0.167**
	Cola	0.15±0.06	0.16±0.04	**0.540**
	Orange juice	0.15±0.05	0.17±0.07	**0.341**
	p**	**0.940**	**0.745**	

SD: Standard deviation, *Wilcoxon test, **Kruskal-Wallis test.

When the color stability of the RBCs was compared after immersion in the orange juice beverage, zenit showed the highest ΔE* value (6.47±1.65), and this color change was considered significant when compared to harmonize and OM (Table 3). Among all RBCs, the ΔE* value of the distilled water was the lowest (1.26), while the ΔE* value of the coffee was the highest (7.04), and this difference was determined to be statistically significant (p<0.001) (Table 4). The differences among the ΔL, Δa, and Δb color change medians of the composite materials according to the staining beverages used were statistically significant (p=0.034, p<0.001, and p=0.001, respectively), and these differences were examined through multiple comparisons (Table 5, 6). When we examined the color change values (ΔE) according to the staining beverages used, the lowest value was found in the distilled water (ΔE=1.26) and the highest degree of color change was found in the coffee group (ΔE=7.04) (Table 4, Figure 4).

Table 3. Comparison of the mean values of color change (ΔE*) of resin-based composites after exposure to staining beverages

Resin-based composites	Beverages		Mean ± SD	p
Harmonize	Distilled water	ΔE	1.41±0.39	**<0.001**
	Coffee	ΔE	7.77±2.03	
	Cola	ΔE	2.09±2.31	
	Orange juice	ΔE	2.87±1.89	
Omnichroma	Distilled water	ΔE	1.42±0.3	**<0.001**
	Coffee	ΔE	6.37±0.85	
	Cola	ΔE	2.55±2.09	
	Orange juice	ΔE	2.99±0.76	
Zenit	Distilled water	ΔE	0.94±0.41	**<0.001**
	Coffee	ΔE	6.97±1.59	
	Cola	ΔE	2.64±1.26	
	Orange juice	ΔE	6.47±1.65	

Kruskal-Wallis test (p≤0.05), SD: Standard deviation.

Table 4. Comparison of color changes of resin-based composites according to staining beverages

	Distilled water (n=30)	Coffee, (n=30)	Cola, (n=30)	Orange juice, (n=30)	
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	p
ΔL	0.46±0.77	-4.54±2.01	-0.14±1.81	-0.25±1.13	<0.001
Δa	0.08±0.41	0.46±0.85	0.63±1.6	-1.32±1.21	<0.001
Δb	0.19±0.89	4.89±1.69	1.13±1.43	3.58±2.15	<0.001
ΔE	1.26±0.42	7.04±1.62	2.43±1.89	4.11±2.24	<0.001

Kruskal-Wallis test (p≤0.05).

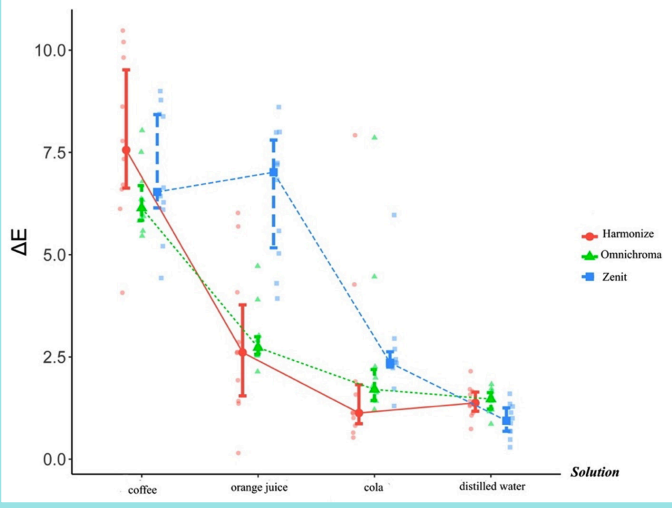

Figure 4. ΔE - solution graph of the resin-based composites.

Table 5. Comparison of the mean values of color changes (ΔL, Δa, Δb, ΔE) of resin-based composites

	Harmonize	Omnichroma	Zenit	
	Mean ± SD	Mean ± SD	Mean ± SD	p
ΔL	-1.58±2.8[a,b]	-0.29±2.11[b]	-1.49±2.39[a]	0.034
Δa	0.39±1.48[b]	0.13±0.75[b]	-0.64±1.45[a]	<0.001
Δb	1.4±2.75[a]	2.71±1.88[b]	3.23±2.37[b]	0.001
ΔE	**3.54±3.08**	**3.33±2.2**	**4.25± 2.87**	**0.35**

Kruskal-Wallis test (p≤0.05).

Table 6. Multiple comparisons of color changes of resin-based composites according to the staining beverages

Distilled water			ΔL	Δa	Δb	ΔE
Harmonize	-	Omnichroma	0.087	0.002	<0.001	0.981
Harmonize	-	Zenit	0.753	0.007	<0.001	0.060
Omnichroma	-	Zenit	0.041	0.924	0.022	0.041
Coffee						
Harmonize	-	Omnichroma	<0.001	0.121	0.636	0.121
Harmonize	-	Zenit	0.234	0.141	0.636	0.540
Omnichroma	-	Zenit	<0.001	0.022	0.142	0.540
Cola						
Harmonize	-	Omnichroma	0.857	0.050	<0.001	0.220
Harmonize	-	Zenit	0.285	0.022	<0.001	0.087
Omnichroma	-	Zenit	0.073	0.103	0.191	0.285
Orange juice						
Harmonize	-	Omnichroma	0.857	0.540	0.448	0.797
Harmonize	-	Zenit	0.962	0.003	0.006	0.006
Omnichroma	-	Zenit	0.730	0.001	<0.001	<0.001

Dwass-Steel-Critchlow-Fligner test (p≤0.05).

DISCUSSION

Various factors, such as plaque accumulation, the effect of coloring foods and beverages on the composite resin structure, insufficient polymerization of materials, degree of absorption, smoking, frequency of interaction with chemical agents, and the surface roughness of the restoration can cause color changes.[11] The roughness and color stability of the composite resin are among the most important factors for a successful esthetic restoration.[12] Choosing the right shade is an important esthetic factor in the direct restoration of teeth using RBCs. For the restoration of teeth with different shades, dental material manufacturers have produced a variety of RBCs with different shades and/or translucency. One of the most important problems faced by dentists is the incompatibility of the color between the RBCs used and the natural tooth. In order to eliminate this issue, many factors, such as symmetry, color, translucency, and the surface features need to be considered.[13]

However, the choice of color increases the time spent in the dental unit and makes the color selection process subjective. The use of smart technologies in the production of RBCs has recently been applied in order to eliminate all these disadvantages. Manufacturers have developed a resin-based OM composite, which has been formulated based on the concept of "Wide Color Matching." OM creates shades which can cover a large number of natural tooth shades in order to reduce the time required for shade selection and also the number of composite shades needed in stock. It has been claimed that this new dental composite produced with Smart Chromatic Technology can match the tooth color thanks to its optical structure whereby the particles reflect the color of the surrounding tooth structure.[14,15] Therefore, in the current study, a novel single shade composite resin with spherical fillers was compared with the nanohybrid composite harmonize, which imparts a chameleon effect, and the zenit composite containing fine radiopaque porcelain fillers.

In many studies[16-18], the average critical value was specified as being 0.2 µm for surface roughness. However, there is no accepted threshold value for the assessment of surface roughness to date. In a clinical study conducted by Jones et al.[19], patients were able to realize when the mean surface roughness was 0.3 µm. In the present study, a significant increase in the mean roughness values of all composite resins was shown after staining (Figure 1-3). We think that this may be related to the acidity of the beverages used and the surface irregularities which occur during the finishing process. With regard to the staining beverages used, when the roughness of each composite filling material was evaluated before the treatment, no statistically significant difference was found among the harmonize, OM, and zenit groups (p=0.738, p=0.969, and p=0.940, respectively) (Table 2). An increase in roughness was observed after staining the harmonize composite in coffee and the OM composite in cola. This change might cause corrosion on the composite resin surface due to the phosphoric acid and sugars in the structure of the solution.[20,21] de Gouvea et al.[21] and Isabel et al.[22] determined that different long-chain organic acids in coffee can dissolve and etch restorative materials, thereby causing surface roughness in composite resins. Therefore, the surface roughness of the harmonize composite in the present study supports these results. Also, these differences can be explained by the differences in the polymer matrices, the types of fillers, and the connections between the filler and the polymer matrix.[23,24] It was observed that the roughness values of the OM composite material were significantly different (p=0.021) after immersion in cola, but there was no significant difference with harmonize and zenit (p=0.414 and p=0.540, respectively) (Table 2). This difference might be related to the supra nano spherical fillers of the OM composite resin. At the same time, since OM composite resin is a new product, the lack of studies on both its mechanical and esthetic performance limits the interpretation of the success of this material.

In the present study, differences in ΔE values were detected in all samples after they were immersed in the beverages (Table 3). The composite resins tested in the present study showed a significant color change after immersion in coffee and orange juice but not in distilled water or cola (Figure 4). The highest ΔE value was obtained with coffee (ΔE=7.04), followed by orange juice (ΔE=4.11), cola (ΔE=1.84), and distilled water (ΔE=1.26) (Table 4). Ardu et al.[25] reported that the amount of discoloration of RBCs varies according to the brand and content of the composite resin; red wine causes the greatest color change among the materials used as staining beverages, followed by coffee, tea, orange juice, and cola.

Studies reporting that coffee causes more discoloration than other beverages support this result.[26-28] Bagheri et al.[29] argued that although cola harms the surface integrity of composite materials due to its low pH value, it does not cause discoloration as much as coffee and tea due to the absence of yellow dye material. Sirin Karaarslan et al.[30] reported

that there was a decrease in L-values in all of the samples after the aging process, and a decrease in L-value indicates that the samples darkened. In the present study, the ΔL* values decreased significantly as expected in all composite groups exposed to coffee, cola, and orange juice beverages (Table 4). ΔL* results are consistent with many studies examining color changes in composite resins exposed to different beverages. In these studies, the effect of discoloration has been observed to result in negative ΔL* values for composite materials.[31-33] In the CIE Lab system, it is stated that the b* coordinate is associated with yellow and blue color. A positive b* value indicates the amount of yellow, and a negative b* value indicates the amount of blue. Tekçe et al.[31] found that in all composite resins, there was a shift towards the blue direction (-Δb*) with distilled water exposure, and towards the yellow direction (+Δb*) with black tea exposure. Poggio et al.[32] also found a significant increase in the Δb values of composite resins exposed to coffee, and their findings support our study. In another study, it was reported that yellow discolorants in coffee cause discoloration by showing low polarity, thus adhering to the surface and penetrating deeply.[34] In the present study, the positive Δb value in all samples immersed in the coffee and orange beverages was thought to be related to this situation (Table 5), with the highest Δb value belonging to the zenit composite (Δb=5.81). Although all staining beverages resulted in an increase in the Δb value, we noted that zenit exhibited the highest level of Δb value among the groups, indicating that the effects of the orange solution on zenit were greater compared to the other RBCs.

In general, RBCs with low filler contents are known to exhibit more color change.[35,36] In this study, when the weight ratios of the particles in their content were examined, zenit (83%) had the highest value, followed by harmonize (81%) and OM (79%) (Table 1). However, in regard to the average ΔE values (p=0.35), the particle weight was not in line with the results of this study, and the results were not statistically significant (Table 5, 6). We examined the monomer structures of the RBCs as we believed that the close similarity in the weight percentages of the RBCs used in this study contributed to this result.

One of the most important factors affecting the degree of discoloration of RBC is the type of monomer.[37] RBCs with high triethylene glycol dimethacrylate (TEGDMA) content are more susceptible to discoloration than RBCs containing urethane dimethacrylate (UDMA) because UDMA is a more color-resistant monomer. This is due to the low water absorption of UDMA monomer and the sufficient degree of visible light polymerization.[28,38,39] When the average values in the present study were taken into account, the OM resin material containing UDMA and TEGDMA had the lowest ΔE value (3.33), however, no statistically significant difference was observed between the ΔE values of the RBC materials (Table 5). The highest ΔE value was obtained in the orange juice solution in zenit (ΔE=7.02) (Table 3). In parallel with this result, a study by Gregor et al.[40] found that the nanoceramic-based Ceram.X Duo was highly affected by acidic fruit juice, and this might be due to a possible acidic attack by the polysiloxane components of the fruit juice. This explains why the nanoceramic-based zenit composite containing butanediol dimethoxylated and glass particles had the highest value.

When the RBC materials were evaluated with one another, the differences between the ΔE color changes were not found to be statistically significant (p=0.350) (Table 5). However, a statistically significant difference was found in the evaluation of color changes of OM composite materials according to the different beverages (p<0.001) (Table 6). These results are in line with those of Ebaya et al.[5] who concluded that universal shade composites have a satisfactory color and accept surface roughness. In contrast, de Abreu et al.[41] and Iyer et al.[42] reported that the color adjustment of the monochrome composite was lower than that of the multi-shade composite, and this may cause esthetic problems. Based on all these findings, the null hypothesis of the present study was partially rejected.

Study Limitations

In vitro studies can't fully mimic oral conditions. Clinical factors like nutritional habits, temperature, humidity, microorganisms, oral structure, saliva quantity, and tongue-cheek function are challenging to assess. Discoloration from oral beverages may be diluted by saliva. Changes in temperature and pH levels can impact dental material color and composite restoration properties. Insufficient literature exists comparing smart monochromatic resins, limiting discussions on color changes and roughness values. Additional *in vitro* and clinical studies are needed to support.

CONCLUSION

All RBCs are prone to acceptable surface roughness after staining, and the most stable roughness values belonged to the zenit composite. Coffee had the highest adverse effect on restoration color and caused unacceptable discoloration in all three RBCs (ΔE>3.3). The universal shade RBC OM showed acceptable values in terms of color stability and roughness and may be clinically recommended with a single-color option.

MAIN POINTS

- "Monochrome composite" is used to denote composite material produced with smart chromatic technology, thus providing a color match for each tooth color.
- "Omnichroma" is a monochrome composite with 260 nm spherical filler, produced with smart chromatic technology, and the ability to adapt to the color of the applied tooth.
- Good color matching eliminates the need for color selection and minimizes in-seat time and wastage of unused composite hues.
- Since color stability is an important factor in the success of treatment in aesthetic composite restorations, the stability of this novel smart monochromatic RBC material against discoloration is a matter of interest.

ETHICS

Ethics Committee Approval: Ethics committee approval was not required as there was no experimental research on humans and no human teeth were used.

Informed Consent: It wasn't obtained.

Authorship Contributions

Surgical and Medical Practices: A.C., B.B.C.Ö., Concept: A.C., B.B.C.Ö., Design: A.C., B.B.C.Ö., Data Collection and/or Processing: A.C., B.B.C.Ö., Analysis and/or Interpretation: A.C., B.B.C.Ö., Literature Search: A.C., B.B.C.Ö., Writing: A.C., B.B.C.Ö.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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RESEARCH ARTICLE

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What is the Risk of Type 2 Diabetes in Relatives of Patients Hospitalized in the Internal Medicine Clinic? A Hospital-Based Survey Study

Birgül Vural Doğru[1], Meral Gün[1], Esra Çavuşoğlu[1], Fatma Tülin Çelik[1], Eylem Türk[2]

[1]Department of Internal Medicine Nursing, Mersin University Faculty of Nursing, Mersin, Türkiye
[2]Clinic of Endocrinology and Metabolism, Mersin University Hospital, Mersin, Türkiye

Abstract

BACKGROUND/AIMS: Type 2 diabetes is an important health problem and its worldwide frequency is increasing day by day. The study was conducted in order to determine the risk of type 2 diabetes in the relatives of patients hospitalized in internal medicine clinics.

MATERIALS and METHODS: This descriptive and cross-sectional study consisted of 337 relatives of patients hospitalized in the internal medicine clinics of a university hospital in the south of Türkiye. Data were collected using the "Introductory Information Form" and the "Finnish Diabetes Risk Score (FINDRISC)" Scale. The chi-squared test, t-test, the Mann-Whitney U test, and Binary logistic regression analysis were used for statistical analysis.

RESULTS: The mean age of the research participants was 42.69±15.80 years and their mean total FINDRISC score was 9.65±5.51. According to the FINDRISC score, 22.3% of the participants were in the high-risk group. In One-Way analysis, the risk of diabetes was determined to be significantly high according to random capillary blood glucose levels, systolic blood pressure, marital status, educational status, and income status ($p<0.005$). Moreover, in logistic analysis, age, body mass index, waist circumference, physical activity and family history of diabetes had a significant effect on the risk of developing type 2 diabetes ($p<0.005$).

CONCLUSION: About a quarter of the participants were in the high-risk group for developing type 2 diabetes within 10 years. By means of tools such as the FINDRISC, the early detection of individuals at risk of diabetes can be provided so as to take measures to prevent or delay diabetes.

Keywords: Type 2 diabetes, risk factor, FINDRISC, patients' relatives, screening

INTRODUCTION

Diabetes is a chronic broad-spectrum metabolic disorder in which the organism cannot benefit from carbohydrates, lipids or proteins due to insulin deficiency or insulin-related defects and so it requires continuous medical care.[1] Generally, life expectancy has increased as a result of advances in developing technology and health care systems; therefore, the incidence of chronic diseases such as diabetes has also increased. Factors such as fast-food habits due to working conditions or time constraints, obesity, low physical activity rates, and family history also pose a risk for diabetes.[2,3]

Diabetes is an important public health issue with an increasing global, national, and regional prevalence. According to the 2019 data of the International Diabetes Federation, there were 463 million (9.3%) individuals aged between 20-79 diagnosed with diabetes mellitus (DM)

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ORCID IDs of the authors: B.V.D. 0000-0002-3546-9656; M.G. 0000-0002-0434-368X; E.Ç. 0000-0003-4138-7494; F.T.Ç. 0000-0002- 8571-9430; E.T. 0000-0003-4047-7463.

Address for Correspondence: Birgül Vural Doğru
E-mail: bvuraldogru@gmail.com
ORCID ID: orcid.org/0000-0002-3546-9656

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in the world and this number is predicted to reach 578 million (10.2%) by 2030 and 700 million by 2045.[4,5] The increase in DM prevalence is highest in low- and middle-income countries (74-96%). In Europe, Türkiye ranks first in terms of DM prevalence with a rate of 11.1% (6.5 million) and almost half of diabetic individuals are not aware of their diagnosis.[4,5] Diabetes prevalence was reported to be 7.2% in the Turkish Diabetes Epidemiology Study (TURDEP-I) conducted nationally in our country in 2002 and it reached 13.7% with an approximately 90% increase as seen in the TURDEP-II study conducted in 2010.[6,7]

Approximately 90% of all diabetic individuals have type 2 diabetes and go through a prediabetic period in which the symptoms of type 2 diabetes do not appear. The rate of prediabetes is 7.5% in the world and 8.2% in Türkiye.[4,5,7] These data demonstrate that DM and DM-related complications will significantly increase both in the world and in Türkiye. Type 2 diabetes is a long-term chronic metabolic disease which progresses asymptomatically for a long period. Significant dysfunctions can develop in organs such as the heart, blood vessels, and kidneys when symptoms appear and even a secondary disease (such as myocardial infarction or kidney failure) accompanying DM can be diagnosed. Therefore, a delay in the diagnosis of type 2 diabetes may lead to increased morbidity, mortality, and health expenditures.[1,4,5] For this reason, it is very important to determine the disease risk and risk factors affecting the development of DM in the prediabetes period, in which symptoms are not seen, in order to prevent type 2 diabetes and/or bring it under control.[4,8-12]

The development of diabetes can be prevented or delayed in these risk groups by adopting healthy living habits such as increased physical activity, healthy nutrition, and the maintenance of normal weight.[1,4,8-12] The relatives of patients hospitalized in internal clinics are also at risk of some diseases [such as diabetes, hypertension (HT), or obesity] due to their family history. For this reason, this study was conducted in order to determine the risk of type 2 diabetes in patients' relatives, so as to inform those at risk regarding protective measures and to direct them towards the relevant units.

The research question is given below:

1. What the risk of type 2 diabetes in the relatives of those patients hospitalized in the internal medicine clinic?

MATERIALS AND METHODS

Study Design

This descriptive and cross-sectional study was conducted in order to determine the risk of type 2 diabetes in the relatives of patients hospitalized in internal medicine clinics.

Study Participants and Sampling

The population of this study consisted of the relatives of patients hospitalized in internal medicine clinics of a university hospital in the south of Türkiye between April, 2019 and August, 2019. The sample size was determined by power analysis taking type 1 error as 0.05 and a power of 80%. The sample consisted of 337 patient relatives.

The relatives of those patients who had not previously been diagnosed with diabetes, who were aged over 18, who had mental and cognitive competence, who did not have hearing, comprehension or speech problems, who agreed to participate in this study, and of whom standing weight and height measurements were possible were included in this study. Those who had previously been diagnosed with DM by a physician and/or did not agree to a blood sugar measurement were excluded.

Data collection

The research data were collected using the "Introductory Information Form" and the "Finnish Diabetes Risk Score (FINDRISC)" scale. The Introductory Information Form includes variables related to sociodemographic characteristics (such as age, gender, marital status and educational status).

The Diabetes Risk Score (FINDRISC) consists of eight questions regarding age, body mass index (BMI), waist circumference, exercise, vegetable-fruit consumption, HT, history of high blood glucose, and family history. The total FINDRISC score ranges between 0 and 26. A total score below 7 points indicates a low 10-year risk of developing type 2 diabetes; a score between 7-11 points indicates mild risk; a score between 12-14 points indicates moderate risk; a score between 15-20 points indicates high risk; and a score above 20 points indicates very high risk.[9] The cut-off value of the scale was determined as 15 or above in some studies which had used FINDRISC to determine the risk of type 2 diabetes.[10,11] In this study, a FINDRISC score of 15 or above was defined as being "high-very high risk" for type 2 diabetes.

Data Collection Procedures

The researchers applied the questionnaire form to those patient relatives who met the inclusion criteria via a face-to-face interview method. Data collection, anthropometric, blood pressure and random capillary blood glucose measurements were performed by the researchers in the patient waiting room. Body weight was measured in a standing position to the nearest 0.1 kg on a calibrated "Seca" electronic balance, with the participants wearing light clothes and no shoes and their height was measured with a wall-mounted meter. The waist circumference of the participants was measured using a non-stretch tape measure. The participants' BMI was calculated and classified according to the World Health Organization criteria. Random blood glucose was determined from a capillary blood sample using a calibrated device from the same brand (Viva Check). The participants' blood pressure was measured from the right arm in a sitting position after a 10-15-minute rest using an appropriate cuff, a perfect aneroid mercury sphygmomanometer (Erka), and a stethoscope (Erka). Those with a FINDRISC score of 12 or above and random capillary blood glucose (RCBG) of 140 mg/dL or above were directed to a healthcare facility for further examination. After the evaluation, all participants were informed regarding their risk levels.

Prior to this research, permission was taken from the Clinical Research Ethics Committee (approval number: 2019/147, date: 03.04.2019) and the Mersin University Hospital where the study was conducted. Before the implementation of the data collection forms, all of the participants were informed about the purpose of this study, and its voluntary and confidentiality principles. Their written and verbal consent were taken.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Science 22.0 (SPSS, IBM Corp., Armonk, NY, USA). Numbers, percentages, means, and standard deviations were used to evaluate descriptive characteristics. The Kolmogorov-Smirnov test was performed to examine normal distribution conformity. The independent t-test, chi-squared test and

Fisher's exact test were used in the statistical analysis of the data. The Mann-Whitney U test was employed for variables which were not normally distributed. Binary logistic regression was performed in multivariate analysis. The goodness of fit of the model was assessed with the Hosmer-Lemeshow test ($p>0.05$) and the significance of the model was assessed with the Omnibus test ($p<0.05$). Statistical significance was accepted as $p<0.05$ in all tests.

RESULTS

The mean age of the 337 patients' relatives was 42.69±15.80 years. Of the participants, 58.2% were female, 65.6% were married, 61.1% had a middle income, 73% were unemployed or retired, and more than half (60.3%) had a high school degree or above.

According to the FINDRISC scores of the participants, the 10-year risk of developing type 2 diabetes was moderate in 15.7%, high in 19.6% and very high in 2.7% (Table 1). The mean total FINDRISC score was determined as being 9.65±5.51 (minimum: 0, maximum: 26). The mean FINDRISC score for women (10.45±10.00) was higher than that for men (8.53±8.00) (Z=-2.99, p=0.003).

In the study, those participants with a FINDRISC score of <15 were defined as the "low to moderate risk" group and those with a score of ≥15 were defined as the "high-risk" group. When the socio-demographic characteristics of the participants were compared according to the FINDRISC group, the risk was found to be higher in those who were married ($p<0.001$), who were illiterate ($p<0.001$) and those who had low incomes ($p=0.044$). There was no significant difference between gender, working status, and the RCBG threshold value and the risk groups ($p>0.05$). Age ($p<0.001$), RCBG ($p=0.001$), BMI ($p<0.001$), waist circumference ($p<0.001$) and systolic blood pressure ($p=0.002$) were low in the high-risk group, being significantly higher compared to the low/moderate risk group (Table 2).

When the FINDRISC scores were compared according to the variables included in the FINDRISC calculation, the FINDRISC score and the risk level were found to increase as age, BMI and waist circumference increased. It was determined that 37.7% of those in the 55-64 age group and 47.1% of those aged over 64 were in the high-risk group in terms of type 2 diabetes and that this difference was significant ($p<0.001$). Of those with a BMI of >30 kg/m^2, 55.4% were in the high-risk group and this difference was significant ($p<0.001$). 58.1% of men with a waist circumference of >102 cm and 36.9% of women with a waist circumference of >88 cm were in the high-risk group and this difference was significant ($p<0.001$) (Table 3). Those who did not exercise, who had high blood pressure or who used antihypertensive medicine, those who had blood glucose at a high levels or at the upper limit and those who had a family history of diabetes were in the high risk group in terms of type 2 diabetes ($p<0.001$); however, there was no significant difference between the groups in terms of vegetable-fruit consumption ($p=0.681$) (Table 3).

Table 1. Participants' 10-year risk of developing type-2 DM

Risk level	n	%	Estimated number of diabetics (n)*
Low: <7 (1/100)	119	35.3	1.1
Mild: 7-11 (1/25)	90	26.7	3.6
Moderate: 12-14 (1/6)	53	15.7	8.8
High: 15-20 (1/3)	66	19.6	22
Very high >20 (1/2)	9	2.7	4.5

*Number of individuals who may be diagnosed with type-2 diabetes in 10 years. DM: Diabetes mellitus.

The variables of age ($p<0.001$), BMI ($p<0.001$), waist circumference ($p<0.003$), physical activity and family history of diabetes ($p<0.001$) had a significant effect on the participants' risk of developing type 2 diabetes. The risk of developing type 2 diabetes within 10 years was found to be 1,347 times higher, especially in those with a family history of diabetes compared to those without. This risk was estimated to be 48 times higher in those who did not exercise than in those who did (Table 4).

DISCUSSION

The mean age of the patients' relatives was 42.69±15.80 years and 22.3% were evaluated as being in the high or very high-risk groups in terms of the 10-year risk of developing type 2 diabetes. Moreover, the FINDRISC score and risk levels were found to increase with increasing age. Insulin resistance may develop with advanced age due to decreased physical activity, an increased incidence of accompanying chronic diseases (especially HT) and increased abdominal fat, etc.; therefore, the risk of developing type 2 diabetes may increase as well.[2,7,10-13] Cosansu et al.[10] determined the risk of developing type 2 diabetes within 10 years as being 7.9%; Kılıç et al.[11] as 11.5%; Awad and Alsaleh[14] as 17.6%; İğci and Basat[15] as 32% and the risk of developing type 2 diabetes was seen to increase with increasing age. Although the mean age of the patients' relatives included in our study group was low, the risk of developing type 2 diabetes within 10 years was found to be high or very high. All these results suggest that type 2 diabetes is a serious health issue.

In our study, the mean total FINDRISC score of the participants was 9.65±5.51 and the mean FINDRISC score for women (10.45±10.00) was found to be higher than that for men (8.53±8.00). This result indicates that the number of risk factors associated with type 2 diabetes is higher in women compared to men. Likewise, Cosansu et al.[10], Berber et al.[16] and Awad and Alsaleh[14] found that the FINDRISC scores of women were higher than those of men. Ural et al.[17] conducted a systematic meta-analysis study investigating the prevalence of obesity and waist circumference in Türkiye and found that the prevalence of both obesity (32.2% in women, 18.2% in men) and abdominal obesity (50.8% in women, 20.8% in men) was higher in women. Additionally, the TURDEP II study revealed that the prevalence of both DM and obesity were higher in women than in men.[7] These results may be associated with the fact that women spend more time on housework, such as cooking and cleaning due to traditional and cultural characteristics, and so cannot spend time on physical activities, thus women have a more sedentary life and become fatter.

The risk of developing type 2 diabetes was found to be higher in those patients' relatives who were married, who were illiterate and those who had low incomes. Likewise, Cosansu et al.[10], Liu et al.[18], Ramezankhani et al.[19] and Oruganti et al.[20] reported that individuals with low incomes and low educational levels had a higher risk of developing type 2 diabetes within 10 years. Furthermore, the literature revealed that those individuals with low income and educational levels also have low levels of health literacy.[21,22] Having a low educational level and low income can create an obstacle in accessing the appropriate resources (correct information, accessing appropriate health services, consuming

Table 2. Comparison of the socio-demographic variables with 10-year risk of developing type-2 diabetes

Variables	Low and medium risk (<15 points), n (%)	High risk (≥15 points), n (%)	Total (n=337), n (%)	Test values
Gender				
Female	146 (74.5)	50 (25.5)	196 (58.2)	X^2=2.86
Male	116 (82.3)	25 (17.7)	141 (41.8)	p=0.111
Marital status				
Married	153 (69.2)	68 (30.8)	221 (65.6)	X^2=26.89
Single	109 (94.0)	7 (6.0)	116 (34.4)	p**<0.001**
Educational status				
Illiterate	8 (61.5)	5 (38.5)	13 (3.9)	X^2=29.73
Primary school	77 (63.6)	44 (36.4)	121 (35.9)	p**<0.001**
High school	61 (80.3)	15 (19.7)	76 (22.6)	
University or higher	116 (91.3)	11 (8.7)	127 (37.7)	
Working status				
Employed	75 (82.4)	16 (17.6)	91 (27.0)	X^2=1.57
Unemployed	187 (76.0)	59 (24.0	246 (73.0)	p=0.240
Income				
Low	76 (76.0)	24 (24.0)	100 (29.7)	X^2=6.22
Middle	157 (76.2)	49 (23.8)	206 (61.1)	**p=0.044**
High	29 (93.5)	2 (6.5)	31 (9.2)	
RCBG				
<140 mg/dL	239 (78.6)	65 (21.4)	304 (90.2)	X^2=1.36
≥140 mg/dL	23 (69.7)	10 (30.3)	33 (9.8)	p=0.271
Age (mean ± SD)	39.47±15.28	53.94±12.06		Z=-7.09 p**<0.001**
RCBG (mean ± SD)	107.58±25.38	122.22±51.86		Z=-3.40 **p=0.001**
BMI (mean ± SD)	25.30±4.70	30.37±4.61		t=-8.25 **p<0.001**
Waist circumference (mean ± SD)	87.21±12.84	102.45±10.22		t=-10.71 **p<0.001**
SBP (mmHg) (mean ± SD)	118.04±13.23	124.60±15.38		Z=-3.40 **p=0.002**
DBP (mmHg) (mean ± SD)	75.76±9.55	77.14±10.88		Z=-0.68 p=0.491

RCBG: Random capillary blood glucose, SD: Standard deviation, BMI: Body mass index, SBP: Systolic blood pressure, DBP: Diastolic blood pressure.

healthy foods, etc.) and in using these resources effectively in order to prevent, control and manage these risk factors. Some studies have also reported that those who are married have a higher risk of developing type 2 diabetes.[10,19] Our study results are consistent with the literature.

In our study, the FINDRISC scores and risk levels of the participants were found to increase as their BMI and waist circumferences increased. Moreover, those patients' relatives who did not exercise were determined to be in the high-risk group in terms of type 2 diabetes. Studies have reported that obesity is the most important changeable risk factor in the development of type 2 diabetes, that the age of obesity onset and the number of obese-years significantly increase the risk of type 2 diabetes,[16,20,23,24] and that weight loss may prevent or delay the development of type 2 diabetes.[4,8,12,24] In obesity, some hormones (adipokines such as resistin) produced by adipose tissue increase insulin resistance. Therefore, obesity contributes to the development of type 2 diabetes and type 2 diabetes contributes to the development of obesity.[2,12,25] Our study results are consistent with the literature.

Regular physical activity increases glucose tolerance and insulin sensitivity and ectopic adipose tissue decreases by burning extra calories. Additionally, exercising increases glucose utilization by increasing muscle mass.[2,12,26-30] Similar to our findings, the literature reported that those individuals with low levels of physical activity have a high risk of developing type 2 diabetes,[11,15,20,23,27] and that excessive sitting contributes to the development of type 2 diabetes independent of sociodemographic characteristics and obesity.[29] Being consistent with the literature,[10,11,13,15,20,23,27] half of the participants were found to be physically inactive and above normal weight and both variables were determined as being independent risk factors in the development of type 2 diabetes.

Table 3. The distribution of FINDRISC Scale scores by FINDRISC variables

Variables	Low and medium risk (<15 points), n (%)	High risk (≥15 points), n (%)	Total (n=337), n (%)	Test values
Age group				
0 point: <45	169 (92.3)	14 (7.7)	183 (54.3)	X^2=50.77
2 points: 45-54	42 (62.7)	25 (37.3)	67 (19.9)	p**<0.001**
3 points: 55-64	33 (62.3)	20 (37.7)	53 (15.7)	
4 points: >64	18 (52.9)	16 (47.1)	34 (10.1)	
BMI (kg/m²)				
0 point: <25 kg/m²	133 (93.0)	10 (7.0)	143 (42.4)	X^2=66.60
1 point: 25-30 kg/m²	96 (80.0)	24 (20.0)	120 (35.6)	p**<0.001**
3 points: >30 kg/m²	33 (44.6)	41 (55.4)	74 (22.0)	
Waist circumference (men)				
0 point: <94 cm	176 (95.1)	9 (4.9)	185 (54.9)	X^2=84.66
3 points: 94-102 cm	60 (66.7)	30 (33.3)	90 (26.7)	p**<0.001**
4 points: >102 cm	26 (41.9)	36 (58.1)	62 (18.4)	
Waist circumference (women)				
0 point: <80 cm	69 (97.2)	2 (2.8)	71 (21.1)	X^2=57.58
3 points: 80-88 cm	70 (98.6)	1 (1.4)	71 (21.1)	p**<0.001**
4 points: >88 cm	123 (63.1)	72 (36.9)	195 (57.9)	
Physical activity				
0 point: Yes	147 (88.0)	20 (12.0)	167 (49.6)	X^2=20.21
2 points: No	115 (67.6)	55 (32.4)	170 (50.4)	p**<0.001**
Vegetable-fruit consumption				
0 point: Every day	172 (78.5)	47 (21.5)	219 (65.0)	X^2=0.228
1 point: Not every day	90 (76.3)	28 (23.7)	118 (35.0)	p=0.681
Hypertension or use of anti-hypertensive medicine				
0 point: No	238 (85.6)	40 (14.4)	278 (82.5)	X^2=56.79
2 points: Yes	24 (40.7)	35 (59.3)	59 (17.5)	p**<0.001**
History of high blood glucose				
0 point: No	239 (87.9)	33 (12.1)	272 (80.7)	X^2=83.51
5 points: Yes	23 (35.4)	42 (64.6)	65 (19.3)	p**<0.001**
Family history of diabetes				
0 point: No	131 (92.9)	10 (7.1)	141 (41.8)	X^2=35.70
3 points: Second-degree relatives	52 (74.3)	18 (25.7)	70 (20.8)	p**<0.001**
5 points: First-degree relatives	79 (62.7)	47 (37.3)	126 (37.4)	

BMI: Body mass index, FINDRISC: Finnish Diabetes Risk Score.

Those who had high blood pressure and used antihypertensive medicine were found to be in the high-risk group in terms of type 2 diabetes. Likewise, some relevant studies determined that those individuals who had HT and who used antihypertensive medicine had a higher risk of developing type 2 diabetes than normotensive individuals.[11,15,16,23] Genetic characteristics, insulin resistance, dyslipidemia and obesity are common risk factors for the development of both type 2 diabetes and HT.[31,32] Identifying at risk individuals by screening with easy-to-apply scales such as FINDRISC and raising awareness will make a significant contribution to the increased quality of life of individuals and reduced morbidity, mortality and costs.

In our study, those patients with a family history of diabetes were found to be in the high-risk group for type 2 diabetes. Our study results are consistent with those that reported that individuals who had a family history of DM had a higher risk of developing type 2 diabetes compared to those with no family history.[10,16,18,20,23] The literature states that high carbohydrate intake causes oxidative stress and increased inflammatory response in individuals with genetic susceptibility in terms of DM, leading to the impairment of insulin sensitivity and insulin receptor signaling and so it increases the risk of developing DM in the long term.[3,33,34]

Study Limitations

Our results cannot be generalized as this study was conducted in only one hospital. One of the limitations of this study was that it was conducted only on the patients' relatives in the internal medicine clinic. Another limitation was that the random blood glucose level was measured from capillaries and not from plasma. However, the targeted sample size was reached and the at risk individuals were informed about

Table 4. Binary logistic regression analysis of factors affecting the risk of developing type-2 DM

Variables	β	p	OR	95% CI
Age	0.138	**0.001**	1.149	1.068-1.235
BMI	0.333	**0.001**	1.395	1.167-1.667
Waist circumference	0.103	**0.003**	1.109	1.036-1.187
RCBG	0.007	0.444	1.007	0.989-1.026
SBP	0.035	0.254	1.036	0.975-1.100
Physical activity	3.883	**0.001**	48.587	8.683-271.860
Family history of diabetes	7.206	**0.001**	1347.989	70.727-25691.358
Marital status	0.606	0.534	1.833	0.272-12.374
Educational status	-0.641	0.347	0.527	0.138-2.006
Income	0.467	0.773	1.595	0.067-38.172

DM: Diabetes mellitus, BMI: Body mass index, RCBG: Random capillary blood glucose, SBP: Systolic blood pressure, CI: Confidence interval, OR: Odds ratio, Independent variables: Physical activity, family history of diabetes, marital status, educational status and income status were categorical variables and age, BMI, waist circumference, RCBG and SBP were continuous variables.

measures of protection from type 2 diabetes and directed towards the relevant units. These factors increase the strength of our study.

CONCLUSION

FINDRISC can help in the early identification of individuals at risk of diabetes. In this study, 22.3% of the patients' relatives were found to be at high risk in terms of developing type 2 diabetes within 10 years. The risk of developing type 2 diabetes was determined to be higher in women, in those who were married, in those who had low income and low educational levels, and in those who had a family history of DM. Moreover, our study revealed that the classic risk factors such as physical inactivity, BMI, waist circumference, and HT also had an important effect on the development of type 2 diabetes. Therefore, strategies (screenings, training/counseling, guidance to related units) should be developed, especially in order to raise awareness in at risk individuals and to prevent and control the development of type 2 diabetes. Performing studies for risk screening can facilitate in taking early precautionary measures in order to prevent or delay diabetes.

MAIN POINTS

- The mean score of the relatives of the patients on the FINDRISC was 9.65±5.51. This result showed that 22.3% of patients' relatives were at high risk of developing type 2 diabetes within 10 years.
- The mean FINDRISC score of women (10.45±10.00) was higher than that of men (8.53±8.00).
- Age, body mass index and waist circumference, physical inactivity and a family history of diabetes increased the risk of developing type 2 diabetes.
- The FINDRISC tool can help in the early identification of individuals at risk of diabetes and facilitate in taking early precautionary measures.
- In terms of type 2 diabetes, screening programs should be applied periodically in order to raise awareness among those individuals with a family history of chronic diseases, in order to prevent or delay the development of DM by identifying at risk individuals.

ETHICS

Ethics Committee Approval: This study was approved by the Ethics Committee of Mersin University Hospital (approval number: 2019/147, date: 03.04.2019).

Informed Consent: Their written and verbal consent were obtained.

Authorship Contributions

Concept: B.V.D., M.G., E.Ç., F.T.Ç., E.T., Design: B.V.D., M.G., E.Ç., F.T.Ç., E.T., Supervision: B.V.D., M.G., Resource: B.V.D., M.G., E.Ç., Materials: B.V.D., M.G., E.Ç., Data Collection and/or Processing: B.V.D., M.G., E.Ç., F.T.Ç., E.T., Analysis and/or Interpretation: B.V.D., M.G., Literature Search: B.V.D., M.G., Writing: B.V.D., M.G., Critical Reviews: B.V.D., M.G., E.Ç., F.T.Ç., E.T.

DISCLOSURES

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RESEARCH ARTICLE

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Fall Event Reports of a Tertiary-Care Hospital: A Retrospective Analysis

Dilara Usta[1], Neşe Altınok Ersoy[2], Fatoş Korkmaz[1], İmatullah Akyar[2], Yasemin Akyürek[3], Mine Durusu Tanriover[4]

[1]Department of Fundamentals of Nursing, Hacettepe University Faculty of Nursing, Ankara, Türkiye
[2]Department of Internal Medicine Nursing, Hacettepe University Faculty of Nursing, Ankara, Türkiye
[3]Department of Quality Coordinatorship, Hacettepe University Adult Hospital, Ankara, Türkiye
[4]Department of Internal Medicine, Section of General Internal Medicine, Hacettepe University Faculty of Medicine, Ankara, Türkiye

Abstract

BACKGROUND/AIMS: The current study aimed to perform a retrospective analysis of fall events in a tertiary-care hospital and identify the related risk factors.

MATERIALS AND METHODS: This research was conducted in a 1,160-bed-capacity tertiary-care hospital in Ankara between June 2016 and June 2017. The sample comprises 241 patient falls among 1,009 fall events in the facility between 2006 and 2016. Data were retrospectively collected with patient preassessment forms, daily nursing documentation forms, and daily medication order protocols. Means and standard deviations for continuous variables, frequency distributions for categorical variables, and chi-square analysis for the correlation between two categorical variables were used.

RESULTS: Of the patients with files investigated, 42.7% were aged from 18 to 65 years, 59.3% were male, 74.1% had a chronic disease, 40.3% could complete daily-life activities independently, and 32% were using medication that increased fall risks. Of the fall events, 29.5% occurred in the pediatric clinics, 29.5% in surgery, and 28.2% in internal medicine clinics. 35.2% occurred during the night shift, and 33% occurred within the first three days of admission. Additionally, 35.7% of the fall events happened due to not taking appropriate safety precautions, 20.2% due to not using the nurse call button, 64.7% were in the patient's room, and 32.6% were due to syncope.

CONCLUSION: It was revealed that the riskiest interval for patient falls is in the first three days of admission and during the night shift. While evaluating fall risks, sociodemographic, medical, environmental, and fall-related independent variables should be considered together. It is recommended that fall risk assessment tools be revised by reviewing patients' specific care needs and clinical conditions.

Keywords: Falls, nursing, patient safety, quality of healthcare, risk assessment

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ORCID IDs of the authors: D.U. 0000-0003-1300-0678; N.A.E. 0000-0001-5081-4035; F.K. 0000-0003-4457-8691; İ.A. 0000-0003-3551-8099; Y.A. 0000-0002-4252-1387; M.D.T. 0000-0001-9565-4389.

Address for Correspondence: Dilara Usta
E-mail: dilarausta6@gmail.com
ORCID ID: orcid.org/0000-0003-1300-0678

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INTRODUCTION

Falls are considered the second leading cause of accidental or unintentional deaths and appear to be a critical patient safety problem for patients admitted for treatment to healthcare institutions worldwide.[1,2] The World Health Organization estimated that each year 646 thousand people die from falls, and fall events mostly occur among individuals older than 65 years of age.[2] The National Safety Reporting System in Türkiye declared that patient falls are the most frequent patient safety issues, and falls constituted 36.2% of patient safety issues in 2018.[3] Falls cause lengthened hospital stays, increased rehabilitation requirements, anxiety and fear, loss of self-confidence, loss of muscle power and function, reduced activity levels and quality of life, and injured patients both physically and psychologically.[4] Also, falls increase health costs, creating an economic load on the healthcare system and society.[5] According to the United Kingdom National Health Service (NHS), falls occurring in England are estimated to cause costs of more than 2.3 billion pounds sterling to the NHS annually,[6] while in Türkiye, falls-related injuries cost 3,302.60 USD and 14.61 additional hospitalization days for each patient.[7]

Falls mostly occur due to many preventable factors linked to the individual or environment. The main factors increasing the risk of falling may be listed as old age, fall history, male gender, amputated extremities, incontinence, anti-convulsant, anti-hypertensive and tranquilizing medication use, cognitive disorders, reduced visual acuity, peripheral neuropathy, lack of muscle power, posture imbalance, vitamin D deficiency, and arthritis.[8] Additionally, being in an unfamiliar environment, the type of diagnosis, medical treatment, and long duration of hospital stay may increase the risk of falls.[9] In order to prevent falls and reduce risks, effective, comprehensive, and structured prevention programs are required.

Identifying fall risk factors and measuring risk levels is a priority for planning preventive interventions because falls are mainly predictable.[10] Risk identification for fall events in Türkiye commonly uses the İtaki (17 years or older) and Harizmi (0-16 years) risk assessment tools, especially developed by the Ministry of Health Quality and Accreditation in the Health and Employee Rights Department. Although the cultural adaptation has not been completed, the Hendrich II Fall Risk Scale and the Morse Fall Scale are commonly used in risk assessment. In addition to risk assessment, an analysis of fall event characteristics specific to an organization is recommended in order to determine preventable risk factors and implement holistic care strategies. In order to plan effective preventive interventions and create organizational policies, it is necessary to determine risk areas, assess risks, and monitor them. Therefore, an analysis of fall event characteristics is needed first of all. As a result, this study aimed to retrospectively analyze fall events in a tertiary-care hospital and identify the risk factors related to patient falls.

MATERIALS AND METHODS

Study Design and Setting

This research was completed in a tertiary-care hospital in Ankara from June 2016 to June 2017. Data were retrospectively collected from fall event report forms and patient files, and the fall event characteristics were analyzed.

The 1,160-bed hospital comprises of three main sections, namely adult, pediatric, and oncology. The adult hospital has a 730 bed-capacity with 30 outpatient, 28 inpatient, ten intensive-care units, and two surgery rooms. In this hospital, an average of 2,700 patients currently receive care in inpatient services per month. The pediatric hospital comprises 270 beds and delivers healthcare services to an average of 11,000 inpatients annually. Finally, the oncology hospital with 160 beds provides outpatient and inpatient healthcare services to approximately 80,000 patients annually.

Prevention and Follow-Up Protocol of the Institution Regarding Inpatient Falls

The tertiary-care hospital where this study was conducted follows a standardized protocol for all units (Fall Events Prevention and Monitoring Procedure) in collaboration with Quality Coordinators. The protocol identifies the fall types, factors increasing risks, and activities to prevent and monitor falls for the patients admitted to the organization or receiving outpatient healthcare services. As a standardized protocol, nurses assess the patients' fall risks using the Hendrich II Fall Risk Scale, plan nursing interventions, and record them on a daily documentation form. During admission to the inpatient clinics, nurses inform the patient and the family about using the nurse call buttons in the patient rooms and wards. Within the standard safety precautions framework, bed rails are elevated, and the bed is kept at the lowest level. Unused medical equipment is removed from the room, and corridors between rooms are tidied up, with devices used for mobility (e.g., wheelchairs, trolleys) being kept with wheels locked. Additionally, windows are locked. Patient rooms and corridors are well-lit, and wet-floor signs are used while cleaning the corridors and rooms.

Additionally, patients keep frequently used personal items (e.g., glasses, water) close to the bed, are encouraged to ask for help with hygiene and excretion needs, and are given information that slippers should not have slippery soles. When situations occur that may increase the risk of falls (e.g., performing interventional implementations, changes in consciousness) and during transfer between wards, fall risks are reassessed, and risk assessment is recorded on the daily nursing documentation forms. On the day of admission, the nurse responsible gives the patient a brochure about the definition, causes, and preventions that should be taken to prevent falls. It is ensured that those patients with high fall risks are accompanied by a caregiver, if possible.

Sampling

The research population comprised 425,751 patients admitted to adult, pediatric, and oncology clinics in the hospital from January 2006 to May 2016. Between these dates, a total of 1,009 fall events occurred and were reported to the Quality Coordinator, and the files for 666 patients who experienced fall events were available to be accessed (66%). Over this ten-year period, the ratio of patients who fell to those admitted showed that the fall frequency was 0.2%. When the tolerance value is accepted as d=0.006, the appropriate sample size was 221 according to sample calculations for the known population. Among the accessible 666 patient files, a total of 241 were randomly chosen for data collection (Figure 1).

Data Collection Procedure and Forms

When fall events occur in the hospital, a fall event report form is completed and sent to the Quality Coordinator by the nurses. The Quality Coordinator records the patients' file numbers on a list. This

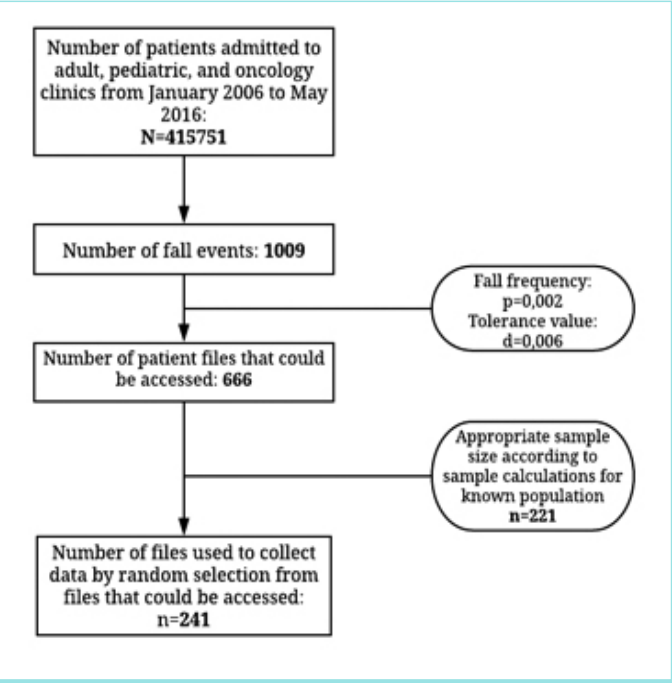

Figure 1. Data collection flow chart.

list containing patients who fell over the ten-year period was obtained from the coordinator, and the patient files were obtained from the hospital archive between May and July 2016 by the researchers. The patient preassessment forms, daily nursing documentation forms, and daily medication order protocols were investigated, and the data were recorded onto a Microsoft Excel file.

Sociodemographic Data and Fall Event Characteristics

Sociodemographic data and fall event features were recorded using a data collection form created by the researchers after a literature review[7,11,12] and based on the institution's fall event report form. This form includes a total of twenty-two questions about age, gender, shift and day of the week when the fall occurred, fall history of the patient, fall risk assessment tool scores for the day of the fall, admission ward, the type of admission, the presence of chronic disease, the type of chronic disease, the use of medications which may cause falls (anti-epileptics and benzodiazepine group medications in medication groups on the Hendrich II Risk Assessment Tool), the independence level for activities of daily living (ADL), the use of assistive devices and the type of device used, the limitation status of the patient, precautions not taken before the fall event, the location of fall, the type of fall, injury status and type if present, the day of admission and the number of days since the patient was admitted.

Dependence Level in ADL

Data related to ADL were obtained from the standard patient preassessment form used in the hospital. This form defines these activities as eating/drinking, personal hygiene, balanced walking, getting up from bed, turning in bed, and toilet requirements under "Daily living activities and functional assessment." The patient's ability to complete activities is assessed as independent, semi-dependent, or dependent.

Fall Risk Assessment

The Hendrich II Fall Risk Assessment Tool was developed by Hendrich et al.[13] in 1995. The highest point obtainable from this scale is 20, with five points and above being assessed as high risk. The Hendrich II Fall Risk Assessment Tool comprises seven factors; namely confusion/disorientation, symptomatic depression, changes in excretion, dizziness, gender, anti-epileptic and benzodiazepine group medication intake, and chair stand test.[13]

Ethical Consideration

The study was approved by the Hacettepe University Non-Interventional Clinical Research Ethics Committee (approval number: 2016-14-GO 16/45-32). Informed consent was not required due to the retrospective nature of this study.

Statistical Analysis

Statistical analysis was completed with the IBM SPSS (Statistical Package for Social Sciences) Statistics Data Editor 23 (United States of America) program. Mean ± standard deviation was used for continuous variables, while frequency distribution was used for categorical variables. Chi-square analysis was used to investigate the relationship between two categorical variables. In the 95% confidence interval, $p<0.05$ was accepted as statistically significant.

RESULTS

Within the scope of this research, 241 files were analyzed. In this sample, it was observed that there were deficiencies in recording the data for some independent variables. For this reason, the numbers of independent variables for which data could be accessed among the 241 patient files are given in parentheses as "(n=...)" in the tables. The data regarding the patients' sociodemographic and clinical characteristics are shown in Table 1, and the characteristics related to falls are presented in Table 2.

When fall risk levels of those patients who fell were assessed according to the Hendrich II scale, there were no statistically significant differences found according to age groups (X^2=2,335; p=0.331), gender (X^2=0.718; p=0.397), use of medication increasing fall risk (X^2=0.206; p=0.650) or the presence of chronic disease (X^2=0.351; p=0.554). A statistically significant difference was identified between the assessed fall risk levels of those patients with the ability to complete daily living activities independently (X^2=6,029; p=0.049).

DISCUSSION

Admission to hospital for any reason brings with it the risk of falls. The current study retrospectively analyzed fall events in a tertiary-care hospital. This analysis dealt with the fall events occurring in healthcare institutions and the sociodemographic characteristics of the participants. It is expected that the findings of this study may contribute to planning individualized care regarding fall prevention in order to improve patient safety in the short term.

This study found that fall events mostly occurred in the surgery and internal medicine clinics. Mata et al.[14] suggested that most adult patients in the postoperative period were evaluated as having high fall risks. In contrast, Hajduchová et al.[15] found that almost half of the patients who fell were admitted to internal medicine units.

Table 1. Distribution of patients' sociodemographic and clinical characteristics (n=241)

Sociodemographic characteristics	n	%
Age		
1-3	48	19.9
4-17	23	9.6
18-65	103	42.7
66-95	67	27.8
Gender		
Male	143	59.3
Female	98	40.7
Unit of admission (n=161)		
Outpatient clinic	119	73.9
Emergency service	37	23.0
Transferred from external center	5	3.1
Chronic disease (n=135)		
No	35	25.9
Yes	100	74.1
Type of chronic disease* (n=154)		
Cardiovascular system diseases	72	46.9
Type 2 diabetes	23	14.9
Malignancy	5	3.2
Hemiplegia	1	0.6
Arthritis	1	0.6
Other**	52	33.8
Ability to complete daily living activities independently (n=149)		
Independent	60	40.3
Semi-dependent	41	27.5
Dependent	48	32.2
Use of assistive devices (n=142)		
No	120	84.5
Yes	22	15.5
Presence of invasive devices (n=144)		
No	35	24.3
Yes	109	75.7
Type of invasive device* (n=147)**		
Peripheral venous catheter	88	59.9
Central venous catheter	28	19.0
Urinary catheter	25	17.0
Hemovac drain	5	3.4
Nasogastric tube	1	0.7
Physical restraint status (n=156)		
No	148	94.9
Yes	8	5.1
Use of medications increasing fall risk (n=150)		
No	102	68.0
Yes	48	32.0

*Multiple data, one patient may have more than one chronic disease, **Anemia, asthma, goiter, chronic obstructive pulmonary disease, chronic renal failure, epilepsy, hyperlipidemia, benign prostate hyperplasia, hyperparathyroidism, Hashimoto's thyroiditis, multiple sclerosis, Parkinson, cirrhosis, hypothyroidism, ***Multiple data, one patient may have more than one invasive device.

Table 2. Distribution of the characteristics related to fall events (n=241)

Characteristics related to fall events	n	%
Clinic		
Pediatrics	71	29.5
Surgical	71	29.5
Internal medicine	68	28.2
Emergency	15	6.2
Psychiatry	10	4.1
Intensive care	6	2.5
Assessment of fall risk (n=139)		
High risk (5 points and above)	93	66.9
No risk (1-4 points)	46	33.1
Shift when fall occurred (n=239)		
Morning (08.00-16.00)	73	30.5
Afternoon (16.00-24.00)	82	34.3
Night (24.00-08.00)	84	35.2
Weekday when fall occurred		
Monday	34	14.1
Tuesday	37	15.4
Wednesday	44	18.3
Thursday	29	12.0
Friday	35	14.5
Saturday	33	13.7
Sunday	29	12.0
Precautions not taken to prevent fall* (n=90)		
No appropriate safety precautions were taken	32	35.7
Not using the nurse call buttons	18	20.2
Caregiver's lack of attention	14	15.4
No appropriate physical restraint precautions were taken	8	8.9
Wet floor	5	5.5
Insufficient information given to patient/caregiver	5	5.5
Unnecessary material left in the clinical area	3	3.3
Lack of assessment of fall risk	1	1.1
Not specified	4	4.4
Location of fall (n=220)		
Patient room	156	70.9
Bathroom	34	15.5
Ward corridor	22	10.0
Outpatient clinic	6	2.7
Surgery room	2	0.9
Type of fall (n=230)		
Syncope	75	32.6
Fall from bed/trolley	65	28.3
Foot slip	49	21.3
Fall from chair/wheelchair	16	7.0
Loss of balance when walking	10	4.3
Fall from mother's lap	5	2.2
Tripping (e.g., cable)	4	1.7
Not specified	6	2.6

Table 2. Continued		
Characteristics related to fall events	**n**	**%**
Injury due to fall (n=92)		
None	63	68.5
Present	29	31.5
Type of injury (n=29)		
Head injury	15	51.8
Pain in hip	3	10.3
Not specified	11	37.9
Admission interval (in days) (n=165) (M=17)		
0-3	14	8.5
4-7	15	9.1
8-15	45	27.2
16-30	48	29.1
31-159	43	26.1
Day of fall since admission (n=185) (M=6)		
0-3	61	33.0
4-7	49	26.5
8-14	29	15.7
15-107	46	24.8
*Multiple data, more than one precaution may be related to one event.		

Although there are different perspectives, it is argued that the fall risks differ due to the different characteristics of surgical and internal medicine patients. Accordingly, surgical patients need to be identified in the high fall-risk group due to lengthened preoperative fasting, the narcotic analgesics used in the postoperative period, and physical activity limitations. Patients admitted to internal medicine clinics have fall risk due to the requirement for long durations of hospital care and having chronic disease diagnoses, which lead to physical movement limitations due to effects on muscle, nerve, and circulation systems. Therefore, when assessing the fall risks of patients admitted to internal medicine and surgery clinics, it is necessary to consider individuals with chronic diseases and factors which may increase their risk of falling in the pre- and post-operative periods.[14,16]

When reporting fall events, recording time intervals allows health professionals to determine when patients frequently fall and are exposed to most risks during the day. In addition, this enables health professionals to take suitable precautions to prevent falls. Majkusová and Jarošová[16] reported that surgical patients fell mostly during the night shift, while McKechnie et al.[17] reported that fall events occurred during the day and evening shifts. Moreover, in long-term departments, it was suggested that falls frequently occurred in the afternoon when the patients were visited by their families/relatives.[16] In our study, most falls were identified as occurring on the night shift between 24.00 and 08.00. This situation is possibly due to the lower number of staff nurses working the night shift than the day and evening shifts. Also, attempting to go unassisted for urgent toilet requirements without disturbing the nurse or caregiver, the short-duration loss of orientation, or orthostatic hypotension occurring after waking may lead to falls at night.

Our study findings showed that patients most frequently fell within the first three days of admission. Hajduchová et al.[15] noted that falls were mostly reported in the first week of admission. It is suggested that this situation is due to the patient experiencing difficulty orienting to the hospital environment in the early period of admission and using devices they are unfamiliar with. Moreover, our findings showed that lengthened admission increased the risk of falling. A prolonged hospital stay is among the most critical risk factors for fall events. Majkusová and Jarošová[16] indicated that long-term patients suffered the most falls compared to other inpatient units. Hospitalization for an extended period may likely cause loss of muscle tone and result in patient facing weakness and being unable to prevent themselves from falling.

In this study, it was identified that falls most frequently occurred in the patient's room. Similarly, it has been reported that fall events frequently occur in environments such as the patient's room, corridors, and bathroom, forming the patient's environment in the hospital setting.[12] Abreu et al.[18] stated that falls were most common in the patient's room, occurring when the nurse was absent and the patient was attempting to stand up without assistance. Also, the patient room is the place where the patient spends most of their time, and falls from bed are frequently experienced. Consequently, it is considered that patients experience difficulties orientating to the room environment during admission and especially to safety precautions related to the bed.

Our study revealed different causes of falls in adults compared to pediatric patients. Adult patients most frequently fall due to syncope, standing up from the bed/trolley, or foot slip. In contrast, pediatric patients frequently fall when standing from the bed/trolley or chairs. Studies conducted with adult patients showed that patients in the hospital have similar causes of falling, which aligns with our results. It was reported that adult patients' most common activities during falls were standing up from the bed, ambulating, going to the toilet, and moving to a chair.[16] When the causes of falls in pediatric patients were investigated, falls were mostly observed due to broken rails, a lack of attention by the family, or not educating the child's primary caregiver about falls.[19] Chang et al.[20] revealed that falls occurred among the 0-6 age group due to jumping out of the bed or lowering the bed railings. Therefore, it is possible to say that interventions to reduce fall risks differ depending on the age groups, and a proper arrangement of the hospital environment is required.

It is known that falls and their related mortality-morbidity rates are higher in childhood and at older ages. However, this study did not identify a significant correlation between age and fall risk levels, with patients who fell found to be middle-aged or older on average. Variations occurring with older age, such as reduced physiological functions and the limitations of daily living activities, an increase in multiple medication use, and chronic diseases, are independent factors increasing fall risk.[20] Additionally, in this study, nearly one-third of fall events were observed in pediatric patients. As pediatric patients are still in the development stage for neuromotor, physical, cognitive, and psychosocial processes, falls occur as a part of this development process and are different from the adult ages.[21] For example, learning to walk at an early age and running while playing leads to falls in children. Not requesting help from caregivers or nurses and meeting hygiene and toiletry requirements due to the excessive importance attached to privacy are among the risk factors for falls adolescents. As a result, when assessing fall risks, focusing on the specific risk factors related to the individual's developmental period is recommended.

In the current study, more than half of the patients with high fall risk were men, but gender was not a significant variable for fall risk. Results have been put forward arguing both for and against gender being a fall

risk factor. Majkusová and Jarošová[16] indicated that falls are expected to happen among females older than 65 due to their higher age and higher hospitalization rate; in contrast, Pereira et al.[22] emphasized high fall rates among the male population. Tanrikulu and Sari[23] found no correlation between gender and fall risks, and our results are similar to their research. However, it is essential to consider that causes of falls may differ according to gender characteristics, such as hearing loss in males and urinary incontinence, living alone, and repeated fall history being associated with increased fall risks.[24]

Functional insufficiency in individuals with chronic disease results in an increased risk of falls. In our study, though most patients had chronic disease diagnoses, no statistically significant difference was found between this situation and fall risk points. In a cross-sectional study, Sibley et al.[25] revealed that elderly patients with at least one or more chronic disease diagnoses had an increased risk of falls. Our study revealed that half of the patients with chronic disease were diagnosed with hypertension and/or diabetes. Gangavati et al.[26] identified that repeated fall risk was 2.5 times higher in elderly patients with hypertension and uncontrolled blood pressure. Similarly, Sibley et al.[25] revealed that patients with hypertension had significantly higher fall risk. Acute orthostatic falls in blood pressure reduce blood flow to the brain, and temporary cerebral ischemia creates syncope-related falls. Findings from a meta-analysis by Yang et al.[27] showed increased fall risks for diabetes patients. Berra et al.[28] concluded that increased fall risks in diabetic individuals were due to irregularities in blood glucose levels. In line with these results, it was revealed that determining specific risk factors of various chronic diseases is essential.

According to our study, more than half of falling patients could not complete ADL independently, and a statistically significant correlation was found between dependence levels and fall risk. Hajduchová et al.[15] concluded that more than half of the patients who fell were moderately or highly dependent according to the Barthel ADL index. Similarly, de Souza et al.[29] revealed that fall risks increased as the need for ambulation support increased. Dependence for ADL occurs when individuals are faced with environmental dangers due to loss of muscle power and physical limitations, which increases fall risks. Dependence in ADL is revealed by the individual's need to use assistive devices. In our study, some patients who fell were identified as using assistive devices (glasses, walkers/walking sticks, or extremity protheses). Choi and Lee[30] emphasized that most individuals requiring physical support when walking had a high risk of falling. Similarly, a weakness of visual acuity is among the risk factors, and nearly one-third of falls are reported to be due to visual impairments.[31] Additionally, some of our patients were found to fall due to not using the nurse call button. Fall events occurring in the patients' rooms were especially related to patients who did not receive assistance when standing up from the bed/chair or going to the toilet. It is known that the use of the nurse call button when attempting to leave a bed or a chair reduces fall events.[32]

Medications that increase fall risks are listed as anti-hypertensive agents, diuretics, B blockers, sedatives and hypnotics, neuroleptics and antipsychotics, antidepressants, benzodiazepines, narcotics, and non-steroidal anti-inflammatory drugs.[33] Signorovitch et al.[34] highlighted that the use of non-insulin anti-diabetic drugs is significantly associated with higher fall risks by resulting in hypoglycemia. It was also shown that polypharmacy had become a critical issue among elderly patients, contributing to their hospital falls.[35] On the one hand, the Hendrich II risk evaluation tool only defines anti-epileptics and benzodiazepines as medications that increase fall risks. On the other hand, in our study, nearly one-third of patients were using at least one of the medications included in the two groups stated in this risk tool, and there was no statistically significant difference between medication use and fall risk scores. Thus, assessment tools need to include the other medication groups that may increase fall risks.

Study Limitations

In our study, some limitations are present due to inaccessible data from the retrospective study design. Consequently, insufficient fall precautions may have been derived from inadequate written records about interventions in the past.

CONCLUSION

Fall events are a crucial public health issue for all age groups and are commonly used as healthcare service quality indicators. In this study, fall events mostly occurred in the internal medicine and surgery clinics between the hours of 24.00 and 08.00, with most patients falling in their room due to syncope, rising from their bed, or foot slip. Fall events occurred most frequently in the first three days of admission, with the risk of falls observed to increase as admission duration lengthened. When the causes of falls were investigated, patients frequently did not take appropriate safety precautions and did not use the nurse call button. Those patients who fell were mainly in the middle-aged group and male and could not complete their daily living activities independently, had at least one chronic disease diagnosis, and were assessed as having high fall risk.

On this basis, we conclude with the following recommendations: individuals with chronic diseases affecting the muscle, nerve, and circulation systems should be closely monitored; patients in surgery clinics should have factors that increase risk in the pre- and post-operative periods defined in detail and included in scale tools; especially those patients at high risk should be assessed at intervals during the night shift; all patients should be accepted as high risk during care interventions on the first three days of admission; family members should be supported in taking an active role in the patient's room, and orientation in the ward and medication groups forming a risk factor for falls should be defined in detail and included in risk assessment tools.

MAIN POINTS

- Falls are critical in causing physiological and psychological damage to individuals by reducing their quality of life.
- Patient falls have become an essential indicator of healthcare service quality.
- A set of sociodemographic, medical, environmental, and fall-related independent variables should be considered when evaluating fall risks.
- Fall risk assessment tools should be revised by reviewing the patient's specific care needs and clinical conditions.

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ETHICS

Ethics Committee Approval: The study was approved by the Hacettepe University Non-Interventional Clinical Research Ethics Committee (approval number: 2016-14-GO 16/45-32).

Informed Consent: Informed consent was not necessary due to the retrospective nature of this study.

Authorship Contributions

Concept: D.U., N.A.E., F.K., İ.A., Y.A., M.D.T., Design: D.U., N.A.E., F.K., İ.A., Y.A., M.D.T., Supervision: D.U., N.A.E., F.K., İ.A., Y.A., M.D.T., Fundings: D.U., N.A.E., F.K., İ.A., Materials: D.U., N.A.E., F.K., İ.A., Y.A., M.D.T., Data Collection and/or Processing: D.U., N.A.E., F.K., İ.A., Y.A., M.D.T., Analysis and/or Interpretation: D.U., N.A.E., F.K., İ.A., Y.A., M.D.T., Literature Search: D.U., N.A.E., F.K., İ.A., Y.A., M.D.T., Writing: D.U., N.A.E., F.K., İ.A., Y.A., M.D.T., Critical Review: D.U., N.A.E., F.K., İ.A., Y.A., M.D.T.

DISCLOSURES

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RESEARCH ARTICLE

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Noise-Induced Cochlear Synaptopathy in Dental Prosthesis Students

Bünyamin Çıldır[1], Suna Tokgöz-Yılmaz[2]

[1]Department of Language and Speech Therapy, Ankara Yıldırım Beyazıt University Faculty of Health Sciences, Ankara, Türkiye
[2]Department of Audiology, Ankara University Faculty of Health Sciences, Ankara, Türkiye

Abstract

BACKGROUND/AIMS: Noise causes damage to cochlear hair cells and loss of sensitivity for low volume sounds. Hidden hearing loss is a functional disorder which can be seen in individuals with noise exposure history but no permanent threshold loss. We aimed to determine which tests can be used to diagnose hidden hearing loss in dental prosthesis associate degree students with normal hearing who are exposed to noise.

MATERIALS AND METHODS: Ninety individuals between the ages of 19-35 whose pure tone average was within normal limits were included in our study. These individuals were divided into two groups according to their noise exposure score as the high-risk group (n=45) and the low-risk group (n=45). Auditory brainstem response (ABR) and amplitude modulation detection tests were performed with and without background noise after standard audiometric tests and otoacoustic emission suppression measurement.

RESULTS: The otoacoustic emission suppression values of those individuals in the high-risk group were found to be significantly lower than those in the low-risk group. As the stimulus level increased, the differentiations (amplitude increase and latency decrease) in the first wave of ABR without background noise were observed in those individuals in the low-risk group. The recognition threshold score which was modulated to the amplitude was found to be lower in the presence of background noise than in the absence of background noise for all participants.

CONCLUSION: Although noise exposure does not result in any permanent differences in hearing thresholds, the otoacoustic emission suppression values, the differentiations of the first wave and the amplitude modulation detection values can provide useful information in the diagnosis of hidden hearing loss in individuals with normal hearing.

Keywords: Hidden hearing loss, auditory brainstem response, otoacoustic emission suppression, amplitude modulation detection

INTRODUCTION

Exposure to high intensity noise may cause unwanted sounds which mask speech and communication, as well as the long-term exposure to such noises causing physical (such as temporary hearing loss, increased blood pressure) and mental effects (such as stress, anxiety, mental difficulty).[1-3] These effects may vary depending on the duration of exposure to noise, the distance to the source and the sensitivity of the person.[1,3]

The loss of the synaptic connection between the inner hair cell and spiral ganglion cells after noise exposure is the first pathological finding of temporary hearing loss.[4] This deterioration is called "synaptopathy" due to the connection loss between the lesion area inner hair cell ribbon synapses and afferent hearing nerves. It is also known as "hidden hearing loss" since it does not reach hearing thresholds.[4]

Hidden hearing loss is a functional disorder which can be seen in individuals with noise exposure history but no permanent threshold

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ORCID IDs of the authors: B.Ç. 0000-0002-5632-1650; S.T.Y. 0000-0002-4656-099X.

Address for Correspondence: Bünyamin Çıldır
E-mail: bunyamin.cildir@gmail.com
ORCID ID: orcid.org/0000-0002-5632-1650

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loss.[5] We can investigate functional distortions in outer hair cells (OHC) by determining the lowest discernible hearing threshold levels in a given frequency region with the use of pure tone audiometry.[6] Hidden hearing loss is assumed to affect low-spontaneous rate fibres with high thresholds, which are responsible for encoding moderate to high noise intensity.[7] In this pathology which occurs after noise exposure, due to the peripheral loss of hearing nerve fibres with a high threshold and low spontaneous rate, no deterioration occurs in low-intensity sounds.[7] High-intensity sounds, consistent with low SR fibre loss, are associated with non-abnormal results.[8] It has been indicated that hidden hearing loss cannot be determined by audiometric results but there is a decrease in the amplitude of wave I of the auditory brainstem responses (ABR) to moderate-to-high intensity stimuli,[8] and amplitude modulation detection values.[9] In the study by Liberman et al.[10], normal hearing individuals with low-risk of noise exposure and normal hearing individuals with high-risk were compared in terms of cochlear synaptopathy, and the amplitude of wave I of the ABR responses was not found to be decreased in the high-risk group. In another study conducted on individuals with and without tinnitus, it was reported that the amplitudes of individuals with tinnitus decreased more with wave I of the ABR compared to the group without tinnitus.[11] Dentists or dental assistants can be exposed to different noise levels and types while working in dental offices or laboratories.[12]

In our study, we aimed to determine whether the ABR and distortion suppression of otoacoustic emissions and amplitude modulation detection (AMDT) tests and speech in noise tests would be useful in determining whether there is latent hearing loss in individuals with dental prosthesis associate degrees with normal hearing. At the same time, the results of dental prosthesis associate degree students (dental auxiliaries) were compared with the results of individuals with normal hearing who were not exposed to noise, and the damage caused by noise exposure to the hearing system was evaluated.

MATERIALS AND METHODS

Our study was approved by the Ethics Committee of Ankara Yıldırım Beyazıt University and implemented according to the Helsinki Declaration (approval number: 56/15). The individuals who applied for occupational health check-ups were informed about the aims of this study and consent was obtained from those who agreed to participate.

Participants: A total of 90 individuals, who were aged between 19-35 years (23.45±3.67) took part in this study. Dental prosthesis associate degree individuals with high-risk (n=45; noise exposure score=5 or above) exposed to noise between the ages of 19-35 were compared with low-risk normal hearing low noise exposure (n=45; noise exposure score=4 or below) according to their one-minute noise questionnaire score. Our study was conducted with Ankara University, Vocational High School, dental prosthesis associate degree students and undergraduate students with normal hearing and no history of noise exposure. This study was conducted in Ankara University Faculty of Health Sciences, Department of Audiology between 2016-2018. Individuals who were over 18 years and with no hearing loss history, neurological disorders, or tinnitus were included in this study (hearing thresholds ≤20 dB HL at 125 to 12,000 Hz). Four participants with hearing thresholds higher than 20 dB HL were excluded from this study. After otoscopy, all participants were tested by pure tone audiometry, immitansmetry, speech in noise, Distortion Product Otoacoustic Emission (DPOAE) suppression measurement, auditory brain stem response, and AMDT with and without background noise. The measurements of all participants were made when the schools entered the semester break. None of the participants entered the laboratory within this time period (approximately 3 weeks).

Evaluation of noise exposure and sensitivity: The participants' noise exposure scores were determined by a 1-minute noise screen questionnaire.[13] Those with a score of 5 or above were evaluated as being high-risk individuals and those with a score of 4 or below were evaluated as being low-risk individuals according to their questionnaire responses. In addition, in order to evaluate the participants' noise sensitivity, we used the Turkish version of the Weinstein noise sensitivity scale which had been tested for its validity and reliability. The total score is calculated by giving 1 to 6 points (agree/disagree) to 21 questions in this scale (the highest possible score is 126).[14] At the same time, the noise level of the dental prosthesis laboratory was measured using the Larson Davis system 824 sound level meter. The noise levels of the laboratory were measured every 10 minutes (10.00-12.00 and 13.00-14.00) during a three-month period (excluding weekends) from the same point in the middle of the laboratory while all devices in the laboratory were working. Measurements were made a total of 18 times every day.

Speech in Noise Test

This test is carried out using monosyllabic word lists in background noise such as narrowband and white noise.[15,16] This test can be performed at different signal to noise ratios as well as at fixed signal to noise ratios.[17] In our study, 50-word monosyllabic word lists were given at 40 dB SL, with a constant +10 dB signal/noise ratio to the ear to be tested for both noise and speech stimuli. Each ear was evaluated separately.

Pure tone audiometry and immitancemeter measurements: Pure tone audiometry were performed with Sennheiser TDH 49 P supra-aural headset in the range of 0.125 to 8 kHz and with Sennheiser HDA 200 circumaural headphones in the range of 8 to 12 kHz according to the British Society of Audiology (2011). The participants' middle ear pressure values were between ± 50 daPa and performed by GSI TympStar device.

Contralateral suppression of distortion product otoacoustic emissions: DPOAE is an electro-acoustic measurement which reflects the mechanical properties of the OHCs. The DPOAE test is performed by simultaneously transmitting two pure tone sounds (to the ear at different frequencies f1 and f2 using an f2/f1 ratio of 1.2).[18] The DPOAE amplitude was chosen when L1 (75 dB SPL) was 10 dB higher than L2 (65 dB SPL). The contralateral DPOAE suppression test causes suppression of OHCs with contralateral noise. The contralateral DPOAE suppression test can either be performed by decreasing the amplitude (Input-Output-I/O function) or by changing the frequency values of the constant amplitude (DP-Gram).[19] We used the Otometrics (Denmark, Taastrup) Capella DPOAE. DP-gram was obtained at octave frequencies of 200, 2,383, 3,359 and 4,004 Hz at 60 dB SPL broadband-contralateral white noise Hz using contralateral TDH39 headphones.

Auditory brainstem response: ABR measurements of the participants were performed in a natural sleep state in a Faraday cage test room using Vivasonic (Canada, Toronto) Integrety™ V500 Auditory Diagnostic System in two channels. The active electrode (F_z) was placed on the upper part of the forehead, the ground electrode (F_{pz}) was placed on the lower part of the forehead, one of the reference electrodes was placed on the left (M1) and the other was placed on the right mastoid (M2) region (electrode skin impedance below 3 kΩ). The click stimuli

(with 1,024 repeats) at alternative polarity were transmitted through ER-3A insert headphones, using a 30 Hz high-pass filter (high-pass). ABR recordings were kept by using a 100 µs stimulus at a rate of 9.1 Hz (rate) at 70, 80, 90 and 99 dB nHL levels to the opposite ear, for both cases of a 55 dB nHL broadband mask and without mask.

Amplitude modulation detection test: The AMDT is used to detect amplitude modulation sounds which are assumed to decrease after noise exposure because of impairment in individual's over-threshold responses. AMDT was performed with and without contralateral narrowband noise (40 dB SPL).[20] The bandwidth of narrowband noise was set to 1/3 of an octave in this study. A sinusoidal sound modulated to 19 Hz with a carrier frequency of 5 kHz at 75 dB SPL level was used. The AMDT test was performed using the Parameter Estimation by Sequential Testing (3 interval-3 alternative selection methods) and the p-value was taken as 0.75. One of three randomly transmitted sounds was modulated to stimulus amplitude and the other two were not modulated. While the target tone was being transmitted, the AM depth was initially set as 6 dB (50%) and was adaptively randomized until the final modulation change size reached 0.45 dB; the mean value of the last two steps was accepted as the threshold.[21] We used AMDT software with the Matlab 2019.b program.

Statistical Analysis

Data analysis was performed using SPSS v.23.0 (Statistical Package for Social Sciences) (SPSS Inc., Chicago, IL, US). The normal distribution of our study was examined with the Shapiro-Wilk test. A chi-square test was used to compare the demographic findings. The non-parametric Mann-Whitney U test was used for comparisons between the high-risk and low-risk groups. The Wilcoxon test was used for in-group comparison and the Spearman test was used for the relationships between two variables. The p-value for statistical significance was accepted as <0.05.

RESULTS

Noise exposure and sensitivity: The average noise level of the dental laboratory was 97±11.3 dB (A) at 10.00 a.m. and 102±9.3 dB (A) at 2 p.m. These hours are when the laboratory was very busy. Of the 45 participants in the high-risk group (dental prosthesis associate degree students), 41 reported that they were exposed to sounds such as wedding halls, ambulances, and traffic noise during the day. 85% of the individuals in the low-risk group stated that they were exposed to traffic noise. As shown in Figure 1, the 1-minute noise screen scores of the individuals in the high-risk group (7.29±1.23) were found to be statistically higher than the low-risk group's scores (2.81±1.35) (p=0.001). The Weinstein's noise sensitivity scale scores of the individuals in the high-risk group (65.44±7.53) were statistically higher than the scores of the low-risk group (34.16±8.14) (p=0.011) (Figure 2). A positive and high correlation was observed between the 1-minute noise screen and Weinstein's noise sensitivity scale of all individuals (r=0.822, p=0.001).

Pure tone audiometry: All participants had normal hearing thresholds (equal to or less than 20 dB HL at 125-8,000 Hz octave frequencies). No statistical difference was observed between the hearing thresholds of the groups (p>0.05).

Speech in noise test: Although no statistically significant difference was found between the scores of speech understanding in noise of the high and low-risk groups for both ears, the scores of the high-risk group were lower than the scores of the low-risk group.

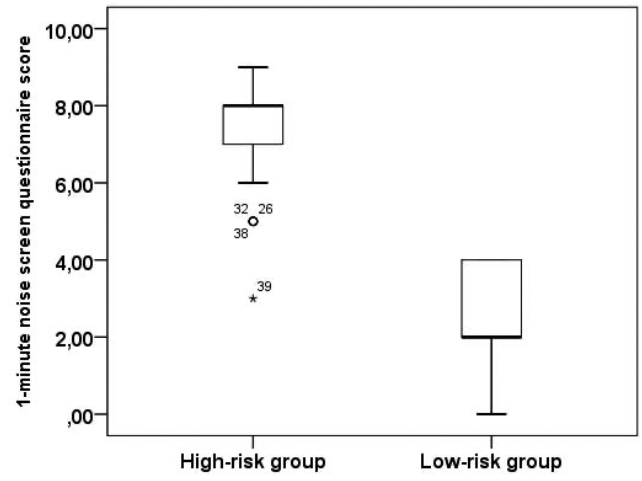

Figure 1. One-minute noise screen questionnaire findings of both groups, error bars show the standard deviation.

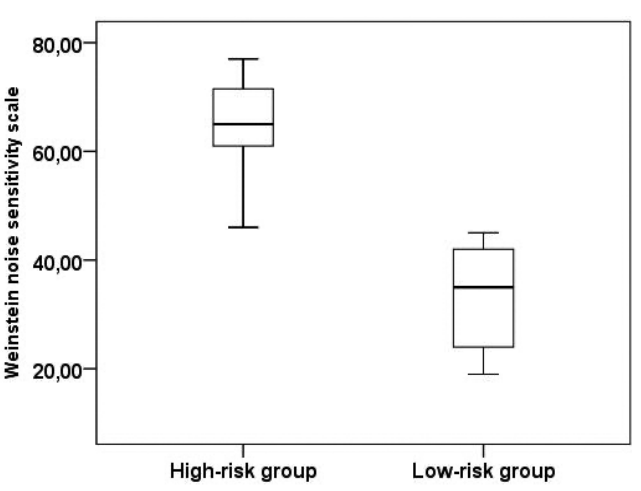

Figure 2. Weinstein noise sensitivity scale findings of both groups, error bars show the standard deviation.

Contralateral suppression of distortion product otoacoustic emissions: Contralateral DPOAE suppression amounts were calculated at all frequencies and were found to be 0.84 dB SPL for individuals at high-risk, and 2.02 dB SPL for individuals with low-risk. The difference in the contralateral DPOAE suppression amounts between the two groups was statistically significant (p=0.014).

Auditory brainstem responses: ABR records of all participants were made on the right ear of 68 patients and the left ear of 16 patients. While the amplitude of wave I of ABR with mask was statistically smaller than the amplitude value obtained without mask at 99 dB nHL in the high-risk group (z=-3.087, p=0.002), the amplitude was found to be bigger at 80 dB nHL without mask (z=-3.155, p=0.002) (Table 1). A negative value was found in the amplitude of wave I of ABR in 10 individuals in the low-risk group and 8 individuals in the high-risk group. The latency of wave I obtained with mask was statistically significantly shorter

than the latency without mask at 90 dB nHL (z=-2.178, p=0.029) and 99 dB n HL (z=-2,449, p=0.014) in the high-risk group. There was no statistically significant prolongation of the ABR wave V latency with mask in the high-risk group (p>0.05).

As shown in Table 2, for the low-risk group, the wave I amplitude (z=-2.587, p=0.010) at 70 dB nHL and the wave III amplitude at 90 dB nHL (z=-2.807, p=0.005) values were found to be statistically lower with mask. There was no statistical difference between the amplitude and latency values of the wave I, III and V with mask and without mask at other (80 and 99 dB nHL) intensity levels (p>0.05). Although there was no statistical difference, it was observed that the amplitude increased as the stimulus intensity level rose.

For the high-risk group, the wave V amplitude was found to be smaller with mask than without mask at 99 dB nHL (z=-2.562, p=0.010) and 90 dB nHL (z=-1.999, p=0.046), but it was found to be bigger at 80 dB nHL (z=-3.905, p=0.001) (Table 1).

There were statistically significant differences in the wave I amplitude at 70 dB nHL (U=288, p=0.001), 80 dB nHL (U=586.5, p=0.011) and 99 dB nHL (U=635.5, p=0.035) with mask between the two groups. However, there was no difference at all stimulus levels without mask (Table 1, 2) (p>0.05).

Amplitude modulation detection threshold: For both groups, the AMDT scores were evaluated both with mask and without mask (Table 3). AMDT values with mask were statistically higher (worse) than the AMDT values without mask in all individuals (p=0.001 for the high-risk group; p=0.035 for the low-risk group). The AMDT values in the high-risk group were lower (better) than the AMDT values in the low-risk group (p<0.001).

DISCUSSION

Noise-related hidden hearing loss is a functional disorder which is seen in individuals who suffer from noise exposure without hearing loss[5] and it is also known as cochlear synaptopathy.[8] In a cochlear synaptopathy study on mice, no difference was observed in the hearing thresholds which were measured with ABR, although half of the synapses between the inner hair cell and spiral ganglion neurons were lost due to noise exposure.[22,23] In synapse loss after noise exposure, while otoacoustic emissions were obtained, the slope of the ABR wave I amplitude was observed at high stimulus levels.[1]

Table 1. Auditory brainstem responses amplitude with/without mask at different stimulus level for the high-risk group

Mask	Stimulus level	Wave I, Mean ± SD	p	Wave III, Mean ± SD	p	Wave V, Mean ± SD	p
With mask	99 dB nHL	0.12±0.28	0.002*	0.33±0.25	0.169	0.45±0.22	0.010*
Without mask		0.21±0.25		0.37±0.27		0.75±0.96	
With mask	90 dB nHL	0.17±0.25	0.608	0.34±0.22	0.797	0.56±0.17	0.046*
Without mask		0.17±0.19		0.31±0.16		0.49±0.17	
With mask	80 dB nHL	0.22±0.23	0.002*	0.31±0.19	0.103	0.50±0.17	0.001*
Without mask		0.11±0.20		0.25±0.20		0.36±0.17	
With mask	70 dB nHL	0.19±0.22	0.063	0.21±0.18	0.395	0.35±0.22	0.331
Without mask		0.16±0.36		0.25±0.22		0.33±0.19	

*p<0.05, SD: Standard deviation.

Table 2. Auditory brainstem responses amplitude with/without mask at different stimulus level for the low-risk group

Mask	Stimulus level	Wave I, Mean ± SD	p	Wave III, mean ± SD	p	Wave V, Mean ± SD	p
With mask	99 dB nHL	0.15±0.14	0.786	0.29±0.16	0.678	0.53±0.22	0.120
Without mask		0.14±0.17		0.27±0.19		0.46±0.25	
With mask	90 dB nHL	0.10±0.16	0.223	0.25±0.15	0.005*	0.38±0.24	0.275
Without mask		0.18±0.22		0.35±0.18		0.44±0.19	
With mask	80 dB nHL	0.77±0.23	0.488	0.23±0.26	0.771	0.36±0.15	0.322
Without mask		0.12±0.17		0.30±0.63		0.40±0.17	
With mask	70 dB nHL	-0.1±0.21	0.010*	0.16±0.30	0.662	0.35±0.27	0.411
Without mask		0.05±0.17		0.19±0.16		0.30±0.14	

*p<0.05, SD: Standard deviation.

Table 3. Amplitude modulation detection test findings with/without mask for two groups

	AMDT with mask		AMDT without mask		
Groups	Median (min.-max.)	Mean ± SD	Median (min.-max.)	Mean ± SD	p
High-risk	-40.1 (-46.1, -32.6)	-39.9±3.16	- 40.8 (-49.8, -28.8)	-41.2±4.57	0.035*
Low-risk	-32.2 (-41.5, -26.3)	-32.7±3.58	-37.6 (-43.1, -31.1)	-37.5±3.19	0.001*
p-value	0.001*		0.001*		

AMDT: Amplitude modulation detection test, Min.: Minimum, Max.: Maximum, SD: Standard deviation, *p<0.05.

As shown in Figure 3, 4, we found a decrease in the suprathreshold ABR wave I amplitude with mask in the high-risk group compared to the low-risk group. This decrease in amplitude value was highlighted in another study about mild and high spontaneous rate fibre loss-induced hidden hearing loss.[4] In animal studies, it has been reported that decreases in wave I amplitude are associated with synaptic loss with long-term exposure to noise, but the measurement of the wave I amplitude in humans does not provide precise information on the evaluation of synaptopathy.[8] Studies have indicated that individuals with noise exposure may experience difficulties in terms of supra-threshold processing skills, such as poor understanding and impaired attention.[24] However, exposure to noise did not cause any hearing loss in the high-risk group in our study.

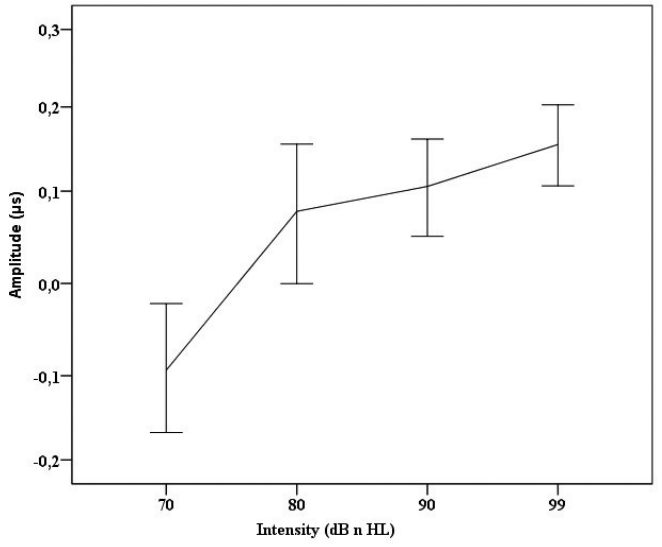

Figure 3. Amplitude findings of wave I of ABR with mask in individuals in the high-risk group.

ABR: Auditory brainstem response.

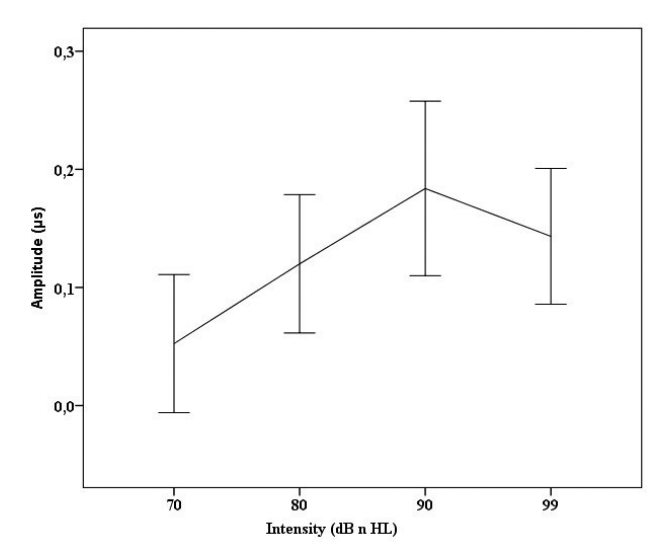

Figure 4. Amplitude findings of wave I of ABR without mask in individuals in the high-risk group.

ABR: Auditory brainstem response.

We observed an increase in the amplitude of wave I without mask and a decrease with mask as the stimulus level increased ($p<0.05$). There was a minimum prolongation in the latency of wave V with mask in comparison to without mask in the high-risk group, which was found to be compatible with previous studies.[25,26] As a finding different from the literature, we found that the masked wave I latency was shorter than the unmasked wave I latency at suprathreshold levels in the high-risk group. In our study, the change in the wave V latency was accompanied by a decrease in the wave I amplitude in the high-risk group, suggesting that there may be hidden hearing loss in these individuals. This change mostly reflects the activities of low spontaneous fibre in the presence of background noise.[27]

The AMDT was performed with and without mask and was lower in the high-risk group than for those in the low-risk group with mask ($p<0.05$). This finding suggests that the temporal modulation of the sound may impair auditory sensitivity and may be useful in diagnosing hidden hearing loss.

The finding that individuals in the high-risk group with mask had lower AMDT scores than those in the low-risk group may be useful in the diagnosis of hidden hearing loss (Table 3). In studies which were previously conducted, it was stated that ABR with mask may reflect the efferent auditory system.[28] In our study, there was no change in the wave I amplitude at stimulus levels of 70 and 80 dB nHL with mask for both groups. This finding is consistent with the study conducted by Matas et al.[29]

In our study, individuals in the high-risk group had lower suppression values with contralateral noise than those individuals in the low-risk group ($p<0.05$). This finding is thought to be due to the fact that contralateral noise results in DPOAE suppression by activating efferent neurons as well as a decrease in afferent electric activity.[30] Marques and da Costa[31] highlighted that especially DPOAE data would be beneficial in the early diagnosis of cochlear impairments before noise induced hearing loss occurs due to noise exposure.

We thought that a decrease in suppression, I-wave amplitude and the AMDT score may indicate hidden hearing loss which leads to a decrease in communication skills. The background noise (40dB SPL) which was used in our study can be used to detect low spontaneous fibre loss, especially since it causes suppression of high spontaneous fibre.

Although the ABR test is the gold standard in the diagnosis of occult hearing loss in our study and in the literature, the diagnosis of occult hearing loss with only the ABR test is insufficient in revealing all the signs of the disease in real terms. Therefore, when diagnosing latent hearing loss, all objective and subjective tests such as AMDT, otoacoustic emission tests, adaptation test, and the ABR test should be used together.

CONCLUSION

The control of noise in high-noise environments such as dental prosthesis laboratories is important for the health of employees due to hearing loss which can be seen in groups with high exposure to noise. In our study, it was observed that ABR wave I amplitude decreased as the intensity increased in the high-risk group. In the low-risk group, it was

observed that, as the stimulus intensity increased, ABR wave I amplitude wave increased. This is a finding that should be taken into consideration in the diagnosis of occult hearing loss. At the same time, periodically performing audiometric tests on technicians working in these locations and using earplugs to minimize the noise exposure of these individuals can help prevent hearing loss. In the process of diagnosing individuals with hidden hearing loss, differentiations in the ABR wave I amplitude, the AMDT and suppression otoacoustic emission (especially DPOAE) may be useful in the early diagnosis of hidden hearing loss.

MAIN POINTS

- Noise exposure can cause wave differences in auditory brainstem responses without causing permanent loss of hearing thresholds.
- Continuous exposure to high intensity noise in dental prosthesis associate degree students can cause permanent loss of auditory nerve cells.
- The combined use of amplitude modulation detection tests, otoacoustic emission tests, auditory brainstem response and speech in noise tests provides useful information in the diagnosis of occult hearing loss.

ETHICS

Ethics Committee Approval: Our study was approved by the Ankara Yıldırım Beyazıt University Ethics Committee and implemented according to the Helsinki Declaration (approval number: 56/15).

Informed Consent: The individuals who applied for occupational health check-ups were informed about the aims of this study and consent was obtained from those who agreed to participate.

Authorship Contributions

Concept: B.Ç., Design: B.Ç., Supervision: B.Ç., Fundings: B.Ç., Data Collection and/or Processing: B.Ç., Analysis and/or Interpretation: B.Ç., Literature Search: B.Ç., Writing: B.Ç., Critical Review: S.T.Y.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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RESEARCH ARTICLE

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Impacts of the COVID-19 Pandemic on Nurses: A Qualitative Study

Ümran Dal Yılmaz, Nurhan Bayraktar

Department of Nursing, Near East University Faculty of Nursing, Nicosia, North Cyprus

Abstract

BACKGROUND/AIMS: Nurses are the largest healthcare professional group providing frontline care in coronavirus disease-2019 (COVID-19). As COVID-19 is a new disease and the medical system and culture of different countries varies, research is needed on the effects of this pandemic on nurses in order to increase knowledge. This study was performed to explore the impacts of the COVID-19 pandemic on nurses.

MATERIALS AND METHODS: This qualitative study was conducted using mass media and social media settings between March, 11th and May, 15th 2020. A total of 31 nursing statements were examined.

RESULTS: Analysis of the statements of the Turkish nurses about the impacts of the COVID-19 pandemic revealed four main themes, namely "emotions", "self-health", "patient care" and "employee rights."

CONCLUSION: Management strategies to support nurses coping with emotions, self-care, patient care and employee rights issues should be developed.

Keywords: COVID-19, Coronavirus disease, pandemic, nursing

INTRODUCTION

In today's modern world, millions of people are at severe risk of acquiring evolving viral infections.[1] A novel coronavirus disease-2019 (COVID-19) was first reported and then became widespread within Wuhan, China, in November, 2019. This disease rapidly spread becoming a global health emergency.[2,3] Since the first case of unexplained pneumonia in Wuhan, COVID-19 has affected many countries worldwide, with over 131 million cases and over 2.8 million deaths being reported globally as of the time of writing.[2,4,5] The COVID-19 pandemic was confirmed to have reached Türkiye in March, 2020, with the first case being officially confirmed on the 11th of March, 2020. As of the 5th of April, 2020, the number of confirmed total cases in the country was over 3.5 million, of which 3,130,977 had recovered and 32,456 had died.[6]

Coronaviruses are a large family of viruses which may cause illness in animals or humans.[2,7] COVID-19 mainly causes respiratory and digestive tract symptoms, with symptoms ranging from mild self-limited disease to systemic multiple organ failure syndrome.[4] COVID-19 is associated with intensive care unit admission, mechanical ventilation and it causes high mortality. In general, the disease is an acute illness but it can be deadly, with an average case fatality rate of 2%.[5] To date, there are no particular medications or vaccines against COVID-19 infection for human therapy.[8,9] Its medical treatment and nursing care mainly include antiviral and traditional medicine treatment, isolation, symptomatic support, and close monitoring.[4]

There have been many negative effects of the COVID-19 pandemics on communities all over the world. As a disaster condition, the pandemic has caused serious disruption to the functioning of communities involving widespread human, material, economic and environmental losses and impacts, which have exceeded the ability of the affected societies to cope using their own resources.[10] In this context, medical

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ORCID IDs of the authors: Ü.D.Y. 0000-0002-9482-6983; N.B. 0000-0002-3072-5788.

Address for Correspondence: Nurhan Bayraktar
E-mail: nurhan.bayraktar@neu.edu.tr
ORCID ID: orcid.org/0000-0002-3072-5788

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workers have important responsibilities in the struggle against this epidemic. Unfortunately, many front-line personnel have sacrificed their own well-being and have been infected and even died.[4] The mental health of healthcare staff has also been greatly challenged during this viral epidemic.[11]

In this global crisis, nurses are the largest healthcare professional group providing frontline care. Nurses' play pivotal roles in the care and management of the novel COVID-19 pandemic.[5] They are in a natural position to take an active role in disaster management because they spend the most time with patients, and they have expertise in providing clinical care, team leadership, and creative problem-solving skills.[12] In order to recognize the vital service of nurses in health care, the World Health Organization designated 2020 as the International Year of the Nurse and Midwife.[13] Clinical nurses have experienced great stress during their fight against COVID-19 which can affect their health and safety and also requires their interpersonal relationships and related knowledge.[14]

In Türkiye, as well as in other countries, nurses are at the forefront of the struggle against COVID-19 in the healthcare team, together with physicians. Nurses play pivotal roles in the organization of health services, safety precautions, planning and the implementation of care, providing training and evaluating the effectiveness of care in the fight against COVID-19. In Türkiye, as a top priority, the government took an effective role in resource allocation, and the education of the public regarding precautions. Nursing managers and the Turkish Nurses Association also have played active roles by providing protective equipment to nurses, ensuring appropriate nurse manpower, and providing transparent information. However, as is the case all over the world, nurses have been physically and psychosocially affected by this pandemic.

As COVID-19 is a novel disease and the medical system and culture of different countries varies, research is needed on the effects of this pandemic on nurses in order to increase knowledge. Understanding the impacts of the COVID-19 pandemic on nurses will be beneficial in developing strategies so as to cope with future outbreaks. The aim of this study was to determine of the impacts of the COVID-19 pandemic on Turkish nurses.

MATERIALS AND METHODS

Research Design

This study was performed retrospectively with a descriptive phenomenological approach to explore the effects of the COVID-19 pandemic on nurses. In this research, Colaizzi's descriptive phenomenological investigation method was applied.[15]

Procedures

A semi-structured tool was used in this study to frame the data collection. The framework of this study included the following areas of questioning in order to investigate the effects of the COVID-19 outbreak on nurses: What are the effects of the COVID-19 outbreak on the emotions of the nurses? What are the effects of the COVID-19 outbreak on the self-health of the nurses? and What are the other effects of the COVID-19 outbreak on nurses?

This study was conducted using Turkish mass media (newspapers, TV channels, web pages of the nursing associations) and social media websites (Facebook and Twitter) between March, 11th and May, 15th 2020, which was the beginning period of this outbreak. Search terms related to the COVID-19 pandemic were monitored daily by the two researchers. Nursing statements regarding the effects of the pandemic were recorded by hand or by mobile phone and then transferred to Microsoft Word documents. Content about the other healthcare professionals' statements was excluded. The confidentiality of the statements was assured by using numbers instead of names. A total of 31 nursing statements were examined.

Ethical Aspects

Ethical approval was obtained from the Near East University Review Board (approval number: YDU/2021/91-1347). Although data collection was performed from mass media and social media, the statements of the nurses were recorded using participant numbers for confidentiality. Informed consent was not required because of the data collection method.

Statistical Analysis

The two co-authors analyzed the data simultaneously following Colaizzi's descriptive phenomenological steps. Content analysis was applied in this study. In this context, the researchers first transcribed the recordings and read the texts several times independently for familiarization. The researchers identified those statements which were of direct relevance to the effects of the COVID-19 outbreak on nurses. Following this, they formulated meanings in these statements and categorized the meanings into clusters of common themes. The meanings and themes throughout the analysis process were compared and discussed by them until consensus on the themes was achieved. Finally, a reflective process by returning to the participant statements from the original mass media or social media settings was performed for validation. In addition, an independent researcher who was experienced in phenomenological research was asked to evaluate the consistency between the data and the themes. Finally, revisions were made in line with their suggestions.

Results

The data about impacts of the COVID-19 pandemics on Turkish nurses were analyzed under the four main themes of "emotions", "self-health", "patient care" and "employee rights" (Table 1).

Emotions

The Emotions theme was composed of clusters of themes including "Anxiety", "Fear", "Fighting", "Threatened", "Anxiety of family members", "Concern about contamination of microorganisms", "Separation", "Longing", "Fear", "Panic", "Sadness", "Happiness" and "Motivation."

Examples of the statements related to this category include:

"At the beginning, I was more anxious, I followed the literature constantly and always had a fear of being infected."

"We fight against COVID-19 at the zero point, we are at risk."

"I left my son with my mother before starting work. We haven't seen each other for a month. We try to eliminate separation by talking on video calls. My child is without me these days..."

"When I was diagnosed with COVID-19, of course, I experienced fear and panic like everyone else."

Table 1. Statements of the nurses regarding the impacts of the COVID-19 pandemics with themes

Significant statements	Theme clusters	Emergent themes
"At the beginning, I was more anxious, followed the literature constantly and always had a fear of being infected."	Anxiety Fear	Emotions
"We fight against COVID-19 at the zero point, we are at risk."	Frightened Threatened	
"We also know from examples in the world that this disease has a high risk of transmission to healthcare workers. Our families are also concerned for us."	Anxiety of family members	
"The anxiety of contamination of microorganisms from hospital to home is affecting me psychologically."	Concern about contamination of microorganisms	
"I miss my family very much." "I left my son with my mother before starting work. We haven't seen each other for a month. We try to eliminate this separation by talking on video calls. My child is without me these days..."	Separation	
"When I was diagnosed with COVID-19, of course, I experienced fear and panic like everyone else."	Fear Panic	
"I feel very disappointed to see people who go out to socialize. People should be aware of the severity of this event"	Sadness	
"I feel happy when patients recover."	Happiness	
"The applause of people on the balconies for healthcare workers motivated me and made me feel better."	Motivation	
"This is my fifteenth hour in these protective gowns. My lungs have faded from constantly taking my breath. In the overalls, I lost all of the water I drank. The pit that the mask and visor caused on my face is not to be mentioned..."	Fluid loss Discomfort in breathing Mask marks	Self-health
"In this epidemic, there is a risk of contamination to ourselves, and we have to protect ourselves." "We, the healthcare providers, are not immune. It should not be forgotten that we are human beings. Who will take care of the patients if we are not good?"	The need to protect self- health	
I had a lot of trouble when I caught COVID-19. There were incomparable joint pains, respiratory distress.	COVID-19 illness Joint pain and respiratory distress due to COVID-19	
"There is always fatigue."	Fatigue	
"We have to provide the care they deserve to a large number of patients with the same efficiency and sensitivity."	Increase in the number of patients Challenge in providing effective care to a large number of patients	Patient care
"Patients are afraid of our protective equipment such as masks, and protective gowns."	Discomfort of patients due to protective measures	
"Prolonged work and fatigue of the nurses can increase the risk of errors."	Increased risk of errors due to fatigue	
"Nurses in intensive care are having difficulties. Sometimes we work with a few hours of sleep. There are nurses who have a 24-hour working shift." "We work day and night without leaving the clinic."	Long working hours	Employee rights
"When first cases in Türkiye were announced, I was on annual vacation. I left my vacation and returned to my job in the intensive care unit."	Working without vacation	
"I was transferred to the corona clinic from my clinic."	Workspace change	
"Nurses can't make their voice heard enough. The phrase "physicians and other healthcare personnel" is used as if it is only physicians providing the entire service. However, nurses are the closest working group to the patients 24/7." "Healthcare providers cannot get the salary they deserve. Nurses should be provided with additional funding during this process."	Underappreciation Not getting paid enough for labor	
"Under these difficult conditions, healthcare workers should not be exposed to violence."	Violence	
It is positive that the Ministry of Health has increased nurse recruitment.	Recruitment increase	
"The personal protective materials are not enough. The meals are inadequate."	Insufficient protective equipment Insufficient food	

"I feel very disappointed to see people who go out to socialize. People should be aware of the severity of this event."

"The applause of people on the balconies for healthcare workers motivated me and made me feel better."

Self-Health

"Fluid loss", "Discomfort in breathing", "Mask scars", "The need to protect self-health", "COVID-19 illness", "Joint pain and respiratory distress due to COVID-19" and "Fatigue" were the clusters of themes related to the "Self-health" theme.

Nurses stated the following:

"This is my fifteenth hour in these protective gowns. My lungs faded from constantly taking my breath. In the overalls, I lost all of the water I drank. The pit that the mask and visor caused my face is not to be mentioned..."

"We, the healthcare providers, are not immune. It should not be forgotten that we are human beings. Who will take care of the patients if we are not good?"

"I had a lot of trouble when I caught COVID-19. There were incomparable joint pains, respiratory distress."

Patient Care

The "Patient care" theme includes clusters of themes; "Increase in the number of patients", "Challenges in providing effective care to a large number of patients", "Discomfort of patients due to protective measures" and "Increased risk of errors due to fatigue."

Examples of the statements related to this category are as follows:

"We have to provide the care they deserve to a large number of patients with the same efficiency and sensitivity".

"The prolonged work and fatigue of the nurses can increase the risk of errors."

Employee Rights

"Employee rights" was another theme originating from clusters of themes including "Long working hours", "Working without vacation", "Workspace change", "Underappreciation", "Not getting paid enough for labor", "Violence", "Recruitment increase", "Insufficient protective equipment" an "Insufficient food."

Nurses stated the following:

"Nurses in intensive care are having difficulties. Sometimes we work with a few hours of sleep. There are nurses who have a 24-hour working shift."

"Nurses can't make their voice heard enough. The phrase "physician and other healthcare personnel" is used as if it is only physicians providing the entire service. However, nurses are the closest working group to the patients 24/7."

"Healthcare providers cannot get the salary they deserve. Nurses should be provided with additional funding during this process."

"Under these difficult conditions, healthcare workers should not be exposed to violence."

Discussion

The results of this study were discussed with the themes including "emotions", "self-health", "patient care" and "employee rights."

Emotions

The number of medical healthcare professionals (doctors, nurses, paramedics) suffering from mental health impacts after epidemics and pandemics are often greater than the physical injury.[16] In the current study, it was determined that the nurses had anxiety and fear of being contaminated by microorganisms. The nurses stated that they could not see their families for a long time and that they missed them. They expressed their sadness that some individuals in the community break the rules of staying at home and do not obey the rules while they are working with devotion away from their families. The nurses who were diagnosed with COVID-19 and recovered stated that they experienced a feeling of fear and panic. In line with these findings, these problems were emphasized in the Turkish Nurses Association's report.[17] The emotional effects of the pandemic have also been emphasized in the international literature.[3,4,11,18-20] Sun et al.[4] performed a study with the aim of exploring the psychology of nurses caring for COVID-19 patients. They found that nurses had psychological helplessness, health threats, a lack of knowledge, and interpersonal unfamiliarity under the threat of epidemic disease, which led to a large number of negative emotions such as fear, anxiety, and helplessness. In another study conducted to explore the mental health status of medical and nursing staff during the COVID-19 pandemic in Wuhan, trends in levels of psychological distress and factors such as exposure to infected people and psychological assistance were identified. 36.9% of participants had subthreshold mental health disturbances, 34.4% had mild disturbances and 22.4% had moderate disturbances in the immediate wake of the viral epidemic.[11] Another study showed that around 85% of the surveyed health care workers were afraid of becoming infected at work.[18] Another study also reported that nurses were trying to cope with the fear and anxiety of contracting the illness themselves and passing the disease on to friends and family.[3] Nurses are parents, siblings, friends and partners with all of the worries and concerns shared by most people providing for and protecting themselves and their families, and so in addition to caring for patients, the well-being of their own families weighs heavily on them as nurses at this time.[21] Accordingly, we found that the nurses stated that they were mutually concerned about their own health as well as their families. In the relevant literature, it is emphasized that mental health services, efficacy of psychological care, and the assessment of psychological care needs are necessary for nursing staff.[16] Mental healthcare and mental healthcare training need to be developed and implemented.[22]

In addition to negative emotions, our participants also expressed their positive emotions such as happiness as a result of the recovery of the patients and motivation from social support and appreciation. A literature review also reported that nurses experience both positive and negative emotions including pride, fear, commitment and other overwhelming emotions.[10] In a similar fashion to this, Sun et al.[4] found the presence of positive emotions in nurses such as confidence, calmness, relaxation, and happiness. Optimism has a protective effect against psychological trauma during disasters.

Self-Health

Nurses expressed their experiences regarding their individual health. The importance of protecting their own health due to the risk of transmission of the disease was emphasized by many nurses. Sweating caused by the use of personal protective equipment, difficulty breathing, and marks on the face caused by the masks were expressed as the main problems. In addition, those nurses who were diagnosed with and recovered from COVID-19 stated that they had problems such as pain and respiratory distress. During disasters and infectious disease outbreaks, nurses sacrifice their own needs in order to actively participate in their work and make selfless contributions as a result of their professional responsibility.[4] One study showed physical health as a basic necessity required to overcome an epidemic, and all of the respondents exhibited a strong need for maintaining health.[14] Another study showed that resilience (tenacity, strength) and social support (objective support, subjective support and availability of support) could significantly predict the mental health in fresh staff. A high level of training and professional experience, resilience and social support are necessary for health care workers who are taking part in their first public health emergency.[19] It is helpful to apply effective interventions in order to meet the needs of those nurses caring for COVID-19 patients.

Patient Care

The statements of the nurses revealed the responsibilities they feel about patient care and society. Their thoughts about giving care to all patients with the same sensitivity, their emotional support to patients, their motivation to heal patients and their expressions about not making mistakes show their sensitivity to care. However, it is important to provide nurses with conditions under which they can effectively maintain healthcare. These issues also have been reported by the Turkish Nursing Association. The Turkish Nursing Association has reported that nurses face barriers to providing care in a manner that does not compromise patient safety.[2,17] Zhang et al.[18] also emphasized that medical systems should ensure that frontline workers have enough time to rest between shifts in order to avoid overworking and making unconscious errors during epidemic relief efforts.

Employee Rights

Nurses expressed their problems such as long working hours, insomnia, changing the clinic where they work, violence, not getting enough salary and the inadequacy of meals. They also stated that nurses could not make their voices heard, despite being the closest healthcare professionals working with patients 24/7. They expressed that they perceived themselves as being like warriors on the frontline. According to the Turkish Nurses Association report during the COVID-19 period, 21.1% of the nurses could not take a break while working, 58.3% of the them work 40-48 hours per week and 50.0% have not been provided with the necessary food for adequate and balanced nutrition.[17] In one study, it was also reported that during the COVID-19 epidemic, some deficiencies were present at a major tertiary general hospital. Prediction capacity and strategic preparatory awareness for public health emergencies were not sufficient. This resulted in an evident lack of workforce and supplies at the beginning of the outbreak.[23]

In this study, it was seen that nurses stated that protective materials were insufficient. The Turkish Nurses Association also showed that nurses stated that they had frequent difficulty in obtaining gloves (5.0%), medical masks (8.5%), visors or goggles (12.4%) and disposable overalls (19.0 %) during their care for patients with COVID-19.[17]

In the current study, many nurses stated that they had been transferred to a corona clinic. The transfer of nurses to pandemic clinics without their orientation was also indicated by the Turkish Nurses Association as an important issue. According to the report by the Turkish Nurses Association, nurses stated that they were not informed (13.1%) or only partially informed (39.7%) about the measures which should be taken in order to protect themselves while providing care to those patients with COVID-19 diagnoses or even those with suspected COVID-19.[17]

Study Limitations

There are certain limitations to the current study which need to be addressed. The search from social media was limited to the open accessible statements of the nurses by the researchers. Individual interviews were not conducted in this study. Another limitation was that accessing the participants individually for validation was not possible because of the data collection method used in this study.

CONCLUSION

In conclusion, after the analysis of the statements of the Turkish nurses about the impacts of the COVID-19 pandemic, four main themes emerged, namely “emotions”, “self-health”, “patient care” and “employee rights.” The results showed that the nurses expressed anxiety and fear regarding contamination, and a longing for their families. Those nurses who were diagnosed with and recovered from COVID-19 stated that they experienced a feeling of fear and panic. The statements of the nurses revealed their experiences about their own health, coping with their problems, as well as the responsibilities they felt about patient care and towards society. In addition, nurses expressed the problems they faced such as their long working hours, insomnia, changing the clinic where they worked, violence, not getting enough salary, and a lack of personal protective equipment and food. It can be concluded that the nurses’ roles and responsibilities in coping with the COVID-19 pandemic are substantial in order to provide health care for the general population. The related institutions and organizations, and nursing managers should develop management strategies with the aim of supporting nurses to cope with their emotions, self-care, patient care and employee rights issues. Establishing psychological coping support may contribute to fulfill the needs of nurses and protect their mental health. Social support, enough time to rest between shifts, avoiding overwork, providing the ideal nurse-to-patient ratio, adequate supplies, and the utilization of personal protective equipment can meet the needs for health and safety among nurses.

MAIN POINTS

- The statements of the Turkish nurses about impacts of the COVID-19 pandemic revealed the 4 main themes of “emotions”, “self-health”, “patient care” and “employee rights.”
- Nurses expressed their anxiety and fear regarding contamination, and a longing for their families.
- Those nurses who were diagnosed with and recovered from COVID-19 stated that they experienced a feeling of fear and panic.

- The statements of the nurses revealed their experiences about their own health, and also the responsibilities they felt about their patient care and towards society.
- Nurses expressed the problems they faced such as their long working hours, insomnia, changing the clinic where they work, violence, not getting enough salary, and a lack of personal protective equipment and food.

ETHICS

Ethics Committee Approval: Ethical approval was obtained from the Near East University Review Board (approval number: YDU/2021/91-1347).

Informed Consent: Informed consent was not required because of the data collection method.

Authorship Contributions

Concept: Ü.D.Y., N.B., Design: Ü.D.Y., N.B., Supervision: Ü.D.Y., N.B., Materials: Ü.D.Y., N.B., Data Collection and/or Processing: Ü.D.Y., N.B., Analysis and/or Interpretation: Ü.D.Y., N.B., Literature Search: Ü.D.Y., N.B., Writing: Ü.D.Y., N.B., Critical Review: Ü.D.Y., N.B.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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RESEARCH ARTICLE

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Determination of Striae Gravidarum and its Affecting Factors During Pregnancy

Betül Mammadov[1], Dilay Necipoğlu[2], Gülşen Vural[2]

[1]Department of Midwifery, Near East University Faculty of Health Sciences, Nicosia, North Cyprus
[2]Department of Nursing, Near East University Faculty of Nursing, Nicosia, North Cyprus

Abstract

BACKGROUND/AIMS: The aim of the study was to determine the formation of striae gravidarum (SG) and its affecting factors during pregnancy.

MATERIALS AND METHODS: This study was conducted as a descriptive-cross-sectional study between April and July, 2018. The population of the study consisted of women (n=239) who gave birth at term in the Women's Health and Maternity Service of a university hospital in Cyprus and volunteered to participate in this study. The data were collected via the "Data Collection Form" consisting of 30 questions.

RESULTS: Thirty one percent of the women had intense striae. SG intensity was mostly located on the abdomen (50.4%), hips (8.5%) and breasts (8.5%). SG development time increased mostly in the third trimester of pregnancy (72.1%). It was found that 57.4% of women had striae in the same fashion as their mothers. The prevalence of striae in pregnancy was significantly higher in those women whose mothers also developed SG ($p<0.001$). It was observed that striae development was higher in women with high body mass index (BMI) in the pre-pregnancy period and after pregnancy ($p<0.001$).

CONCLUSION: Those women who had family history of SG (especially in their mothers) and whose BMI was higher both before and after pregnancy had more SG.

Keywords: Striae gravidarum, midwifery, nursing, pregnancy

INTRODUCTION

Many changes occur in women's bodies during pregnancy. Striae gravidarum (SG) is among the physiological changes which develop in the female body during pregnancy. SG may develop during pregnancy with individual differences in terms of size, shape and region.[1] SG starts out as erythematous, red or purple linear bands and then turns into mother-of-pearl patterning and then it heals, leaving an atrophic scar. Deep striae may cause itching, burning, discomfort or bleeding. Although the factors causing the formation of SG are not known precisely, some risk factors have been defined. These are; the age of the mother, the presence of striae in the family history, race, the weight of the mother during pregnancy, the weight of the new-born and the size of the head circumference, being primigravida, hormonal changes during pregnancy and increased lateral tension in the connective tissue as a result of increased regional distension.[1-5]

SG is seen in approximately 50-90% of pregnant women and is more common in the last trimester of pregnancy.[6] SG is generally seen in the breasts, abdomen, hips, thighs and axillary regions.[7] In the literature, there are many studies regarding the prevention of SG.[1-7] The most important reason for this is that SG does not disappear after it occurs and becomes an aesthetic body perception problem for women in the postpartum period.[8,9]

Due to the increased importance which women place on beauty and aesthetics, the demand to reduce or prevent SG has also increased.[10] It is seen that many herbal and cosmetic products are commonly used

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ORCID IDs of the authors: B.M. 0000-0002-9051-0279; D.N. 0000-0001-8213-5854; G.V. 0000-0001-7304-685X.

Address for Correspondence: Dilay Necipoğlu
E-mail: dilay.necipoglu@neu.edu.tr
ORCID ID: orcid.org/0000-0001-8213-5854

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to reduce or prevent SG from occurring. A systematic review showed that the herbal and cosmetic products used to date are not sufficient in preventing SG.[10] For this reason, it is thought that more studies are needed in order to determine the factors which are effective in the development of SG and the methods used to prevent this condition. Knowing the risk factors in the formation of SG is important in terms of guiding the training and care to be given to pregnant women by midwives and nurses.

The aim of the study was to determine the frequency and severity of SG occurring during pregnancy in puerperal women and the factors affecting the formation of SG. In this context, the research questions were;

1) How common is SG in pregnant women?

2) What are the factors affecting the development of SG in pregnant women?

3) How severe is SG in pregnant women?

4) What are the methods used by pregnant women to prevent SG?

MATERIALS AND METHODS

Design of Study

The study was designed in a descriptive cross-sectional manner.

Population and Sampling of the Study

It was determined that the number of births in a year at the University Hospital was between 550-600. The sample of this study was taken as n=600 and the population of the study was calculated with a sample formula of the known universe with a 95% confidence interval and a 5% margin of error (n=234). During this study, n=239 cases were investgated. The population of this study consisted of women (n=239) who were in the inpatient ward of the Gynaecology and Obstetrics Department of a University Hospital located in the Turkish Republic of North Cyprus, who had just given birth and were willing to participate in this study.

Variables of the Study

The independent variables of this study were sociodemographic factors and the products used to prevent the striae, while the dependent variable was the presence of SG.

Inclusion Criteria

This participants of this study were women who had just given birth, who spoke Turkish, and were willing to participate.

Application of the Study

The data were collected with the "Data Collection Form" comprising 30 questions prepared by the researchers. The data collection form was prepared after taking the advice from experts (3 specialist nurses). A pilot study was conducted using the data collection form (n=30, and these participants were subsequently included in this study as there was no change in the data collection forms). The first section of the data collection form consists of 12 questions on the socio-demographic characteristics of the women (age, education, number of pregnancies, weight, height etc.); the second section consists of 18 questions related to (SG development, the number of SG, the time of the SG occurrence, family history of SG and the products they used to prevent SG and how regularly they used them etc.). The location of the SG was determined and its severity was recorded as mild, moderate or severe. The presence of 1-5 striae in a localised region was classed as mild, 6-10 striae was classed as moderate and 11 or over striae was classed as severe SG.[11,12] In addition, visuals were added to the questionnaire in order to determine the location of the striae. The body regions of puerperant women with SG were visually evaluated by the researchers.

The data were collected between the 1st of April and the 30th of July, 2018 by a face-to-face interview technique lasting 15 to 20 minutes with the women who had given birth at the hospital. When interviewing the women face-to-face, a time when they felt comfortable and did not have any pain was selected. The researchers observed the SG regions, regarding their location and severity and recorded this information in order to analyse the development of SG.

Ethical Considerations

In order for the data collection forms to be administered, institutional permission, Near East University Ethics Committee permission (approval number: YDU-2017/45-385) and informed consent were obtained from the participants and the relevant institutions.

Statistical Analysis

The Statistical Package for Social Sciences software version 21.0 (IBM SPSS Corp.; Armonk, NY, USA) package software was used to analyse the data. Percentage, frequency and chi-squared tests (χ^2) were used to analyse the data. The data were evaluated with a 95% confidence level and level of significance of $p<0.05$.

RESULTS

A total of 83.7% of the women who developed SG during pregnancy were between the ages of 25-40 years and 74.4% (n=96) of them had postgraduate degrees. It was determined that 53.5% (n=69) of the women who developed SG were primiparous and 89.1% gave birth to babies whose birth weight was within the normal margins (2,500-4,000 gr.) (Table 1). Thirty one percent of the participants (n=40) had severe SG (11 or over) and in order of frequency, the regions in which it was observed were the abdomen (50.4%), hips (8.5%) and breasts (8.5%) (Table 2). When the women were asked when they developed SG, they stated that the increase in striae was more severe in their third trimester (72.1%). 79.9% of the women who had SG stated that before pregnancy, they had no striae on their bodies (Table 3).

When the family history of women who developed SG was considered, 84.5% of them had a first degree relative with a history of SG. The presence of SG in their family history was determined to be a statistically significant factor with regards to the development of SG (Table 1), ($p<0.001$). When the women who had SG were asked who the family member who had SG was, 57.4% of them responded by saying their mother or grandmother had SG, so it was determined this significantly affected the development of striae during their pregnancy ($p<0.001$). The development of striae both before and after pregnancy was found to be related to body mass index (BMI). It was determined that women with higher BMI had more striae (both before pregnancy; $p<0.001$, and after pregnancy $p<0.001$). It was also found that the difference between

the BMI before and after pregnancy was not related to the formation of SG (p=0.713).

When the cosmetic and herbal products which women used to prevent SG during pregnancy were considered, 70.5% of them stated that they developed striae regardless of using these products. It was determined that the use (p=0.061) of various cosmetic creams and herbal ointments (almond oil, olive oil, cocoa butter, baby oil etc.) and the different frequencies of use (sometimes, 1-3 times a day etc.) did not prevent striae development (p=0.792). Also, it was also determined that smoking (p=0.276), multiple pregnancies (p=0.366), birth method (p=0.465), the baby's gender (p=0.620), or the presence of polyhydramnios (p=0.523) did not affect the development of SG significantly (Table 1).

DISCUSSION

It is estimated that SG develops in over half of pregnancies and its aetiology is not yet known.[9] When the literature is reviewed with regard to the causes and precautions taken against SG, it can be seen that there are very few studies in this field. According to the results of our study, women who have a family history of SG (especially in their mother) are more likely to develop SG (p=0.001). Our results showed that another important factor affecting SG was a high BMI. For example, our study showed that a high BMI before and during pregnancy increased the development of striae (p=0.001). The prevalence study conducted by J-Orh et al.[11] on 180 pregnant women regarding SG showed that young women with a family history of SG and those who had a high BMI before and during pregnancy were more susceptible to SG. The results of the study conducted by Ghasemi et al.[13] showed similar results, indicating that genetic and physical factors play a significant role in the development of SG. As a result of the literature review conducted by Farahnik et al.[14] in 2016, it was determined that the most important risk factors in the development of SG were: being a young mother, the presence of a family history of SG (especially in the mother), an increased BMI before and during pregnancy and a heavy birth-weight new-born. When the results of other studies are considered, it can be seen that the factors affecting SG are genetic and physical aspects such as: being a young mother, the presence of a family history of striae, high pre-pregnancy BMI, and excessive weight gain during pregnancy.[15-19] As a result of our study, this finding, which supports the literature, revealed that genetic factors are effective in the development of striae.

Table 1. Socio-demographic characteristics of women (n=239)

Socio-demographic characteristics		Striae gravidarum, (n=129) (54%)		No striae gravidarum, (n=110) (46%)		χ^2	p
		n	%	n	%		
Age	18-24	4	3.1	2	1.8	3.248	0.189
	25-40	108	83.7	95	86.4		
	41 and above	17	13.2	13	11.8		
Education level	Primary education	7	5.4	3	2.7	3.761	0.154
	Secondary education	26	20.2	14	12.7		
	Higher education	96	74.4	39	84.5		
Number of pregnancies	Primiparous	69	53.5	71	64.5	3.010	0.084
	Multiparous	60	46.5	39	35.5		
Birth weight of babies	Below 2,500 gr	8	6.2	8	7.3	0.248	0.883
	2,500-4,000 gr	115	89.1	98	89.1		
	Over 4,000 gr	6	4.7	4	3.6		
Smoking	Yes	35	27.1	37	33.6	1.193	0.276
	No	94	72.9	73	66.4		
Multiple pregnancy	Yes	8	6.2	4	96.4	0.819	0.366
	No	121	93.8	106	3.6		
Type of delivery	Caesarean section	87	67.4	79	71.8	0.536	0.465
	Normal vaginal delivery	42	32.6	31	28.2		
Baby's gender	Female	58	45	53	48.2	0.248	0.620
	Male	71	55	57	51.8		
Presence of polyhydramnios	Yes	15	11.6	10	9.1	0.408	0.523
	No	114	88.4	100	90.9		
Family history of SG	Yes	20	15.5	68	61.8	15.894	0.001
	No	109	84.5	42	38.2		
The relationship to an individual with SG in the family	None	20	15.5	42	38.2	17.656	0.001
	Mother	74	57.4	45	40.9		
	Sister	27	20.9	14	12.7		
	Other (aunt etc.)	8	6.2	9	8.2		

χ^2: Chi-squared tests, p<0.05.

Our study also showed that there was no significant relationship (p>0.05) between the formation of SG during pregnancy and the various cosmetic and herbal ointments used (almond oil, olive oil, cocoa butter, baby oil etc.). Different results can be seen among the randomised controlled studies related to the use of various herbal and cosmetic ointments used in order to prevent SG. These studies showed that although the use of products reduces the severity of SG, they cannot remove SG or prevent it from occurring. For example, in one study conducted with 100 nulliparous women to measure the effects of olive oil in preventing SG, the women were separated into experimental and control groups. 1 mL of olive oil was topically applied twice a day to the abdomen area. The results showed that olive oil did not affect the severity or prevent the occurrence of SG.[20] Similarly, a study in which 360 nullipara women used olive oil and Saj cream showed that there were no differences between the control group and the experimental group (p>0.05).[21] The study conducted by Taavoni et al.[22] in 2011 on the effects of olive oil in preventing SG during the second trimester showed that there were no differences in SG formation between the control and experiment groups, thus demonstrating that the use of olive oil did not prevent SG. When the results of the studies examining the effects of cocoa butter and bitter almond oils had on SG were examined, it could be seen that these oils also did not prevent striae development in pregnancy.[23-25] Similar to the results in the literature, our results also showed that the cosmetic creams and herbal oils and the frequency with which women used these did not prevent the occurrence of SG.

It is thought that the reason that the cosmetic creams and herbal oils used by the women participating in our study and the frequency with

Table 2. Information on women's use of products during pregnancy (n=239)

		Striae gravidarum, (n=129) (54%)		No striae gravidarum, (n=110) (46%)		χ^2	p
Product use during pregnancy (cream, oil)	Yes	91	70.5	72	65.5	0.709	0.400
	No	38	29.5	38	34.5		
Used product during pregnancy	None	38	29.5	38	34.5	9.023	0.061
	Cosmetic product	56	43.4	56	51.0		
	Vegetable oils	35	27.1	16	14.5		
The area of the body where the product was used	None	38	29.5	38	34.5	7.396	0.119
	Abdomen	43	33.3	36	32.7		
	Abdomen + breasts	8	6.2	17	15.5		
	Abdomen + hips	20	15.5	5	4.5		
	Abdomen + hips + breasts	20	15.5	14	12.7		
Frequency of product use	Never used	38	29.5	38	34.5	1.694	0.792
	Sometimes	22	17.1	14	12.7		
	Once a day	40	31.0	36	32.7		
	2 times a day	24	18.6	17	15.5		
	3 times per day	5	3.9	5	4.5		

χ^2: Chi-squared tests, p<0.05.

Table 3. Distribution of some features of striae gravidarum (n=129)*

SG features		n	%
How many SG developed	1-5	42	32.6
	6-10	47	36.4
	11 or above	40	31.0
Area where SG developed	Abdomen	65	50.4
	Hips	11	8.5
	Abdomen + breasts	18	14.0
	Breasts	11	8.5
	Abdomen + hips	12	9.3
	Abdomen + hips + breasts	6	4.7
	Hips + breasts	6	4.7
SG development trimester	First trimester	10	7.8
	Second trimester	26	20.2
	Third trimester	93	72.1
Presence of striae before pregnancy	Yes	48	20.1
	No	191	79.9

*Only those women who developed striae gravidarum were included.

which they used them did not work was their genetic tendencies to develop SG. Our results showed that increased BMI can affect striae and that this is due to the fatty tissue under the skin becoming thicker and stretching the skin, thus causing SG. Although no significant relationship was found between the age of the women and the development of SG in our study (p=0.189), the literature states that SG is more common in younger women. This is due to the structure of the fibrils in younger women being more breakable, which allows stretch marks to occur more easily.[11] The ages of the women participating in our study were similar and so it is thought that if this study is repeated with participants from different age groups, this might affect the results.

The study conducted by Canpolat et al.[12] in 2010 showed that polyhydramnios is related to SG and that SG is seen in all polyhydramnios cases. This situation, which they assumed to be due to the abdomen region being wider thus increasing the tension in the skin, did not appear as a factor which increased striae in our study (p=0.523). It was also seen that smoking during pregnancy did not affect SG and it is assumed that this is due to the number of pregnant women who smoke being low and that there were not enough sample numbers to test the validity of this proposition. Also, although smoking has many harmful effects, it did not directly affect SG (p=0.276).

Study Limitations

Our research is limited to those women who applied to a university hospital in North Cyprus to give birth between April and July, 2018 and who also agreed to participate in this research. Increasing the sample size would increase the power of this study.

CONCLUSION

It was found that approximately half of the women participating in our study developed SG and SG intensity increased mostly in the third trimester. It was found that the development of striae before and after pregnancy was higher in those women with a family history of SG and a high BMI. Many factors (maternal age, genetic predisposition, skin type, etc.) which cause SG during pregnancy are beyond the control of midwives and nurses. With good prenatal care and education, other factors affecting the development of SG can be controlled by midwives and nurses. Therefore, during pregnancy, it is necessary to monitor and control the mother's weight, to direct her to appropriate exercises, to maintain body hydration, to provide adequate fluid intake and to be followed up regarding edema.

In addition, in order to determine the formation of SG and its related factors during pregnancy, we recommend carrying out analytical and randomized controlled scientific studies on women with different genetic structures, from different cultures, living in different climates, and experimental studies using different products which are intended to prevent the formation of SG.

MAIN POINTS

- Approximately half of the women had striae gravidarum.
- Striae gravidarum severity increased mostly in the third trimester.
- The prevalence of striae in pregnancy was higher in those women whose mothers developed striae gravidarum.
- The development of striae gravidarum before and after pregnancy was higher in women with high BMI.
- Using various vegetable oils and cosmetic creams did not effectively prevent striae formation in pregnancy.

Acknowledgments: The authors would like to thank all participants who voluntarily participated in this study.

ETHICS

Ethics Committee Approval: This study was approved by the Near East University Ethics Committee (approval number: YDU-2017/45-385).

Informed Consent: Informed consent were obtained from the participants and the relevant institutions.

Authorship Contributions

Concept: B.M., D.N., G.V., Design: B.M., D.N., G.V., Supervision: G.V., Fundings: B.M., G.V., Materials: B.M., D.N., G.V., Data Collection and/or Processing: B.M., D.N., Analysis and/or Interpretation: D.N., Literature Search: B.M., D.N., G.V., Writing: B.M., D.N., Critical Review: B.M., G.V.

DISCLOSURES

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CASE REPORT

CYPRUS
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A Rare Gallbladder Anomaly Mimicking Choledochal Cyst; Hourglass Gallbladder

Feyyaz Güngör[1], Nihan Acar[2], İbrahim Cüneyit[1], Osman Nuri Dilek[1]

[1]Department of General Surgery, İzmir Katip Çelebi University, Atatürk Training and Research Hospital, İzmir, Türkiye
[2]Department of Anatomy, Pamukkale University Faculty of Medicine, Denizli, Türkiye

Abstract

Biliary tract anomalies are surprises which may cause surgeons unexpected issues. Although biliary system anomalies are frequently seen (42-58%), an hourglass gallbladder is a rare condition which cannot be given a specific rate, since very few cases have been reported in the literature. In this study, a case in which an hourglass gallbladder was unexpectedly detected during an operation is presented in light of the literature data.

Keywords: Hourglass gallbladder, anomalies, diagnosis, treatment

INTRODUCTION

Anatomical variations of the biliary system are seen in 42-58% of the population.[1,2] The hourglass gallbladder, which is one of these variations, has been reported in single case reports in the literature but its incidence is unclear. It is considered to be congenital in the paediatric population and to develop after episodes of cholecystitis in adults. There are no typical findings in clinical presentation and preoperative laboratory tests. It may be detected on preoperative imaging if suspected. Although it is very rare, it is important in terms of morbidity and mortality in patients who develop complications in surgical treatment.

CASE PRESENTATION

A 54-year-old male patient presented with right upper quadrant pain provoked after high-fat meals for three months. His past surgical and medical history, physical examination and laboratory tests were unremarkable. Abdominal ultrasound (US) detected choledochal cyst and cholelithiasis. Magnetic resonance cholangiopancreatography (MRCP) also confirmed the diagnosis of choledochal cyst and classified it as type 2 according to Todani classification (Figure 1). Written informed consent was obtained from the patient and elective surgery was planned. Extrahepatic biliary tract resection was planned conventionally and the patient was operated on after preoperative preparations were completed. During the exploration, it was found that the gallbladder was in the normal position, the gallbladder narrowed from the fundus to the body and then widened again around the neck and the cystic duct was open from the usual site to the distal common bile duct (Figure 2). The extrahepatic biliary ducts were evaluated as completely normal. It was understood that the part which was interpreted as a choledochal cyst was the body and neck part of the gallbladder shaped like an hourglass. Cholecystectomy was performed (Figure 3) and the patient was discharged uneventfully on second day postoperative. The pathological examination was reported as chronic cholecystitis.

DISCUSSION

It is reported that the hourglass gallbladder was first described by Morgagni in 1769.[3] Its incidence is unknown and there are very few case reports in the literature. In post-mortem studies, the duplication rate of any part of the biliary system is 1 in 4,000, and the hourglass gallbladder is a much rarer variant of congenital biliary malformation.[3,4] Although its pathogenesis is unclear, it is considered to be congenital in the paediatric population and to occur due to chronic inflammation and fibrosis caused by cholecystitis.[5] Cases may present with all common symptoms of biliary pathologies which makes differential

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ORCID IDs of the authors: F.G. 0000-0002-4066-6072; N.A. 0000-0003-0720-3794; İ.C. 0000-0003-0555-2114; O.N.D. 0000-0002-6313-3818.

Address for Correspondence: Feyyaz Güngör
E-mail: feyyaz.gngr@gmail.com
ORCID ID: orcid.org/0000-0002-4066-6072

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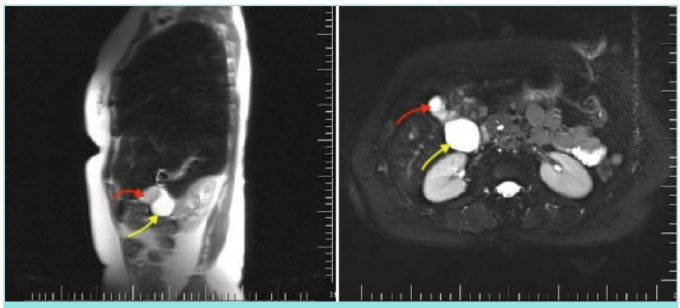

Figure 1. Sagittal and transverse section magnetic resonance cholangiopancreatography (T2 weighted). The yellow arrow was reported as choledochal cyst and the red arrow was reported as gallbladder.

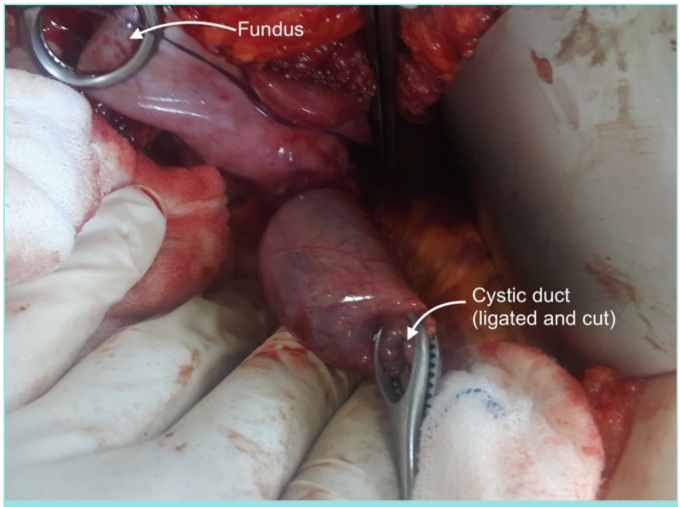

Figure 2. Preoperative image. Cystic duct (ligated and cut) and fundus marked.

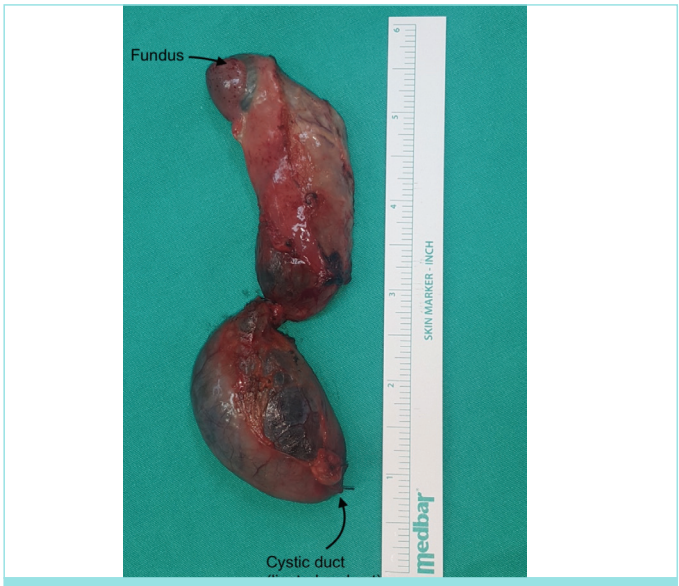

Figure 3. Specimen of hourglass gallbladder.

diagnosis difficult. Laboratory tests are usually normal unless there is an obstructive lesion. It can be detected via US by an experienced radiologist. In the literature, it is reported that similar images may also occur in the segmental type of gallbladder adenomyomatosis.[6] If hourglass gallbladder is suspected or any sign of variation is detected, further evaluation should be carried out in order to confirm the diagnosis and determine whether there is a relation with the biliary tree. Subsequently, MRCP and computed tomography should be performed and if there is still a conflict, hepatobiliary scintigraphy or endoscopic retrograde cholangiopancreatography (ERCP) can be preferred. Although it is an invasive technique, ERCP has a sensitivity of up to 100% in the diagnosis of biliary cysts.[7]

Laparoscopic cholecystectomy is the initial treatment in symptomatic cases. However, in cases which cannot be diagnosed preoperatively such as the case presented here, conventional surgery is also a safe and effective way to evaluate the biliary tract properly.

CONCLUSION

Gallbladder anomalies are rare entities which can rarely be detected with preoperative imaging. Therefore, the surgeon's attention during surgery is vital for diagnosis. In order to prevent possible complications, it is important to follow the rules for safe surgical dissection and to keep in mind potential variations of the biliary system.

MAIN POINTS

- Gall bladder anomalies are rare entities.
- Diagnosis is difficult and can usually be detected preoperatively.
- When detected in the preoperative period, it can be treated with laparoscopic surgery.
- However, in cases which cannot be diagnosed preoperatively such as the one presented here, conventional surgery is also a safe and effective way to evaluate the biliary tract properly.

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ETHICS

Informed Consent: Written informed consents were obtained from the patient who participated in this study and also for the publication of the photos used.

Authorship Contributions

Concept: N.A., Design: İ.C., Supervision: İ.C., Fundings: İ.C., Literature Search: F.G., Writing: F.G., N.A., O.N.D., Critical Review: O.N.D.

DISCLOSURES

Conflict of Interest: The authors have no conflicts of interest to declare.

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CASE REPORT

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Cyprus J Med Sci 2024;9(1):73-75

Percutaneous Mitral Cleft Repair with MitraClip: An Interesting Case of Owl Eye Appearance in the Mitral Valve

Cenk Conkbayır[1,2], İsmail Ateş[3], Alptekin Özkoç[2]

[1]Department of Cardiology, Cyprus Health and Social Sciences University, Güzelyurt, North Cyprus
[2]Clinic of Cardiology, Dr. Burhan Nalbantoğlu State Hospital, Nicosia, North Cyprus
[3]Clinic of Cardiology, İstanbul Şişli Kolan Hospital, İstanbul, Türkiye

Abstract

We present a case of a successful MitraClip procedure in a 73-year-old male patient with severe mitral regurgitation and an intriguing "owl eye" appearance of the mitral valve. The patient had a history of coronary artery bypass graft surgery ten years previously and experienced recurrent pulmonary edema due to regurgitation. Following the MitraClip procedure, the patient's symptoms improved, and his quality of life significantly increased.

Keywords: Coronary surgery, mitraclip, mitraclip, mitral regurtitation, owl eye

INTRODUCTION

The aim of this case report was to describe a successful MitraClip procedure in a 73-year-old male patient with a history of coronary artery bypass graft surgery (CABG) and recurrent pulmonary edema caused by severe mitral regurgitation with a cleft in the mitral valve.

CASE PRESENTATION

A 73-year-old male patient presented to the emergency room with shortness of breath, dyspnea, and orthopnea. Physical examination revealed an S3 gallop, a severe pansystolic murmur, and crackles in the upper lung fields. The patient's history included recurrent pulmonary edema, reduced quality of life, and chronic obstructive pulmonary disease (COPD) treated with bronchodilators. Echocardiography showed an enlarged left atrium, moderate left ventricular dysfunction [ejection fraction (EF): 40%], and severe mitral regurgitation. Transesophageal echocardiography (TEE) further identified a mitral cleft on the posterior mitral valve. Coronary angiography revealed severe stenotic lesions in the left anterior descending, circumflex, and right coronary arteries, while the saphenous and left internal mammary artery (LIMA) bypass grafts were patent.

Given the patient's history of CABG, patent bypass grafts, COPD, frequent hospital admissions due to pulmonary edema, and high EuroSCORE (calculated as 14), the heart team recommended a high-risk MitraClip procedure instead of redo open-heart surgery. Informed consent was obtained from the patient and his family after a detailed discussion of the procedure and its associated risks.

Preoperative preparation included the administration of intravenous diuretics, bronchodilators, and oxygen to minimize cardiac and pulmonary-related risks. The patient was placed under general anesthesia and intubated for the MitraClip procedure. A 7-French sheath was inserted, followed by a septostomy performed 3.7 cm away from the mitral valve in order to optimize the entrance of the left atrium and enhance the success of the MitraClip procedure. Under three-dimensional TEE guidance, two MitraClips were successfully inserted, providing an intriguing "owl eye" view of the mitral valve, as demonstrated by 3D echocardiography (Figure 1). Color Doppler imaging revealed mild mitral regurgitation, while X-ray imaging confirmed the presence of the MitraClips (Figure 2). The severe mitral regurgitation (Figure 3) was effectively treated with two MitraClips, as evidenced by mild mitral regurgitation on 2D echocardiography post-procedure

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ORCID IDs of the authors: C.C. 0000-0002-6594-1915; İ.A. 0000 0003 4921 5582; A.Ö. 0000 0001 8704 9875.

Address for Correspondence: Cenk Conkbayır
E-mail: cenkconk@hotmail.com
ORCID ID: orcid.org/0000-0002-6594-1915

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(Figure 4). Post-procedure, the patient's symptoms improved, he was extubated, and subsequently discharged. Follow-up revealed no cardiac or lung-related issues, and the patient's quality of life significantly improved.

DISCUSSION

Patients with severe mitral regurgitation and additional risk factors, including advanced age, COPD, prior CABG surgery, low EF, and high EuroSCOREs, face a significant risk of mortality and a diminished quality of life.[1,2] In cases where there is a history of prior CABG surgery with patent LIMA, cardiac surgeons may be hesitant to perform a redo sternotomy due to potential complications and the risk of injuring the LIMA, which can adhere to the sternum due to fibrotic changes between the pericardium and sternum. Conversely, anesthesiologists may be concerned about respiratory complications in COPD patients during the peri- and post-procedural periods. However, with recent advancements in percutaneous mitral valve procedures such as the MitraClip, success rates are increasing as has been shown in a recent meta-analysis where both surgery and MitraClip demonstrated a similar safety profile and shorter length of stay in high-risk patients.[1] The literature has also demonstrated that percutaneous mitral valve clip repair may offer a survival benefit, especially within the initial 1 to 2 years, particularly in those patients with medically managed chronic functional mitral regurgitation.[2,3] Additionally, studies have shown that the MitraClip procedure is both effective and safe in randomized multicenter studies.[3,4] The literature has also discussed "the surgical double orifice technique", which can provide an "owl eye" view similar to that achieved with the percutaneous MitraClip procedure performed in our case, in cases of severe mitral valve regurgitation.[5]

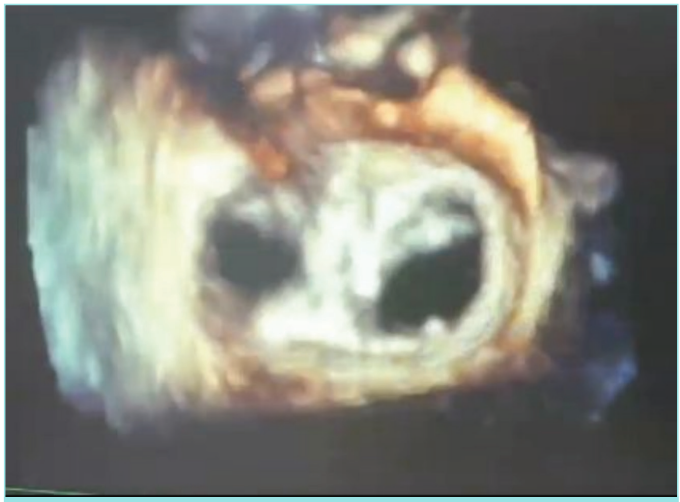

Figure 1. "Owl eye" appearance after MitraClip procedure, visualized with 3D transesophageal echocardiography.

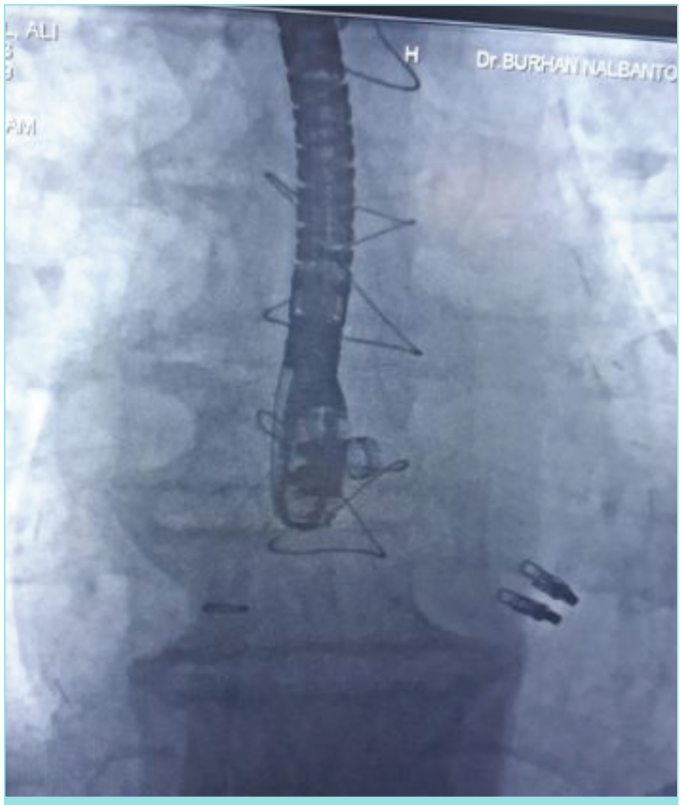

Figure 2. X-ray image showing the presence of MitraClips.

CONCLUSION

This case report highlights a successful percutaneous mitral valve repair with MitraClip in a high-risk patient with severe mitral regurgitation and a unique "owl eye" appearance of the mitral valve. The procedure

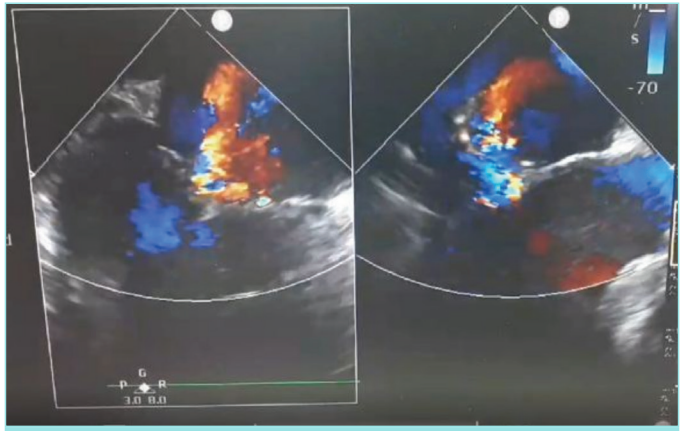

Figure 3. Pre-procedural image illustrating severe mitral regurgitation.

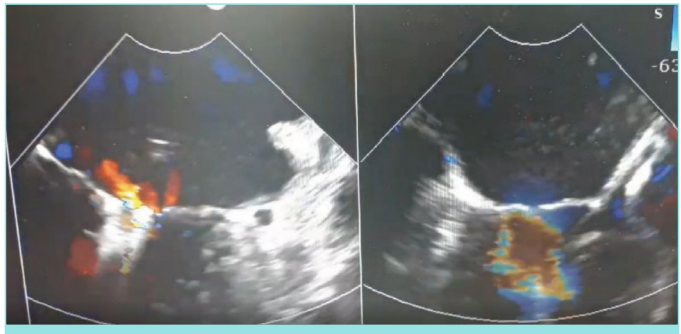

Figure 4. Post-procedural image depicting mild mitral regurgitation following MitraClip intervention.

provided significant symptomatic relief and improved the patient's quality of life. Percutaneous mitral valve repair should be considered as a viable option in carefully selected patients, especially those with significant comorbidities or previous cardiac surgeries.

MAIN POINTS

- The MitraClip procedure provided significant symptomatic relief and improved the patient's quality of life.
- Percutaneous mitral valve repair should be considered as a viable option in carefully selected patients, especially those with significant comorbidities or previous cardiac surgeries.
- We present an interesting case of mitral valve repair with MitraClip in a high-risk patient with severe mitral regurgitation and a unique "owl eye" appearance of the mitral valve.

ETHICS

Informed Consent: Informed consent was obtained from the patient.

Authorship Contributions

Surgical and Medical Practices: C.C., İ.A., A.Ö., Concept: C.C., İ.A., A.Ö., Design: C.C., İ.A., A.Ö., Data Collection and/or Processing: C.C., İ.A., A.Ö., Analysis and/or Interpretation: C.C., İ.A., A.Ö., Literature Search: C.C., İ.A., A.Ö., Writing: C.C., İ.A., A.Ö.

DISCLOSURES

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