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ORIGINAL ARTICLE / ORİJİNAL MAKALE

Infant mortality rates and causes of infant deaths in Kilis province between 2012 and 2018

Kilis ilinde 2012-2018 yılları arasındaki bebek ölüm hızları ve bebek ölüm nedenleri

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ABSTRACT

Objective: The objective of this study was to determine the infant mortality rate and the causes of infant death in Kilis Province, Turkey. **Methods:** This was a descriptive and retrospective study which utilized records and documentation from the death register and post-mortem reports. Annual infant deaths occurring in Kilis between January 1, 2012 and December 31, 2018 which were reported to the Kilis State Hospital and then to the Kilis Provincial Directorate of Health, were reviewed. **Results:** The infant mortality rate for Kilis was 18.4 deaths per 1000 live births between 2012 and 2018. Infant deaths were higher for male, preterm, and low-birthweight (LBW) babies. 54% percent of the infant deaths occurred in preterm babies. More than half (%61.7) of the mothers who died in labor did not have the minimum number of prenatal care visits (at least 4 visits) recommended by World Health Organization. Disorders related to short gestation and low birth weight, not elsewhere classified (26.6%), congenital malformations, deformations, and chromosomal abnormalities (19.4%), and other respiratory conditions originating in the perinatal period (13.0%) were the three leading causes of infant deaths between 2012 and 2018. **Conclusions:** The infant mortality rate in Kilis for the seven year period was higher than the national and the regional estimates. Our study showed that most infant deaths occurred in male, preterm, and low birth weight (LBW) infants. Most of the deaths among infants were preventable through promotion of institutional deliveries, early recognition of danger signs, strengthening of referral systems and periodic retraining of health care professionals.

Keywords: Infant, mortality, cause of death, Turkey

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ÖZ

Amaç: Bu çalışmanın amacı, Kilis ilindeki bebek ölüm hızlarını ve bebek ölüm nedenlerini belirlemektir. **Yöntem:** Çalışma, ölüm kayıtlarının ve ölüm sonrası raporlarının incelenmesiyle yapılan tanımlayıcı retrospektif bir çalışmadır. 1 Ocak 2012 ve 31 Aralık 2018 tarihleri arasında Kilis'te meydana gelen ve Kilis Devlet Hastanesi'ne ve ardından Kilis İl Sağlık Müdürlüğü'ne bildirilen yıllık bebek ölümleri incelenmiştir. **Bulgular:** Kilis'te bebek ölüm hızı 2012-2018 yılları arasında 1000 canlı doğumda 18.4 ölüm olarak belirlendi. Erkek, erken doğmuş ve düşük doğum ağırlıklı (DDA) bebeklerde bebek ölümleri daha yüksekti. Bebek ölümlerinin yüzde elli dördü erken doğan bebeklerde meydana gelmiştir. Ölen bebeklerin annelerinin yarısından fazlası (%61.7) Dünya Sağlık Örgütü'nün önerdiği asgari doğum öncesi bakım ziyaretlerine (en az 4 ziyaret) sahip değildi. Kısa gebelik ve düşük doğum ağırlığı ile ilgili bozukluklar, başka yerde sınıflandırılmamış (%26.6), konjenital malformasyonlar, deformasyonlar ve kromozomal anormallikler (%19.4) ve perinatal dönemden kaynaklanan diğer solunum rahatsızlıkları (%13.0) 2012-2018 yıllarında ölen bebeklerin başlıca üç ölüm nedeni olmuştur. **Sonuç:** Kilis'te yedi yıllık dönemdeki bebek ölüm hızı ulusal ve bölgesel tahminlerin üzerindedir. Çalışmamız bebek ölümlerinin çoğunun erkek, preterm ve düşük doğum ağırlıklı (DDA) bebeklerde meydana geldiğini göstermektedir. Kurumsal doğumların teşvik edilmesi, tehlike işaretlerinin erken tanınması, sevk sisteminin güçlendirilmesi ve sağlık profesyonellerinin periyodik olarak yeniden eğitilmesiyle bebek ölümlerinin çoğu önlenebilir.

Anahtar kelimeler: Bebek, mortalite, ölüm nedeni, Türkiye

Introduction

Infant mortality represents a substantial proportion of mortality in children under-5 years. Like under-5 mortality rate, infant mortality rates (IMRs) measure a child's chance at survival. They also represent the economic, environmental and social circumstances in which children (and others in society) live, including their healthcare.[1] Besides giving us important information regarding infant and maternal health, the infant mortality rate (IMR) is a considerable sign of a society's overall health.[2] Since data on the prevalence and incidence of diseases (morbidity data) usually are not available, mortality rates are frequently used to identify more vulnerable societies.[1]

According to the World Health Organization (WHO) in 2017, 4.1 million (75%) of overall under-5 deaths happened within the first year of children's lives. The risk of infant mortality was the highest in the World Health Organization African Region (51 deaths per 1000 live births), over 6 times greater than that in the World Health Organization European Region (8 deaths per 1000 live births). Worldwide, IMR has declined from an estimated rate of 65 deaths per 1000 live births in 1990 to 29 deaths per 1000 live births in 2017. Annual infant deaths have decreased from 8.8 million in 1990 to 4.1 million in 2017.[3]

IMRs are usually very low across the OECD (Organization for Economic Co-operation and Development) but do vary moderately from country to country. In most OECD countries IMRs stand at somewhere between 2.5 and 5 deaths per 1000 live births, with the OECD average IMR at 3.8. Rates are the lowest at fewer than 2.5 deaths per 1000 live births in Finland, Estonia, Norway, Japan, Sweden, and Slovenia, and the highest at 12.1 and 9.2

deaths per 1000 live births in Mexico and Turkey, respectively.[4] The IMR for Turkey in 2017 was 9.3 deaths per 1000 live births. In 2017, the highest IMRs in the Turkey were registered in Kilis (17.5 deaths per 1000 live births) and Hakkari (16.8 deaths), and the lowest in Çankırı (4.6 deaths), Eskişehir and Amasya (5.3 deaths).[5]

There is a difference between contributors to infant mortality and causes of infant mortality. A cause leads directly to a death. Conversely, a contributor is a risk factor that makes the death more likely to occur.[6] Worldwide, the leading causes of death among children under age 5 in 2017 were preterm birth complications, acute respiratory infections, intrapartum-related complications, congenital anomalies, and diarrhea. Neonatal deaths accounted for 47% of under-5 deaths in 2017.[7] In 2017, the IMR in the United States was 5.8 deaths per 1000 live births. The five leading causes of infant death in the United States in 2017 were: birth defects, preterm birth and low birth weight, maternal pregnancy complications, sudden infant death syndrome, and injuries (e.g., suffocation).[2] Globally, ending preventable child deaths will necessitate targeted interventions to the age specific causes of death among teenagers and children.[8]

However, there is inadequate population level data on the current predictions of IMR in Turkey. Since infant mortality represents the health and social development of community, of course, the first step in reducing infant mortality is to define and to resolve the causes of this phenomenon. Therefore, the present study aimed to evaluate the IMR and causes of death in Kilis Province, Turkey.

Methods

Study group and design

This study was a descriptive retrospective study which utilized records and documentation of the death register and post-mortem reports. Annual infant deaths (live birth with death before 1 year of age) occurring in Kilis between January 1, 2012 and December 31, 2018 which reported to the Kilis State Hospital and then to the Kilis Provincial Directorate of Health, were evaluated. Infant deaths registered by the Turkish Statistical Institute were also reviewed. In total, the data of 376 deceased infants was analyzed. Collected variables (when available) were gender of infant, mothers' nationality, maternal age at childbirth (years), gestational age at birth, number of prenatal care visit, smoking during pregnancy, place of birth, mode of delivery, number of infants born, birth weight, place of death, and causes of infant mortality. The International Statistical Classification of Diseases and Related Health Problems (ICD) Problems, 11th Revision (ICD-11) was used to code causes of death.[9] The IMR has been defined by the WHO as the number of deaths of children under-one year of age, expressed per 1000 live births.1 Preterm was defined as infants born alive before 37 completed weeks of gestation.[10] The low birth weight (LBW) rate at the population-level is an indicator of a public health problem that includes long-term ill health, poor quality health services, and maternal malnutrition. On an individual basis, LBW is a significant predictor of newborn survival and health. LBW was described as a weight of less than 2500 g (up to and including 2499 g) regardless of the gestational age.[11]

Statistical analyses

The data was analyzed using IBM SPSS statistical software, version 23. Descriptive statistics were used for continuous variables as means and for categorical and dichotomous variables as percentages.

Ethical considerations

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The approval was received from the Ethics Committee of Kilis 7 Aralık University (2019/10-1).

Results

Table 1 shows the numbers and rates of infant deaths based on the year of death from 2012 to 2018. There were 376 infant mortality cases documented in Kilis between 2012 and 2018. In 2018, around 41 children died before reaching one year of age in Kilis; this was equivalent to an IMR of 14.5 deaths per 1000 live births. Infant deaths (up to one year of age) decreased from 46 in 2012 to 41 in 2018. The infant mortality rate for Kilis between 2012 and 2018 was 18.4 deaths per 1000 live births. During the 7 years from 2012 to 2018, the IMR in the Kilis decreased from 16.2 deaths per 1000 live births to 14.5 deaths per 1000 live births. The highest IMR in Kilis corresponded to 2014 (24.6 deaths per 1000 live births). On the other hand, the lowest IMR was recorded in 2016 (13.3 deaths per 1000 live births). In Kilis between 2012 and 2018, the overall IMR for male infants was 20.2 deaths per 1000 live births, 23% higher than the rate for female infants (16.4 deaths per 1000 live births).

Table 1. Infant mortality rate (deaths per 1000 live births) in Kilis Province, Turkey, between 2012 and 2018

	Number of live births			**Number of infant deaths**			**Infant mortality rate (deaths per 1000 live births)**		
Year	**Total**	**Male**	**Female**	**Total**	**Male**	**Female**	**Total**	**Male**	**Female**
2012	2844	1401	1443	46	31	15	16.2	22.1	10.4
2013	2867	1505	1362	70	42	28	24.4	27.9	20.6
2014	3100	1598	1502	76	38	38	24.6	23.8	25.3
2015	3000	1564	1436	54	25	29	18.0	16.0	20.2
2016	2873	1477	1396	39	17	22	13.3	11.5	15.8
2017	2872	1486	1386	50	37	13	17.5	25.0	9.4
2018	2914	1517	1397	41	23	18	14.5	15.2	12.9
Total (2012-2018)	**20470**	**10548**	**9922**	**376**	**213**	**163**	**18.4**	**20.2**	**16.4**

Table 2 demonstrates the characteristics of mothers, pregnancies, deliveries, and children among the cases of infant deaths that happened during the study period. From 2012 to 2018, 376 infants died: 56.6% were boys (n=213) and 43.4% were girls (n=163). Mothers of 73.1% of these infants were Turkish citizens. The mean maternal age was 26.29±8.07 years (range 15–44). The number of infant deaths were the highest among mothers aged between 20-34 years old (271 infant death) and the lowest among mothers over the age of 35 years old (52 infant death). More than half (54.0%) of the infants were born before 37 weeks gestation. Most of the infants were born to women who had participated at least one prenatal care visit and 38.3% of them were born to mothers who had participated the suggested 4 prenatal care visits. About 6.0% had a mother who smoked at the beginning of the pregnancy. Most babies were born in health facilities (83.5% or 314 babies). And regarding the delivery method, 50.5% of

infant deaths were delivered by normal vaginal delivery, while 39.6% were delivered by cesarean section. Twin and singleton births constituted 7.4% and 92.6% of the cases, respectively. More than half (56.1%) of the infants were LBW (up to and including 2499 grams). Maternal/general hospital had the majority of deaths, accounting for 92.3% of all cases.

Table 2. Frequency distribution of demographic data of the dead infants and their mothers

Characteristics (n=376)	**n**	**%**
Gender of infant		
Male	213	56.6
Female	163	43.4
Mothers' nationality		
Turkish	275	73.1
Syrian	101	26.9
Maternal age at childbirth (years) (mean ± SD = 26.29 ± 8.07)		
≤19	53	14.1
20-34	271	72.1
≥ 35	52	13.8
Gestational age		
≤36 weeks	203	54.0
≥ 37 weeks	173	46.0
Antenatal care		
No antenatal care	126	33.5
1-3 visits	106	28.2
At least 4 visits	144	38.3
Smoking during pregnancy		
No	354	94.1
Yes	22	5.9
Place of birth		
Health facilities	314	83.5
Home	62	16.5
Mode of delivery		
Vaginal delivery	190	50.5
Cesarean Section	149	39.6
Unknown	37	9.8
Number of infants born		
Singleton	348	92.6
Multiples	28	7.4
Birth weight		
<2500 grams	211	56.1
≥2500 grams	165	43.9
Place of death		
Health facilities	347	92.3
Home	29	7.7

The top 10 causes of infant deaths between 2012 and 2018 were disorders related to short gestation and low birth weight not elsewhere classified (26.6%), congenital malformations, deformations and chromosomal abnormalities (19.4%), other respiratory conditions originating in the perinatal period (13.0%), respiratory distress of newborn (9.3%), bacterial sepsis of newborn (8.0%), intrauterine hypoxia and birth asphyxia (3.5%), sudden infant death syndrome (2.9%), transitory endocrine and metabolic disorders specific to fetus and newborn (1.9%), injury, poisoning and certain other consequences of external causes (1.6%), and other acute lower respiratory infections (1.3%) (Table 3).

Tablo 3. Leading causes of infant deaths in Kilis province, Turkey, from 2012 to 2018

Rank	Causes of Infant Deaths (ICD-10 Codes)	n	%
1	Disorders related to short gestation and low birth weight, not elsewhere classified (P07)	100	26.6
2	Congenital malformations, deformations, and chromosomal abnormalities (Q00–Q99)	73	19.4
3	Other respiratory conditions originating in the perinatal period (P28)	49	13.0
4	Respiratory distress of newborn (P22)	35	9.3
5	Bacterial sepsis of newborn (P36)	30	8.0
6	Intrauterine hypoxia and birth asphyxia (P20-P21)	13	3.5
7	Sudden infant death syndrome (R95)	11	2.9
8	Transitory endocrine and metabolic disorders specific to fetus and newborn (P70–P74)	7	1.9
9	Injury, poisoning and certain other consequences of external causes (S00–T98)	6	1.6
10	Other acute lower respiratory infections (J20–J22)	5	1.3
	All Other Causes	**47**	**12.5**
	Total Infant Deaths	**376**	**100.0**

The top 10 causes of Turkish infant death between 2012 and 2018 were disorders related to short gestation and low birth weight, not elsewhere classified (28.0%), congenital malformations, deformations and chromosomal abnormalities (19.6%), other respiratory conditions originating in the perinatal period (10.2%), respiratory distress of newborn (9.8%), bacterial sepsis of newborn (8.4%), intrauterine hypoxia and birth asphyxia (2.5%), transitory endocrine and metabolic disorders specific to fetus and newborn (2.2%), sudden infant death syndrome (2.2%), injury, poisoning and certain other consequences of external causes (1.8%), and necrotizing enterocolitis of fetus and newborn (1.5%) (Table 4).

The top 10 causes of Syrian infant death between 2012 and 2018 were disorders related to short gestation and low birth weight, not elsewhere classified (22.8%), other respiratory conditions originating in the perinatal period (20.8%), congenital malformations, deformations and chromosomal abnormalities (18.8%), respiratory distress of newborn (7.9%), bacterial sepsis of newborn (6.9%), intrauterine hypoxia and birth asphyxia (5.9%), sudden infant death syndrome (5.0%), other acute lower respiratory infections (3.0%), other gastroenteritis and colitis of infectious and unspecified origin (2.0%), and pulmonary hemorrhage originating in the perinatal period (2.0%) (Table 5).

Table 4. Leading Causes of Turkish Infant Deaths in Kilis Province, Turkey, From 2012 to 2018

Rank	Causes of Infant Deaths (ICD-10 Codes)	n	%
1	Disorders related to short gestation and low birth weight, not elsewhere classified (P07)	77	28.0
2	Congenital malformations, deformations and chromosomal abnormalities (Q00–Q99)	54	19.6
3	Other respiratory conditions originating in the perinatal period (P28)	28	10.2
4	Respiratory distress of newborn (P22)	27	9.8
5	Bacterial sepsis of newborn (P36)	23	8.4
6	Intrauterine hypoxia and birth asphyxia (P20-P21)	7	2.5
7	Transitory endocrine and metabolic disorders specific to fetus and newborn (P70–P74)	6	2.2
8	Sudden infant death syndrome (R95)	6	2.2
9	Injury, poisoning and certain other consequences of external causes (S00–T98)	5	1.8
10	Necrotizing enterocolitis of fetus and newborn (P77)	4	1.5
	All Other Causes	**38**	**13.8**
	Total Turkish Infant Deaths	**275**	**100.0**

Table 5. Leading Causes of Syrian Infant Deaths in Kilis Province, Turkey, From 2012 to 2018

Rank	Causes of Infant Deaths (ICD-10 Codes)	n	%
1	Disorders related to short gestation and low birth weight, not elsewhere classified (P07)	23	22.8
2	Other respiratory conditions originating in the perinatal period (P28)	21	20.8
3	Congenital malformations, deformations and chromosomal abnormalities (Q00–Q99)	19	18.8
4	Respiratory distress of newborn (P22)	8	7.9
5	Bacterial sepsis of newborn (P36)	7	6.9
6	Intrauterine hypoxia and birth asphyxia (P20-P21)	6	5.9
7	Sudden infant death syndrome (R95)	5	5.0
8	Other acute lower respiratory infections (J20–J22)	3	3.0
9	Other gastroenteritis and colitis of infectious and unspecified origin (A09)	2	2.0
10	Pulmonary hemorrhage originating in the perinatal period (P26)	2	2.0
	All Other Causes	**5**	**5.0**
	Total Syrian Infant Deaths	**101**	**100.0**

Discussion

The IMR (18.4 deaths per 1000 live births) in the present study, during the period of 2012 and 2018, was higher than the regional and national predictions. Between 2012 and 2018, IMR of Turkey was declining at a moderating rate to minimize from 11.6 deaths per 1000 live births in 2012 to 9.3 deaths per 1000 live births in 2018.[12] In the European Union (EU) in 2018, around 14,600 children died before reaching one year old. This is equivalent to an IMR of 3.4 deaths per 1000 live births. During the 7 years from 2012 to 2018, the IMR in the EU decreased from 3.8 deaths per 1000 live births to 3.4 deaths per 1000 live births.[13] The regional differences in IMRs may be due to differences among regions in the efficiency and quality of the health system, such as income inequality, the social environment, and individual attitudes and lifestyles.[14]

This study found that the five leading causes of infant deaths were disorders related to short gestation and low birth weight, not elsewhere classified (26.6%), congenital malformations, deformations and chromosomal abnormalities (19.4%), other respiratory conditions originating in the perinatal period (13.0%), respiratory distress of newborn (9.3%), and bacterial sepsis of newborn (8.0%). The leading reported cause of infant deaths in Turkey according to the Ministry of Health is

prematurity, followed by congenital anomaly, which together comprise almost half of all infant deaths. This identical structure is usually found around the world, and there is interaction among birth weight relevant causes such as prematurity, congenital anomaly, intravascular hemorrhage, respiratory distress, etc.[15] Expansion of prevention and cure of these reasons is vitally important for an infant's prospects of survival.[16]

The leading causes of infant mortality among Turkish citizens were disorders related to short gestation and low birth weight, not elsewhere classified, and followed by congenital malformations, deformations, and chromosomal abnormalities. The leading causes of infant mortality among Syrian citizens were disorders related to short gestation and low birth weight, not elsewhere classified, and followed by other respiratory conditions originating in the perinatal period. There were minor differences in some of the other leading causes of infant deaths among ethnic groups. For instance, sudden infant death syndrome was the eighth leading cause of infant deaths among Turkish infants, whereas this cause of infant death was ranked seventh among Syrian infants.

More than half (56.1%) of the infant deaths in our study occurred among babies with low-birth weight < 2500 g with a higher risk of death among infants born alive before 37 weeks of pregnancy (54.0%) in comparison to term-born infants (37-41 weeks gestation), which corresponds to the findings of previous studies.[17-19] Birth weight and gestational age are the two most significant determining factors affecting the survival and health of babies. Babies who were born very early or very small have a much higher risk of death and both long-term and short-term disability than those born at term (37–41 weeks of pregnancy) or with birth weight of less than 2500 grams.[20] Infants born alive before 37 weeks of pregnancy usually have a low birth weight, but occasionally full-term babies are also born underweight. These causes can include a poor maternal nutrition or mother's chronic ill-health status. The outcomes of inadequate nutritional intake and poor nutritional status for women throughout pregnancy not only directly influences the health status of women but may also have a negative influence on early development and birth weight.[21] Sufficient prenatal care is required to providing that full-term babies are born at a healthy weight.[8]

The WHO strong recommendations at least 4 prenatal care visits based on a review of the efficiency of different models of prenatal care. Prenatal visits provide opportunities for reaching pregnant women with interventions that may be vital to their well-being and health and that of their babies.[22] For instance, if the prenatal period is used to inform families and women about signs of danger and primary symptoms about the risks of delivery and labor, it may ensure the route for providing that pregnant women do, in practice, deliver with the assistance of a skilled health service provider. The prenatal period ensures a possibility to provide information on birth spacing, which is recognized as a significant factor in reducing the risk of infant mortality.[23]

The present study found that more than half (%61.7) of the mothers of infants who died did not have the minimum number of prenatal care visits (at least four visits) suggested by the WHO. Investigators researching the efficiency of prenatal care interventions on newborn and maternal health consequences have reached contradictory results. Recently, in two studies carried out in both low- and high-income countries, it was demonstrated that there is inadequate proof of the impact of prenatal care on the reduction of infant deaths.[24, 25] These systematic reviews were carried out only among socially defenseless and disadvantaged women and compared lower number of prenatal care with the standard model (depending on the number of visits). On the other hand, in studies carried out in Indonesia and India, positive impacts of prenatal care in preventing infant deaths were demonstrated.[26, 27]

Our results show that, in the Kilis between 2012 and 2018, the overall IMR for male babies was 20.2 deaths per 1000 live births, 23% higher than the rate for female babies (16.4 deaths per 1000 live births). Males in

Turkey have consistently recorded higher IMR than females.[28] In most countries, IMRs are higher for male infants.[29] This has been explained by gender differences in biological and genetic makeup, with boys being biologically weaker and more sensitive to premature death and diseases.[30]

There are some limitations of this study. First, IMRs depend on the underlying reason of death as recorded on a certificate of death by a doctor. Inaccurate ICD-10 coding and low rates of autopsies that affirm the reason of death may occur. Second, current data on substantial variables such as breastfeeding, maternal nutritional status, and sanitation and hygiene were unavailable; and therefore, not included in the analysis.

In conclusion, our findings suggest that the IMR in Kilis for the seven year period was higher than the regional and national estimates. Our study showed that most infant deaths occurred in male, preterm, and low birth weight (LBW) infants. Additionally, most infant deaths were among infants whose mothers did not receive at least 4 prenatal care visits during pregnancy. The three major causes of infant deaths in Kilis were disorders related to short gestation and low birth weight, not elsewhere classified (26.6%), congenital malformations, deformations, and chromosomal abnormalities (19.4%), and other respiratory conditions originating in the perinatal period (13.0%). Most of these preventable deaths still happen at home and within health facilities.

The burden of mortality among infants can be decreased by the strengthening of reproductive and child health programs, referral system, the promotion of institutional deliveries, early recognition of danger signs by health workers through training, health education regarding promotion of at least 2 years between pregnancies and improving the literacy status of the community as a long term goal.[31] Preventing complications and deaths from premature birth begins with a healthy pregnancy. Quality of healthcare before, between and throughout pregnancies would allow more women to have positive pregnancy experiences. WHO's prenatal care suggestions involve key effective interventions to help prevent preterm birth, for example, counseling on optimal nutrition and healthy dietary practices, and substance use and tobacco use; fetal measurements including use of ultrasound to help detect multiple pregnancies and to determine gestational age; and at least eight contacts with healthcare providers during pregnancy to describe and to manage other risk factors. Improved contraceptive access and increased empowerment could also help decrease premature births.[10] Once pregnant, a mother should receive regular and early prenatal care. This type of care helps support the best consequences for baby and mother.[8]

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Contribution of all authors: Çam HH; Designed the study, editing the final paper and training of data collectors and supervises the data collection process. Karasu F; Designed the study, participated in the process of data collection, performed data clerk & data analysis, interpreted the result, and drafted and critically reviewed the manuscript. She contributed in drafting and writing of the manuscript, supervised the data collection process, interpreted the result and reviewed the manuscript. All authors read and approved the final manuscript.

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