

ORIGINAL ARTICLE

Awareness and Attitudes of Healthcare Professionals Regarding Denied Pregnancies

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Abstract

Objective: A denied pregnancy is a condition in which the expectant mother does not recognize her pregnancy even though it is advanced. In a denied pregnancy, the expectant mother realizes her pregnancy either in the twentieth week of pregnancy or when labor begins. The fact that the expectant mother is unaware of her pregnancy carries life-threatening risks for both mother and baby. In full denial pregnancies, births often take place in environments prone to complications and without any medical assistance. In addition, there are very negative and tragic consequences such as death of the newborn, postpartum emotional distress, trauma and rejection of the newborn. The first intervention to mothers who deny their pregnancy is done by health professionals.

Material and Methods: In this study, we aimed to measure the awareness and attitudes of healthcare professionals about denied pregnancies through two clinical vignettes. Sociodemographic Form and Awareness and Attitude Screening Questionnaire consisting of 14 questions each were given to 240 healthcare professionals living in İstanbul. T test, ANOVA and Post Hoc Test were used to analyze the data.

Results: The significance level of the study was taken as $p < 0.05$. As a result of the study, it was observed that the health workers who participated in the research had difficulty in defining and making sense of the phenomenon and their awareness was low. Participants reported feeling more anger for the clinical vignette with a high rate of neonatal neonatality. However, obstetricians, midwives and psychiatrists would be the first people these patients would encounter.

Conclusion: Increasing the awareness of healthcare professionals will provide appropriate medical care, psychological support and forensic medical assistance to these patients.

Keywords: pregnancy, denial, denial of pregnancy, health care worker, attitude

INTRODUCTION

A health worker is someone who provides care and services to the sick and disabled, either directly as a doctor or nurse, or indirectly as an assistant or assistant staff. Awareness can be defined as a person's nonjudgmental observation of internal and external

stimuli and developing an understanding of what is going on in the current situation (1,2). Attitudes on the other hand can be described as evaluations, ranging from positive to negative, that effectively summarize previous life experiences and guide thought and action (3).

A denied pregnancy is when the expectant mother does not realize that she is pregnant, even though it is advanced. If the pregnancy is recognized at the twentieth week of pregnancy or later, it is defined as a "partially denied pregnancy". If the pregnancy is recognized when labor begins, it is defined as a "fully denied pregnancy" or "complete denial of pregnancy" (4).

Denial of pregnancy is not a new phenomenon. As early as 1681, gynecologist François Mauriceau reported that expectant mothers who menstruated throughout their pregnancy could ignore the fact that they were carrying a baby because of this bleeding. Mauriceau called this phenomenon "*méconnaissance de la grossesse*" (unawareness of pregnancy) (5). It is not known exactly how common denied pregnancy is. The most comprehensive study on this subject was conducted by Wessel and Buscher in Berlin, Germany, between 1995 and 1996. A total of 29,462 births were examined in the screening study covering 5 institutions and 19 hospitals providing birth services throughout the city and it was observed that the rate of expectant mothers who realized their pregnancy after the twentieth week was (1/475) and the rate of expectant mothers who realized their pregnancy with the onset of premature contractions or at the time of birth was (1/2455) (6). The rate of partially denied pregnancies was found to be (1/400) in Austria (7), (1/516) in the USA and (2.3/1000) in France (8). Fully denied pregnancy rates were reported as (1/2455-2500) in Austria⁷, (1/2500) in England (1/2500) (9) and (3/10.000) in France (8). In an epidemiologic study conducted by Yüce et al. in Turkey, expectant mothers who partially denied their pregnancies were reported as (1/526) (10). It is argued that denied pregnancy is not a rare phenomenon. The rate of fully denied pregnancies is 3 times higher than the rate of triplet births and the rate of partially denied pregnancies is 2 times higher than the rate of blood incompatibility (6).

Based on the idea that possible cases can be prevented by defining the characteristics of expectant mothers who deny their pregnancies in this case, which carries great risks for the mother and newborn, the researchers examined the characteristics of expectant mothers who deny their pregnancies (11,7). As a result of these studies it was underlined that it is not possible to define the characteristics of expectant mothers who

deny their pregnancies with precise lines. Expectant mothers who experience this phenomenon constitute a heterogeneous group. Therefore, it has been reported that it is not possible to identify which women are at risk (7).

There are risky consequences of denied pregnancies. Not recognizing the pregnancy makes it impossible for the expectant mother to bond with her baby and prepare for her role as a mother during pregnancy, and there is a lack of prenatal care. Because these women are unaware of their pregnancy; unprepared, sudden, unexpected, rushed births often occur in an environment that is more prone to complications and the mother and newborn do not receive the necessary medical care (7). Lack of pregnancy follow-up and a lifestyle and an appropriate diet for pregnancy can negatively affect the development of the baby in the womb and reduce the chances of survival of the newborn after birth. It was also reported that the fetal and neonatal mortality rate in these babies was around 7% (4). Researchers reported significantly higher fetal risk and much poorer pregnancy outcomes in denied pregnancies compared with population perinatal statistics (12).

Neonaticide is used to describe the killing of a baby by one of its parents within the first 24 hours after birth (13). Mothers who cause the death of their newborn babies (neonaticide) are usually sent to prison or released on parole (14-16). Stotland (1998) noted in his study that denied pregnancies are sometimes a mystery to psychiatrists as well as to the rest of the world, noting that at the time he wrote his study, another young woman was on trial for the murder of her newborn baby (15). Researchers reported that the expectant mother reacted to an unexpected birth in the form of acute dissociation, so the condition should be considered within the scope of "mental disorders that temporarily affect the perception and interpretation of the person's judgment". They argued that the acute stress reaction of the mother is a short-lived transient state, that there is usually confusion during the event, and therefore the actions against the baby should not be considered as a conscious action (4).

It was thought that the awareness of health workers about denied pregnancies was very low and their attitudes towards completely denied pregnancies,

especially those resulting in neonaticide, were very negative.

When the literature was examined, no study was found to examine the knowledge, awareness and/or attitudes of healthcare professionals who will be in first contact with these patients and manage the treatment process about denied pregnancies. A study shows that 38% of expectant mothers who are not aware of their pregnancy visit doctors, yet they do not receive a pregnancy diagnosis (7). However, if these specialists are aware of the phenomenon of denied pregnancies and diagnose the symptoms, they will provide early diagnosis and intervention. In fully denied pregnancies, they will be able to manage the process by being aware of the case. In this way, the risk to the health and life of the mother and baby can be (relatively) avoided.

Denial of pregnancy can lead to negative and tragic consequences such as neonaticide, postpartum emotional disturbance, trauma or rejection of the newborn. The primary caregivers of these patients are obstetricians, midwives, psychiatrists and physicians. Increasing the awareness of these professionals on the subject will provide appropriate medical care, psychological support and forensic medical assistance to these patients. The aim of this study is to investigate the awareness and attitudes of professional group members who may encounter patients with denied pregnancies.

MATERIAL AND METHODS

In the research conducted in an online survey environment, approval was obtained from the Üsküdar University Non-interventional Research Ethics Committee (Approval Number: B.08.6.Yök.2.Üs.0.05.0.06/2017/324). Healthcare professionals reached through social media were invited to fill out the Awareness and Attitude Screening Questionnaire. The sample of the research consists of 240 healthcare professionals living in Istanbul.

Data Analysis Techniques

T test was used to test whether the difference between the means of two unrelated samples was significant. When more than two groups were compared, one-way analysis of variance (ANOVA) was used in unrelated samples. In cases where there was a significant difference, multiple comparison tests (post hoc test)

were used to understand which groups the difference was between. The significance level of the research was taken as $p < 0.05$. The findings obtained as a result of the analysis were transformed into tables and interpreted in accordance with the research questions.

The data collection tools used in the research are presented below:

Sociodemographic Form: With this form prepared by the researchers, the participants' age, gender, marital status, whether they or, for male participants, their spouses had experienced pregnancy, whether they had children, and their occupations were obtained.

Awareness and Attitude Screening Questionnaire: In this questionnaire prepared by the researchers, two clinical vignettes were given and the same questions were asked for each vignette.

Vignette 1: Ms. Ayşegül is a 24-year-old young woman who has been engaged for one year, graduated from high school, does not work, has not been diagnosed with a psychiatric illness before and can lead a normal daily life. She gives birth in the toilet of the hospital where she goes to with complaints of abdominal pain and leaves the hospital after putting the baby in a plastic bag and leaving it in the toilet garbage. The baby is found hours later by hospital staff and is treated in the neonatal intensive care unit. Ms. Ayşegül was identified through security camera footage and a judicial process was initiated. In her testimony, she stated that she went to the hospital with abdominal pain, that she did not know she was pregnant, that she panicked when she saw the baby's head in the toilet, that she did not know what to do, that she wanted to get rid of the baby in a state of shock, that she threw it in the trash and returned home immediately, and that she did not say anything to her family. It is noteworthy that she repeatedly said "I was not pregnant" throughout her testimony. However, when the detailed history was taken, she stated that she had not menstruated for 6-7 months. Ms. Ayşegül's parents, with whom she lived in the same house, could not believe it and stated that their daughter was not pregnant. Her fiancé stated that there was no problem between her and Ms. Ayşegül, that they were going to get married in 2 months, and that he was not aware of the pregnancy because he had been living in another city for work for the last 3 months.

Vignette 2: Ms. Zehra is 36 years old, a senior nurse, working in an oncology hospital. She has been married for 10 years and has two children aged 8 and 5. She has no known psychiatric illness or psychosocial stress factors. She presented to the internal medicine outpatient clinic with complaints of abdominal pain and abdominal distension, and the doctor suspected pregnancy, and an evaluation revealed a 32-week (8-month) pregnancy. Ms. Zehra's statement that she was not aware that she was pregnant surprised all her family members. She had not had her period for 8 months and had visited the doctor several times 6 months ago with nausea, vomiting and weakness. Ms. Zehra's husband is also surprised. He stated that his wife had two previous pregnancies, knew the symptoms of pregnancy well, and could not believe that she missed this advanced pregnancy because she was a healthcare professional. When questioned about their sexual life, he said that they had a regular sexual life but did not use protection. Pregnancy follow-up was started with a delay and Ms. Zehra gave birth at term.

Both clinical vignettes are followed by 14 questions related to the vignette. The questions can be answered in five different ways as "completely disagree, partially disagree, undecided-do not know, partially agree, completely agree". While analyzing the data, the answers were evaluated in 3 groups as agree, undecided and disagree.

RESULTS

When the sociodemographic characteristics of the participants were analyzed, it was observed that 197 of them were female and 43 of them were male. While 80 participants reported being married, 160 reported being single. 2 of the participants were high school graduates, 57 were undergraduate, 129 were master's and 51 were doctoral graduates. Among the participants, 171 were psychologists, 39 were psychiatrists and 30 were members of other health professions. It was observed that 167 of the participants had a history of pregnancy for themselves or their spouses, while 73 of them did not. 177 participants were reported to have a history of childbirth in themselves or their partner. 63% said that they or their spouse did not have a history of childbirth.

Participants were presented with 2 different clinical

vignettes. Although there was a case of denied pregnancy in both cases, in the first case, unlike the second case, an example is given of a woman who was younger, did not realize the pregnancy until delivery and attempted a criminal neonatology. In the second case, a nurse with a better status in the community whose pregnancy was discovered incidentally 1 month before delivery was presented. In the research, the same questions were asked about the 2 clinical vignettes. The findings of this study are given in Table 2.

According to these results, the belief that the case was a concealed pregnancy, that is, the person knew that she was pregnant but hid it from the environment, was 40.4% for the first case and 18.3% for the second case. The difference was statistically significant.

The belief that the picture was related to a mental illness was 42.9% in the first case and 30.4% in the second case. The difference was statistically significant.

The belief that the person would have accepted that she was pregnant if the pregnancy had been recognized earlier and reported to her was 36.1% for the first case and 63.3% for the second case. The difference was statistically significant.

The belief of all participants that the person was not sincere in saying "I didn't know I was pregnant" was 44.2% for the first case and 28.8% for the second case. The difference was statistically significant.

The rate of attributing the failure to recognize the pregnancy to the person's negligence and irresponsibility was 23.3% for the first clinical vignette and 27.5% for the second vignette. The difference is statistically significant.

The proportion interpreting the situation as an unwanted pregnancy and unconscious denial of it was 66.2% for the first clinical vignette and 51.2% for the second clinical vignette. The difference is statistically significant.

The rate of perceiving the picture as a physiological disorder related to the brain's perception and interpretation of changes in the body was 34.2% for the first case and 30% for the second case. The difference was statistically significant.

Table 1. Sociodemographic characteristics of the participants

| | | n | % |
|--|-----------------|-----|--------|
| Gender | Female | 197 | 82,1 % |
| | Male | 43 | 17,9 % |
| Marital Status | Married | 80 | 33,3 % |
| | Single | 160 | 66,7 % |
| Education | High School | 2 | 0,8 % |
| | Undergraduate | 57 | 23,8 % |
| | Master's Degree | 129 | 53,8 % |
| | PhD | 51 | 21,2 % |
| Profession | Psychologist | 171 | 71,2 % |
| | Psychiatrist | 39 | 16,2 % |
| | Other | 30 | 12,5 % |
| Experience of pregnancy in their partner or themselves | No | 167 | 69,9 % |
| | Yes | 73 | 30,4 % |
| Spouse's or own birth history | No | 177 | 73,8 % |
| | Yes | 63 | 26,2 % |

Table 2. Differences between the respondents' interpretations of the two vignettes

| | | | n | % | p |
|---|--------|-----------|-----|--------|--------|
| Concealed pregnancy, knowing that you are pregnant but hiding it from others | Case 1 | Disagree | 75 | 31,2 % | 0,003 |
| | | Undecided | 68 | 28,3 % | |
| | | I agree | 97 | 40,4 % | |
| | Case 2 | Disagree | 143 | 59,6 % | |
| | | Undecided | 53 | 22,1 % | |
| | | I agree | 44 | 18,3 % | |
| Psychosis, mood disorder with psychotic features, mental retardation | Case 1 | Disagree | 91 | 37,9 % | <0,001 |
| | | Undecided | 46 | 19,2 % | |
| | | I agree | 103 | 42,9 % | |
| | Case 2 | Disagree | 112 | 46,7 % | |
| | | Undecided | 55 | 22,9 % | |
| | | I agree | 73 | 30,4 % | |
| If it had been recognized earlier and reported to her, she would have admitted that she was pregnant. | Case 1 | Disagree | 70 | 29,4 % | 0,003 |
| | | Undecided | 82 | 34,5 % | |
| | | I agree | 86 | 36,1 % | |
| | Case 2 | Disagree | 40 | 16,7 % | |
| | | Undecided | 48 | 20,0 % | |
| | | I agree | 152 | 63,3 % | |
| "I didn't know I was pregnant" is not sincere, it is not a statement of fact. | Case 1 | Disagree | 65 | 27,1 % | <0,001 |
| | | Undecided | 69 | 28,8 % | |
| | | I agree | 106 | 44,2 % | |
| | Case 2 | Disagree | 94 | 39,2 % | |
| | | Undecided | 77 | 32,1 % | |
| | | I agree | 69 | 28,8 % | |

| | | | | | |
|--|--------|-----------|-----|--------|--------|
| Negligence and irresponsibility | Case 1 | Disagree | 123 | 51,2 % | <0,001 |
| | | Undecided | 61 | 25,4 % | |
| | | I agree | 56 | 23,3 % | |
| | Case 2 | Disagree | 116 | 48,3 % | |
| | | Undecided | 58 | 24,2 % | |
| | | I agree | 66 | 27,5 % | |
| Unwanted pregnancy and unconscious denial | Case 1 | Disagree | 38 | 15,8 % | <0,001 |
| | | Undecided | 43 | 17,9 % | |
| | | I agree | 159 | 66,2 % | |
| | Case 2 | Disagree | 64 | 26,7 % | |
| | | Undecided | 53 | 22,1 % | |
| | | I agree | 123 | 51,2 % | |
| A physiological disorder associated with the brain's perception and interpretation of change in the body | Case 1 | Disagree | 81 | 33,8 % | <0,001 |
| | | Undecided | 77 | 32,1 % | |
| | | I agree | 82 | 34,2 % | |
| | | Disagree | 86 | 35,8 % | |
| | | Undecided | 82 | 34,2 % | |
| | | I agree | 72 | 30,0 % | |
| Lack of awareness of their own reproductive capacity | Case 1 | Disagree | 79 | 32,9 % | <0,001 |
| | | Undecided | 73 | 30,4 % | |
| | | I agree | 88 | 36,7 % | |
| | Case 2 | Disagree | 127 | 52,9 % | |
| | | Undecided | 58 | 24,2 % | |
| | | I agree | 55 | 22,9 % | |
| Resentment and anger | Case 1 | Disagree | 113 | 47,1 % | <0,001 |
| | | Undecided | 57 | 23,8 % | |
| | | I agree | 70 | 29,2 % | |
| | Case 2 | Disagree | 176 | 73,3 % | |
| | | Undecided | 44 | 18,3 % | |
| | | I agree | 20 | 8,3 % | |
| Pity | Case 1 | Disagree | 97 | 40,4 % | 0,001 |
| | | Undecided | 62 | 25,8 % | |
| | | I agree | 81 | 33,8 % | |
| | Case 2 | Disagree | 141 | 58,8 % | |
| | | Undecided | 53 | 22,1 % | |
| | | I agree | 46 | 19,2 % | |
| Can't adapt to motherhood | Case 1 | Disagree | 41 | 17,1 % | <0,001 |
| | | Undecided | 41 | 17,1 % | |
| | | I agree | 158 | 65,8 % | |
| | Case 2 | Disagree | 142 | 59,2 % | |
| | | Undecided | 60 | 25,0 % | |
| | | I agree | 38 | 15,8 % | |
| I would like to take part in the psychosocial medical support team | Case 1 | Disagree | 22 | 9,2 % | <0,001 |
| | | Undecided | 52 | 21,7 % | |
| | | I agree | 166 | 69,2 % | |
| | Case 2 | Disagree | 25 | 10,4 % | |
| | | Undecided | 58 | 24,2 % | |
| | | I agree | 157 | 65,4 % | |

The rate of those who evaluated the picture as not being aware of one's own reproductive capacity was 36.7% for the first case and 22.9% for the second case. The difference was statistically significant.

In this research, the emotions created by the vignettes presented to the participants were also questioned. Accordingly, while the feeling of anger and rage was reported as 29.2% in the first case, this situation was 8.3% for the second case. The difference is statistically significant.

While the feeling of pity for the first case was 33.8%, the feeling of pity for the second case was 19.2%. The difference is statistically significant.

The opinion that these cases would not be able to adapt to motherhood was found to be 65.8% for the first case and 15.8% for the second case. The difference is statistically significant.

Finally, participants were asked whether they would like to be included in the psychosocial medical support team of the cases in this clinical vignette. While the rate of those who wanted to take part in the follow-up of the first case was 69.2%, the rate of those who wanted to take part in the follow-up of the second case was 65.4%. The difference is statistically significant.

DISCUSSION

The phenomenon of denied pregnancy, which we define as the situation in which the expectant mother realizes the pregnancy only after the 20th week of pregnancy or at the time of delivery, draws attention as an unrecognized and overlooked medical condition although it is seen in our society.

The phenomenon of denied pregnancy, which can also be experienced by mothers who have had previous pregnancies and given birth, is not related to a condition that impairs mental functions such as psychosis, mood disorder or mental retardation. Except for their denied advanced pregnancy, these women appear normal and can go about their daily lives without any problems.

It is equally surprising that many women who deny their pregnancy do not gain weight during their pregnancy, some women even lose weight compared to their pregnancy periods, they experience bleeding

perceived as menstrual bleeding, and even in their bikini photos, there is no obvious change in their bodies to suggest pregnancy. It has also been reported in studies that their spouses and close relatives do not recognize the pregnancy either.

These expectant mothers do not recognize the physiological signs of pregnancy, are unaware of the presence of the baby in their womb and are neither emotionally nor socially prepared for birth and the role of motherhood. These women, who are unable to adopt a pregnancy-appropriate lifestyle, pregnancy-specific diet, and prenatal care, may give birth unexpectedly and without any medical assistance. As a result of births in these inappropriate conditions, the newborn may die soon after birth due to drowning, blood loss or trauma, and the expectant mother may be prosecuted by the law for the murder of her newborn. Denied pregnancy can have negative and tragic consequences, such as neonatitis, postpartum emotional distress, post-traumatic stress disorder, depression or rejection of the newborn.

According to the results of this study, in the first case of attempted neonatid in the clinical vignette, a significant proportion of the health personnel considered it as a psychotic symptom or a concealed pregnancy. This acute dissociative state, in which the expectant mother, faced with an unexpected birth, reacts with symptoms of surprise, shock and, in some cases, panic, may explain the inability of the expectant mother to provide the necessary interventions to the newborn. In this picture, there is no planned action, but rather a situation where it is not possible to provide the necessary support to a newborn baby in need of protection and care.

Jenkins et al (2011) reported that 38% of expectant mothers who did not realize their pregnancy visited their physicians for various reasons during pregnancy but did not receive a diagnosis of pregnancy. As awareness of the phenomenon of denied pregnancy increases, it is thought that the risk to the health and life of the mother and the newborn can be prevented by diagnosing the symptoms and early intervention by obstetricians, midwives, physicians and psychiatrists who come into contact with these expectant mothers in the first place.

Schauberger, Friedman et al. (2007) reported that the mother's psychiatric consultation after birth is critical, especially if the baby is to be left in the care of the mother. Researchers have reported that patients who reject pregnancy symptoms do not reject their maternal role, but rather accept their newborn. Schauburger stated that specialists should approach these patients with compassion and empathy and emphasized that pregnancy denial may be secondary to deep psychosocial and psychiatric wounds that require careful attention.

As shown in Table 2, the respondents gave statistically significantly different interpretations to the two clinical vignettes. The first case presented was a younger, inexperienced woman who committed a criminal act of labor and left the baby to die, while the second case was a more mature, experienced nurse with status in the community. It is noteworthy that the respondents did not give a dominant answer related to explaining the situation or emotions for both phenomena. None of the questions asked in the survey about the interpretations that explain the situation or the emotions generated by the clinical vignettes reached 70%. The answers given by the participants for any item did not fall below 5%. 'Strongly disagree', 'Undecided' and 'Agree' options were close to each other. This shows that two cases of denied pregnancy presented differently from each other, can be confusing for the participants and their awareness of this situation is low. Such a high rate of participation in completely different explanations between the interpretations of the two vignettes presented in Table 2 shows that the respondents had great difficulty in interpreting this picture.

The statistically significant difference in almost all items for the two clinical vignettes is a good example of how a similar situation can lead to different interpretations on the other side depending on the age, status and consequences of the action.

The mother experiences a psychological shock during labor, which starts suddenly when she least expects it, and may experience dissociation during labor and post-traumatic stress disorder after delivery. These patients should be treated with compassion and empathy and should be referred to a mental health unit. Mental health workers should be aware of the case of denied

pregnancy and provide appropriate treatment and support to the mother.

CONCLUSION

The results of this study suggest that participants from psychologists, psychiatrists and other professional groups experienced ambivalence in the face of vignettes describing cases of denied pregnancy and had difficulty in recognizing and making sense of the picture.

The views that the picture could be a concealed pregnancy, could be due to psychosis or mental retardation, could be explained by ignorance of pregnancy signs and inexperience, could be due to negligence and irresponsibility, could be an unconscious denial of an unwanted pregnancy, or could be related to the woman's lack of awareness of her own reproductive capacity, were all adopted in close agreement. The fact that approximately 1/4 - 1/3 of the respondents remain undecided for each question shows the confusion created by the table.

Participants reported feeling less able to trust their judgment on other issues. Participants reported feeling more anger for clinical vignette 1, in which the birth was more likely to end in neonatidis.

However, obstetricians, physicians, midwives and psychiatrists are the first to come into contact with mothers who deny their pregnancies, to diagnose them and to provide medical and psychological assistance. It is thought that more studies on the phenomenon of denied pregnancy will increase the knowledge and awareness of healthcare professionals and social support specialists about the phenomenon.

Physicians can prevent a possible danger by ordering a pregnancy test in women who have reached childbearing age and present to them with complaints such as nausea, abdominal pain, weight gain, abdominal distension, and absence of menstruation, even if they report otherwise, taking into account the possibility of denial of pregnancy.

In our research, it was observed in clinical vignettes that healthcare professionals were unfamiliar with the concept of denied pregnancy and may be prone to characterize the picture as concealed pregnancy,

psychotic denial, lack of mental skills, and crime.

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Authors' Contributions: The authors contributed equally to the study.

Ethics Committee Approval: This study was approved by the Ethics Committee for non-Interventional Research of T.C. Üsküdar University (Approval Number: B.08.6.Yök.2.Üs.0.05.0.06 /2017/324) and adhered to the principles of the Declaration of Helsinki.

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