

Analyzes of Knowledge, Attitude, and Practice of Turkish Midwives and Puerperal Women Regarding Pharmacovigilance

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Abstract: Spontaneous reporting of adverse drug reactions (ADRs) is the backbone of the pharmacovigilance system. However, underreporting is still a fundamental hurdle around the globe that must be resolved. To analyze Turkish midwives' and puerperal women's knowledge, attitude, and practice regarding pharmacovigilance. A cross-sectional study on midwives (n=36) and puerperal women (n=227) was carried out from September 2019 to June 2020 in a State Hospital in Turkey. Data were collected by a questionnaire and analyzed by Mann-Whitney U, Kruskal-Wallis, and the Chi-Square tests. The knowledge level of midwives was significantly higher than that of the puerperal women. Although all midwives knew of adverse drug reactions, only half of the puerperal women had heard this. The awareness of the pharmacovigilance term was 97% and 2% in midwives and puerperal women, respectively. Similarly, 81% of the midwives were aware of the Turkish Pharmacovigilance Center (TPC), whereas only 1% of the puerperal women realized the fact. More than half of the midwives knew they could directly report ADRs to TPC. However, most did not know how they could send or report ADRs. Interestingly, only five midwives knew that congenital anomalies and congenital disabilities had been included in ADRs. Although the knowledge, attitude, and practice of Turkish midwives were significantly better than puerperal women regarding pharmacovigilance, it is apparent that both groups were insufficient to get involved in the pharmacovigilance system properly.

Keywords: Attitude; knowledge; midwives; pharmacovigilance; practice; puerperal women

INTRODUCTION

The World Health Organization (WHO) defines pharmacovigilance as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems”¹. Health professionals' spontaneous reporting of adverse drug reactions (ADRs) plays a pivotal role in the pharmacovigilance system². In this sense, the pharmacovigilance system's central problem is underreporting ADRs². In order to improve pharmacovigilance activities, the first regulation was published in 2005, and the last was put into force in

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2014 in the Republic of Turkey³. According to Turkish laws, doctors, dentists, pharmacists, nurses, and midwives are the healthcare professionals permitted to report ADRs. In addition, consumers have been involved in the Turkish pharmacovigilance system as potential reporters.

Although a considerable amount of studies regarding the knowledge, attitude and practice (KAP) of doctors, dentists, pharmacists, and nurses have been conducted, it seems that less attention has been given to the potential contribution of midwives to the pharmacovigilance system. In a 2013 study on nurses and midwives in Turkey, knowledge of pharmacovigilance was 44.7%, and the correct definition of pharmacovigilance was 23.3%, apparently showing the insufficient information gained by this type of healthcare professional⁴. However, in this study, investigators preferred to unify nurses and midwives as one group, preventing proper analysis of the midwives' knowledge. Similarly, another study focusing on the KAP of physicians, pharmacy professionals, health officers, nurses, and midwives showed that most health care professionals had a positive attitude, inadequate knowledge, and poor practice towards adverse drug reactions (ADR) reporting. The study did not compare the results of the midwives with those of the other professionals, so no specific data regarding the midwives could be extracted⁵. Another study collecting data from nurses and midwives (without discrimination) pointed out serious problems regarding ADR reporting⁶. As potential reporters, consumers have been evaluated in terms of KAP of pharmacovigilance in several studies, and it has been shown that patient reporting is relatively rare in most countries⁷. However, there is no study investigating the KAP of Turkish consumers regarding pharmacovigilance, indicating the requirement to conduct such studies.

Considering the close relationship and interaction between midwives and puerperal women, a particular type of consumers, we, in the present study, aimed to investigate the KAP of the subjects towards pharmacovigilance to increase the attention and contribution of these reporters to the pharmacovigilance system.

MATERIALS AND METHODS

Study Design and Settings

This observational, cross-sectional, questionnaire-based study was carried out from September 2019 to June 2020 in a State Hospital in Turkey. The approval was obtained from the Ethics Committee for Clinical Trials (Approval date and number: 03.06.2019 and 2019/04-02) and permission from City Health Directorate. The midwives and puerperal women gave written consent before enrollment in the study. G*power analyses were performed prior to the study, and the number of volunteers was calculated to be at least 128 for puerperal women ($\alpha=0.05$, $\beta=0.80$, effect size=0.50) (G*power version 3.1.9.2. Germany). On the other hand, we aimed to stimulate all the midwives on the hospital staff in which the study was carried out to get involved, and all of them agreed to participate (n=36).

Questionnaire

The questions for the information section were constructed according to the Turkish regulations regarding the pharmacovigilance system by a specialist on pharmacovigilance (i.e., a pharmacovigilance contact point of a university hospital), and those for demographic and attitude/practice sections were prepared according to

particular articles^{5,6,7,8}. After that, the study team evaluated and modified it regarding objectivity, comprehensibility, and quantification sufficiency. Finally, a literature teacher edited the text for grammatical and writing errors. The first, second and third parts of the questionnaire contained demographic information, knowledge and attitude/practice of the volunteers, respectively (19 questions excluding demographic ones). There were 16 questions within the knowledge part, 15 designed as "yes or no/no idea", and the last one was open-ended (16 points in total). Using the mean score (8 points), those with a score of less than eight points were accepted to have inadequate knowledge. Whenever the subjects correctly answered the third question, investigators asked the fourth and the fifth questions to both group of subjects. If the responses to the fourth and fifth questions were correct, they were allowed to respond to the sixth question. An affirmative answer to the sixth question enabled the investigators to ask the remaining questions in the knowledge section. The format of the first question in the attitude/practice section was similar to those in the information section, whereas the remaining contained excess options. The investigators asked these questions when subjects responded correctly to the third question. The questionnaire was applied to the volunteers by the interviewers with a face-to-face technique.

Statistical Analysis

Data regarding the total point of the knowledge part of the questionnaire was tested for normal distribution by the Shapiro-Wilk test. The Null hypothesis for normality was rejected for both groups ($P=0.001$ and $P=0.0001$). Therefore, comparisons between two groups (i.e., between midwives and puerperal women) and more than two groups were analyzed by the Mann-Whitney U test and Kruskal-Wallis Test, respectively. The data was, hence, presented as median. For categorical data, the Chi-Square test was performed for the comparisons between groups. All statistical analyses were done using specific computer program statistical package. P values less than 0.05 were accepted to be significant.

RESULTS AND DISCUSSION

Demographics of Subjects

The demographic characteristics of midwives ($n=36$) and puerperal women ($n=227$) are outlined in Tables 1 and 2, respectively. The midwives questioned age, job experience, and education level, whereas the puerperal women asked about age, job, residential address, and education level.

Table 1. Demographic Characteristics of Midwives

Demography	N=36
Age (mean \pm SEM)	35.19 \pm 1.34
Job experience (years)	13.20 \pm 1.55
Education level (n (%))	
High School (lycee)	6 (17)
Associate degree (graduated from 2-year university)	8 (22)
Bachelor's degree (graduated from 4-year university)	21 (58)
Postgraduate degree (master's or doctorate)	1 (3)

Knowledge of Subjects

Regarding the knowledge section, the average total point of the midwives (median: 6) was significantly higher than that of the puerperal women (median: 1) (Mann-Whitney U test: $Z = -10.170$, $P = 0.0001$). Further analysis concerning the effect of education levels of the midwives on the total points showed no statistically significant difference between subgroups (Kruskal-Wallis Test, $X^2 = 1.313$, $P = 0.519$) (Figure 1).

Table 2. Demographic Characteristics of Puerperal Women

Demography	N=227
Age (mean±SEM)	28.48±0.42
Job (n (%))	
Housewife	207 (92)
Other (Civil servant, Worker, Teacher, Accountant etc.)	20 (8)
Education level (n (%))	
None	13 (6)
Primary school	67 (30)
Secondary school	71 (32)
High School (lycee)	57 (24)
University	19 (8)
Residential address (n (%))	
City	143 (63)
Town	70 (31)
Village	13 (6)

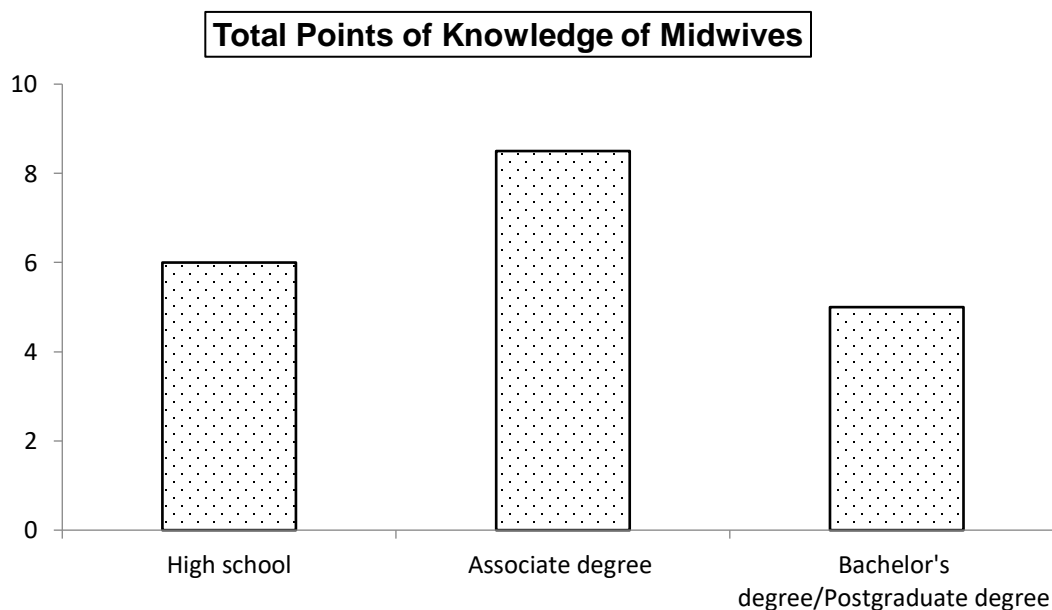


Figure 1. Total Points of Knowledge of the Midwives According to Their Education Level are Presented. Kruskal-Wallis Test is Performed, and the Data are Expressed as a Median.

Table 3. Responses of Subjects to Questions in the Knowledge Section

Number	Questions	n (%) of Yes		Chi-square	P
		Midwives (n=36)	Puerperal women (n=227)		
1	Have you heard the term adverse drug reactions (ADRs)?	36 (100)	116 (51)	30.459	0.0001
2	Have you heard the term pharmacovigilance?	35 (97)	5 (2)	217.543	0.0001
3	Are you aware of the Turkish Pharmacovigilance Center (TPC)?	29 (81)	2 (1)	182.117	0.0001
4	Can midwives directly report ADRs to TPC?	22 (61)	0 (0)	143.518	0.0001
5	Can patients directly report ADRs to TPC?	6 (17)	1 (0.5)	25.625	0.0001
6	Are you aware of the ADRs reporting form?	21 (58)	1 (0.5)	128.413	0.0001
7	Can this form be obtained from internet sources?	13 (36)	0 (0)	78.721	0.0001
8	Can this filled form be sent to TPC by post?	12 (33)	1 (0.5)	64.720	0.0001
9	Can this filled form be sent to TPC by e-mail?	14 (39)	1 (0.5)	78.408	0.0001
10	Can this filled form be sent to TPC by fax?	9 (25)	1 (0.5)	44.745	0.0001
11	Can ADRs be reported to TPC online?	11 (31)	1 (0.5)	57.983	0.0001
12	Can ADRs be reported to TPC by phone?	10 (28)	1 (0.5)	51.322	0.0001
13	Can unwanted effects due to cosmetic products be sent online?	10 (28)	2 (1)	45.629	0.0001
14	Can ADRs due to vaccines be reported?	15 (42)	2 (1)	78.877	0.0001
15	Are congenital anomalies and/or birth defects included in ADRs?	5 (14)	1 (0.5)	25.208	0.0001
16	In how many days should ADRs be reported?	1 (3)	0 (0)	1.120	0.290

Although all midwives knew the term ADR, only half of the puerperal women stated that they had heard it (Table 3). The awareness of the pharmacovigilance term was 97% and 2% in the midwives and the puerperal women, respectively (Table 3). Similarly, 81% of the midwives were aware of the Turkish Pharmacovigilance Center (TPC), whereas only 1% of the puerperal women realized the fact (Table 3). Among 29 midwives who were aware of TPC, 22 knew they could directly report ADR to TPC (Table 3).

Table 4. Responses of Subjects to Questions in the Attitude/Practice Section

Questions	n (%) of Yes		Chi-square	P
	Midwives (n=36)	Puerperal women (n=227)		
Have you previously reported ADRs to TPC?	3 (9)	0 (0)	12.459	0.0001
If yes, what was the reason(s)?				
ADR was not mentioned in the short product information	0 (0)	0 (0)	-	-
ADR was serious	0 (0)	0 (0)	-	-
I wanted to share my experience	0 (0)	0 (0)	-	-
I was worried about my health/patient's health	1 (3)	0 (0)	1.120	0.290
I wanted an intervention performed.	0 (0)	0 (0)	-	-
No comment	2 (6)	0 (0)	6.412	0.011
If not, what was the reason(s)?				
ADR was already mentioned in the short product information	5 (13)	1 (0.5)	25.208	0.0001
ADRs were not quite serious	8 (22)	1 (0.5)	38.259	0.0001
I was not interested in reporting ADRs	0 (0)	0 (0)	-	-
I did not feel confident in analyzing the relationship between the drug and the side effect	2 (6)	0 (0)	6.412	0.011
Reporting ADRs is unnecessary	1 (3)	0 (0)	1.120	0.290
ADR reporting system was time-consuming and impractical	0 (0)	0 (0)	-	-
No comment	17 (47)	225 (99)	106.948	0.0001

In addition, 21 out of 22 were aware of the ADR reporting form (Table 3). Thirteen of 21 midwives reported that this form could be obtained from internet sources (Table 3). According to the responses of 21 midwives to the questions regarding the way of transmitting reporting forms, sending by e-mail, by post and online were the most ranked options compared to the others (Table 3). Ten out of 21 midwives reported that unwanted effects due to cosmetic products could be sent online (Table 3). According to five midwives, congenital anomalies/birth defects were included in ADRs (Table 3). There was only one midwife who exactly knew the fact that ADRs should be reported in a maximum of 15 days (Table 3). As the percentages of correct responses of the puerperal women to the questions regarding the term pharmacovigilance (2%) and the existence of the Turkish Pharmacovigilance Center (TPC) (1%) were extremely low, the remaining dependent questions were not asked to the most of the subjects (See Table 3 for the shallow values).

Attitude/Practice of Subjects

The critical question of this section was that we asked if they had previously reported an ADR to TPC. Three out of 36 midwives were affirmative, while 33 were adverse to this question (Table 4). One midwife stated that she was worried about her

health/patient's health, so she sent a report to TPC (Table 4). Most of those who have not made a report (17 midwives) had no comment, while others declared a few reasons (Table 4). None of the puerperal women reported an ADR, and almost all had no comment about their attitude (Table 4). Only the first two options were selected by two subjects apart from each other (Table 4).

The primary finding of the present study was that the knowledge level of the midwives, even if insufficient, was significantly higher than that of the puerperal women. Secondly, most midwives were aware of ADR, pharmacovigilance, and TPC. In contrast, there were problems regarding how reporting could be done and the types of ADRs midwives would preferentially report. Thirdly, almost none of the midwives reported an ADR in the past, and most had no opinion about the issue. Finally, as consumers, puerperal women were totally out of the play, according to the results.

Although total points gained from the knowledge section by the midwives were relatively low (Figure 1), high response rates of the questions regarding the terms ADR (100%) and pharmacovigilance (97%) and the existence of the TPC (81%) indicated that most midwives were aware of the pharmacovigilance concept and the heart of the system established in Turkey. Additionally, more than half of the midwives knew that they could directly report ADRs to TPC (61%) and were aware of the ADR reporting form (58%) (Table 3). In a previous study conducted on Turkish nurses and midwives (as a combined single group), 44.7% of the subjects claimed to know pharmacovigilance, 24.3% of them acknowledged the necessity of reporting the adverse reactions to a centre, and only 13.1% of them were aware of the ADR reporting form⁴. These results are far below ours, and the difference does not seem to result from the demographic variations as the features of the volunteers of the two studies were almost identical. Probably, during the ten years after this previous study (conducted in 2010), nurses and midwives would have been able to get much more information about pharmacovigilance and gain a significant amount of experience regarding the system in Turkey. A recent study carried out in Ethiopia showed that 20.18%, 30.70% and 22.81% of the healthcare professionals (nurses, physicians, pharmacy professionals, health officers, and midwives) knew the term pharmacovigilance, the responsible body that monitors ADR in Ethiopia, and availability of ADR reporting forms, respectively⁵. Although midwives of the study constituted 8.8% of these healthcare professionals, knowledge levels regarding the latter parameters were lower than our subjects. This difference may result from Turkey's more advanced health and pharmacovigilance system than Ethiopia. Expressly, 48% of the midwives of another study declared that they had heard about the term pharmacovigilance⁶.

All these satisfactory answers to the questions mentioned above of the present study refer to a good level of a theoretical state of the issue; however, responses to the questions regarding the practical aspect of the pharmacovigilance system were problematic. For instance, only 36% of the midwives knew the internet sources essential for obtaining ADR reporting forms (Table 3). Among those who knew the existence of the form, most did not know the sending methods of the filled forms (Table 3). The lack of knowledge regarding this issue is the main reason for underreporting ADRs among midwives. Nevertheless, the order of preference of the midwives was as follows: by e-mail, by post, through online submission, by phone, and by fax (Table 3). Similarly,

79.82% of the Ethiopian healthcare professionals, including midwives, did not know how to report⁵.

According to the Turkish pharmacovigilance system, unwanted effects due to cosmetic products can be sent online, and only 28% of the midwives were aware of that (Table 3). In addition, 42% of the midwives realized that reporting ADRs due to vaccines, which is also legally up to Turkish midwives, is possible (Table 3). Interestingly, only 14% of the midwives knew that congenital anomalies/birth defects were included in ADRs (Table 3), whereas 42.11% of the Ethiopian healthcare professionals knew that teratogenic phenomena should be reported⁵. As healthcare workers close to pregnant and puerperal women, one would expect the midwives to have sufficient knowledge about and sensitivity toward the reactions of teratogenicity.

In contrast to a previous study wherein 76.74% of the nurses/midwives reported ADRs that they encountered⁶, only three midwives in the present study (9%) stated that they had previously reported ADRs to TPC. One of them declared that she was worried about her patient's health, so she sent the report (Table 4). On the other hand, among those who did not send any report in the past, the opinion that ADRs were already mentioned in the short product information, ADRs were not entirely serious, and reporting ADRs unnecessarily put them off from reporting (Table 4). Similar reasons were stated by the nurses/midwives of another study conducted in Côte d'Ivoire, a sub-Saharan African country⁶. Furthermore, two midwives in our study stated that the lack of confidence in analyzing the relationship between the drug and the side effect prohibited them from reporting it (Table 4). Ethiopian healthcare professionals also mentioned the same reason as one of the leading discouraging factors contributing to underreporting⁵.

The first step to improving the pharmacovigilance system is to educate the healthcare professionals properly. Without a well-designed education, healthcare professionals cannot get involved in the pharmacovigilance system, generate a positive attitude towards the concept of pharmacovigilance, and play an influential role in ADR reporting. Thus, most studies revealed that most healthcare professionals pointed out the potential of educational interventions as a fostering factor in ADR reporting^{9,10}. Education methods can be modified depending on the audience, conditions, and resources. Principally, conventional lecturer-based education could be given to undergraduate and graduate students with different origins. The positive effects of pharmacovigilance education on students of different origins have been widely demonstrated^{11,12,13,14}.

Additionally, postgraduate training courses such as lectures and workshops may be a good option for those who actively deal with patients. Thus, an active intervention with a seminar presentation followed by a passive year-long regular intervention (monthly broadcast of text messages) was effective in healthcare professionals¹⁵. In support of this, an educational intervention improved the community pharmacists' pharmacovigilance knowledge and attitude scores in a previous study¹⁶. Accordingly, acquiring knowledge by education was found to have a statistically significant association with ADR reporting in a previous study⁵. In addition to education programs, promotional documents regarding the national pharmacovigilance system could be given out to individual staff by clinical pharmacologists or pharmacovigilance contact points of the hospitals. Consultations regarding causality assessment of ADRs and ADR reporting are one of the primary duties of clinical pharmacologists. However, regulatory

authorities associated with the national pharmacovigilance system should support and promote clinical pharmacologists to perform these activities. To motivate the staff, some kind of incentives in association with ADR reporting could be put in place by the respective departments of the governments. Moreover, attaining the reporting forms, filling them out, and sending them to the relevant units should be as practical as possible to decrease the additional workload of the healthcare professionals⁸.

As to puerperal women, the shallow total point gained from the knowledge section demonstrated that this type of consumer is not ready to get involved in the pharmacovigilance system in Turkey. It is known from previous studies that ADR underreporting is inversely related to the health care professionals' knowledge and attitude⁵. This golden principle seems to be proved for Turkish consumers of the present study as they did not know anything about pharmacovigilance and hence could not generate any attitude towards the issue. Consumers worldwide have been evaluated and found to rarely report ADRs in most countries due to a lack of knowledge and positive attitude⁷. Suppose the governments and the other stakeholders desire to promote consumers to get involved in the pharmacovigilance system. In that case, they have to develop various methods to educate these potential reporters regarding pharmacovigilance and the system in their countries. As puerperal women are in close contact with midwives, increasing the knowledge of these healthcare workers and certifying them as validated trainers for pregnant and puerperal women could be a rational strategy for achievement. Besides, public service announcements broadcast on TV could be very efficient as Turkish consumers spend their most of time watching television. In addition, informing cards about pharmacovigilance and ADR reporting tools given out to the consumers in outpatient or inpatient clinics may reveal a significant contribution to the system.

The study's main limitation is that the sample sizes of the study groups are not big enough to adequately represent the universes of midwives and puerperal women and arrive at definite conclusions. However, the results may be utilized for future meta-analyses that would draw an accurate picture of the topic.

To be a performer in pharmacovigilance, one should first gain adequate knowledge about the topic and then generate a sensitive attitude towards the issue. In the present study, it was shown that neither the midwives nor the puerperal women showed any signs of sufficient knowledge about the topic and considerable attitude. Therefore, regulatory authorities and other stakeholders should make a great effort to train those who are permitted to report ADRs. However, all the interventions should be performed in a determined and perpetual manner.

CONCLUSION

Although Turkish midwives' knowledge, attitude, and practice were significantly better than puerperal women regarding pharmacovigilance, it is apparent that both groups were insufficient to get involved in the pharmacovigilance system properly. Therefore, proper measures may be enacted to drive these subjects' attention to the issue.

ACKNOWLEDGEMENT

The study was conducted without any funds obtained. One of the co-authors, i.e. Eylem Toker, moved from Kahramanmaraş Sütçü İmam University to Tarsus University after the completion of the study. Therefore her current address is as follows: Tarsus University, Faculty of Health Sciences, Department of Midwifery, Mersin/Turkey.

CONFLICT OF INTEREST

There is no conflict of interest.

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