Observational Study

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Obstetrician–gynecologists' perspectives towards medication use during pregnancy

A cross-sectional study

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Abstract

A vast majority of studies evaluated pregnant women's knowledge and attitudes towards using medications during their pregnancy, with few global and lack of regional studies conducted to spot obstetrician-gynecologists practices in this regard. This study aims to assess Obstetrician–gynecologists' knowledge of medication teratogenicity potential, their frequently used resources, and their residency training contribution to medication use during pregnancy. This is a cross-sectional, survey-based study targeting licensed Obstetrician–gynecologists who are practicing in Saudi Arabia using a validated self-administered web-based questionnaire developed by the American College of Obstetricians and Gynecologists. A total of 60 obstetrician-gynecologists were included in the study. Most participants were female (72%) with median age and clinical experience of 42 and 13 years, respectively. The majority (87%) agreed that Isotretinoin is contraindicated, while around 60% of respondents were unsure about the safety of herbal remedies use. Online databases (e.g., Lexi-Comp and Micromedex) were chosen as the top utilized medication resources (45%). Around 48% strongly agreed that liability is a concern if there were adverse pregnancy outcomes following the use of medications. Regarding their training assessment, obstetrician-gynecologists who had been in practice for more than 15 years were significantly more likely to rate themselves as well qualified (*P* value < .05). The majority adequately and significantly rated their training on prescribed medications (58.3%), OTC medications (45%) and dietary supplements or herbal remedies (32%) (*P* value < .05). Obstetrician–gynecologists showed a different level of knowledge about the risks and safety of medications when used during pregnancy. More efforts are needed to optimize medication selection, herbal avoidance, and training performance.

Abbreviations: FDA = Food and Drug Administration, OTC = over-the-counter.

Keywords: attitude, gynecologist, knowledge, medication, obstetrician, teratogenicity

1. Introduction

Pregnant women undergo unique physiological changes that may affect the pharmacokinetic properties of various medications.[1] Around 40% of pregnant women uses either over-the-counter (OTC) or prescribed medications during their pregnancy to treat chronic or acute conditions, such as nausea, vomiting, diabetes, asthma, and hypertension.[2,3] Pharmacological agents contribute to significant, preventable congenital abnormalities, leading to a rise in public health concerns about using medications during pregnancy.[4] To produce such an effect, the medication must possess certain properties that allow it to cross the placenta, including but not limited to being unbound, weak base, lipid-soluble, and having a low molecular weight.[1] Also, the fetus's stage of development is a crucial point to consider when using medication during pregnancy.[1]

Most pregnant women know that medication use during pregnancy is paramount, which leads them to seek medical advice before taking any medication.[2] A vast majority of studies evaluated pregnant women's knowledge and attitudes towards using medicines during their pregnancy.[2,5–7] One of which was conducted in Saudi Arabia in 2014, which concluded that women claim to receive inadequate medication-related information from physicians and pharmacists; instead, they rely on medication leaflets to attain such information.[2]

Obstetrician–gynecologists are frequently faced with inadequate and imprecise information to make decisions for clinical management.[8] Although some medications' teratogenicity

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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potential is well known, there is limited information on the safety of many other medications used during pregnancy due to ethical considerations. Pregnant and lactating women are typically excluded from clinical trials.[9] A study published in 2010 in the United States examined Obstetrician–gynecologists' knowledge and informational resources regarding the safety of medication use during pregnancy. Results showed that the number of years in practice was associated with their response choice to medication safety questions. Most responders indicated sufficient access to helpful information regarding medication teratogenicity potential. However, more than half of the participants selected the lack of a single comprehensive source of information as the most significant barrier.[8] Another study evaluating community pharmacists' knowledge about medication safety during pregnancy in Saudi Arabia found a significant difference between age groups and country of graduation in knowledge test scores.[10]

To the best of our knowledge, no studies were conducted to spot the knowledge of Obstetrician–gynecologists in Saudi Arabia and their access to information about the risks of medication use during pregnancy. Such a study is highly warranted due to the physicians' knowledge and practice's effect on the patients' health. For that, this study aims to assess Obstetrician–gynecologists' knowledge of the medication teratogenicity potential, their frequently used resources, and their residency training contribution to medication use during pregnancy.

2. Materials and methods

The present study is a cross-sectional, survey-based study targeting licensed obstetrician-gynecologists practising in Saudi Arabia. Saudi and non-Saudi practitioners were eligible to fill out the questionnaire. Over 6 months, data were collected using a validated self-administered web-based questionnaire developed by the American College of Obstetricians and Gynecologists.[8] The questionnaire is organized into 5 domains. The first domain (7 items) includes the participants' demographic data. The second domain focused on assessing the knowledge about prescription medications, OTC, dietary supplements, and herbal products in the first trimester (23 items). The third domain was about the references used to obtain appropriate and updated information on medication use during pregnancy (15 items). The fourth domain was to demonstrate the physician's attitudes toward medication use during pregnancy (6 items). The last domain was regarding the rating of the participant's training in medication use during pregnancy (6 items). The questions utilized in the questionnaire included multiple choice, check all that apply, Likert-like scale, and fill-in-the-blank questions. With almost 350 clinicians registered as Obstetrician–gynaecologist specialists or consultants in Saudi Arabia, the sample was calculated to be 184 with a 95% confidence interval and 5% confidence level) as follow:

$$SS = \left[Z^2 p\ (1-p)\right] / C^2$$
$$= \left[(1.96)^2 \text{x}\ 0.5\ (1-0.5)\right] / (0.05)^2 = 384.16$$

$$SS/[1 + \{(SS1)/Pop\}]$$
$$= 384.16/[1 + \{(384.161)/350\}] = 184$$

King Saud University Medical City's Institutional Review Board approved this study (19/0929). Following ethical approval, an online survey was sent to the department of Obstetrics & Gynecology in 6 large hospitals around the Kingdom to be distributed among their employees. Reminders were sent to non-responders, and visits were conducted to some sites with low response rates.

Data were analyzed using SPSS version 25. Categorical variables were presented as numbers and percentages, while continuous variables were presented as mean and SD if normally distributed. However, if not normally distributed, median and IQR were used. Shapiro–Wilk test was used to assess for normal distribution. Analyses were tested for significance using an α of 0.05.

3. Results

A total of 60 obstetrician–gynecologists, completed the survey, with a response rate of 33%. The flowchart for the inclusion and exclusion process is shown in Figure 1. Most participants were female (72%), with a median age of 42. The median years of practice among the participants were 13 years. Around 40% were full-time hospital practitioners, and most (85%) were working in the central region (i.e., Riyadh). Seventy per cent of the participants reported providing routine care/gynecologic exams. Characteristics of participants included in the study are presented in Figure 2 and Supplemental Digital Content (Appendix 1, http://links.lww.com/MD/H763).

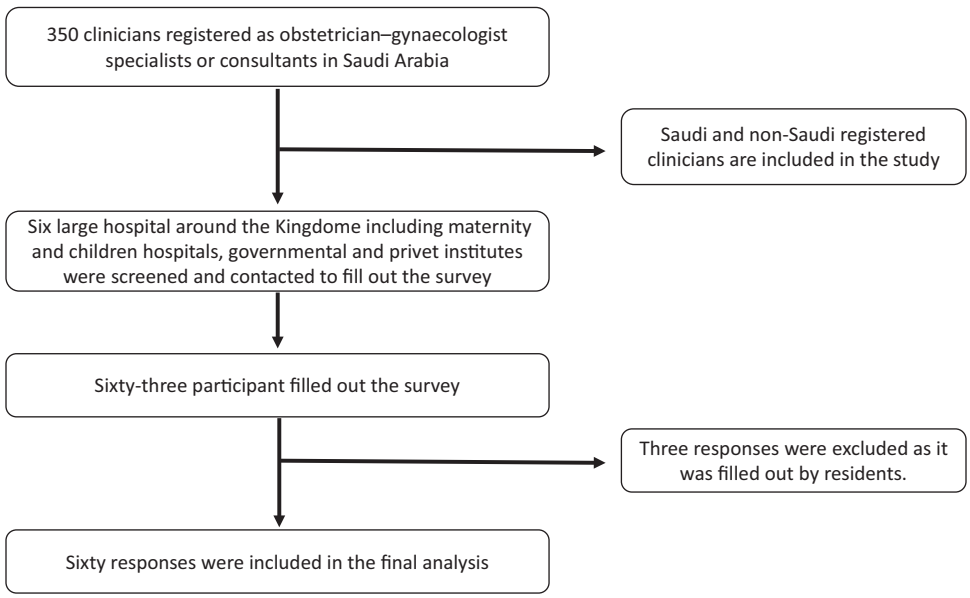

Figure 1. Flowchart for the inclusion and exclusion process.

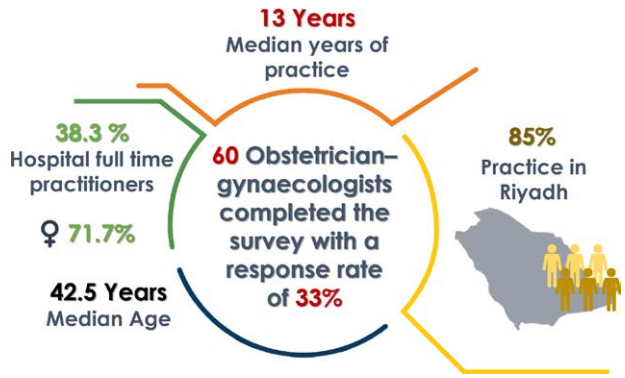

Figure 2. Participants' demographic characteristics.

3.1. Assessment of medication use during the first trimester of pregnancy

Participants' assessment of 23 selected medications regarding fetus safety if taken during the first trimester is presented in Supplemental Digital Content (Appendix 2, http://links.lww.com/MD/H764). Regarding prescription medications (Fig. 2), the majority (87%) agreed that Isotretinoin is contraindicated. However, 8.3% of them were not sure. For Alprazolam, 25% considered it unsafe, 35% indicated that it required a risk-benefit assessment, and 30% were unsure. Most participants (76.7%) consider acetaminophen safe to use. Regarding dietary supplements (Fig. 3), 75% stated that vitamin A supplements are not safe during the first trimester. Around 2-thirds (60%) of respondents were unsure about the safety of herbal remedies during pregnancy.

3.2. Information resources utilized by obstetrician-gynecologists

Regarding the information resources used to answer questions, online databases (e.g., Lexi and Micromedex) were chosen as the top resources utilized by obstetrician-gynecologists to obtain information about the teratogenicity of medications (45%), followed by pharmacist consultation, FDA label, and colleagues' conversation (21.7%). Further information is provided in Table 1.

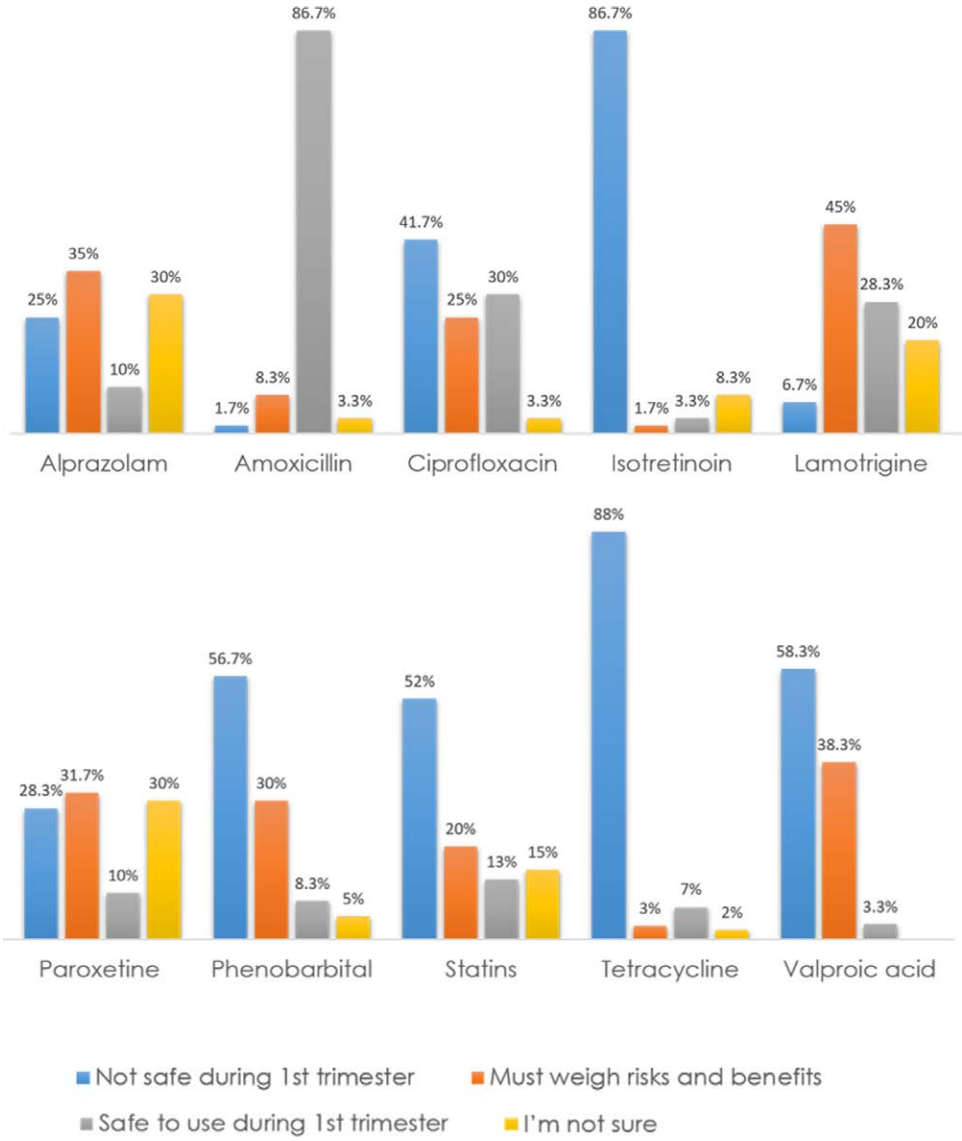

Figure 3. Assessment of prescription drug use during the first trimester of pregnancy.

Table 1

Information resources utilized by obstetrician–gynecologists.

Source	Always	Usually	Most often	Not used
Physicians' desk reference (PDR)	20	26.7	8.3	45
ACOG publications	18.3	33.3	33.3	15
Other books (most of these wrote "Briggs's drugs in pregnancy and lactation")	18.3	21.7	26.7	33.3
Consultation with genetic counselor	6.7	20	58.3	15
Package insert	8.3	30	26.7	35
Online sources (such as UpToDate, ePocrates, Reprotox, Micromedex, Lexicomp)	45	43.3	11.7	0
Journal articles	13.3	35	18.3	33.3
Conversation with colleagues	21.7	38.3	25	15
Pharmacist	21.7	40	18.3	20
Teratology information service	16.7	21.7	15	46.7
Educational seminars, meetings, or CME activities (not sponsored by pharmaceutical companies)	13.3	28.3	26.7	31.7
Centers for Disease Control and Prevention (CDC)	18.3	21.7	20	40
Pharmaceutical manufacturer or its representative	11.7	20	16.7	51.7
Food and Drug Administration (FDA)	21.7	38.3	25	15
Pharmaceutical-sponsored seminars, meals, meetings, or other activities	8.3	13.3	21.7	56.7

ACOG = American college of obstetricians and gynecologists.

3.3. Obstetrician–gynecologists' attitudes toward medication use during pregnancy

A Likert-Like scale was used to assess the proportion of obstetrician-gynecologists agreeing or disagreeing with various statements related to the information on the use of medications during pregnancy. Forty-eight per cent strongly agreed that liability is a concern if there were to be an adverse pregnancy outcome following the use of medications. Additionally, 41% agreed on the lack of sufficient information about the safety of medication use during pregnancy, while 31% reported a lack of accessibility to the available information. Interestingly, 26.7% reported a lack of time to communicate the information available to patients as one of the drawbacks. Additional details are provided in Table 2.

3.4. Obstetrician–gynecologists' rating of their training

Participants were asked to rate their training on medication use during pregnancy, and the results are presented in Table 3. Those who had been in practice for more than 15 years were significantly more likely to rate themselves as well qualified (P-value < 0.05). The majority adequately and significantly rated their training on prescribed medications (58.3%), OTC medications (45%) and dietary supplements or herbal remedies (32%) (P value < .05).

4. Discussion

To our knowledge, this is the first study in the nation that assesses Obstetrician–gynecologists' knowledge of medications' teratogenicity potential as well as the impact of their residency training on their decisions. The resources routinely used were also assessed.

For a medication to be desirable, it must fulfill the following criteria: safe, effective, and indicated.[11] During pregnancy, women should refrain from taking medications as much as possible due to the teratogenicity risk. However, certain medical conditions require urgent or ongoing treatment, and deciding to use them is not without apprehension.[1] Thus, obstetrician-gynecologists play a vital role in identifying when medications are warranted and which are safe to be given during each trimester, in addition to adequately counseling patients.

To assist in decision-making, the Food and Drug Administration (FDA) formerly stratified the medications' teratogenic effects into 5 categories (i.e., A, B, C, D, and X), possessing fewer safety profiles when moving downwards. However, it is challenging to assess the risk-benefit ratio using this classification. In 2015, the FDA updated their pregnancy and lactation rule to overcome this issue.[12] Nevertheless, even with the new FDA stratification, it is extremely challenging for physicians to make treatment decisions in this population. That is due to the diversity in fetal damage manifested in the same medication when taken at different trimesters,[1] and the exclusion of pregnant women from clinical trials due to ethical considerations, leaving great uncertainty.[13,14] Therefore, safety information is commonly obtained from other sources such as animal experiments, nonclinical data, case reports, and epidemiological data,[13] of which possess abundant limitations, adding to the ambiguity of treatment decisions in this population.

In this study, the participant's level of knowledge regarding medication teratogenicity potential was assessed and revealed a great variation. Most respondents reported inaccessibility to current information about medication teratogenicity risk and a lack of sufficient data, emphasizing the need for updated, accessible references to aid clinical decisions. A multidisciplinary team including clinical pharmacists in the services of Obstetrics and Gynecology as medication specialists would be of great benefit.

Table 2

Proportion of obstetrician-gynecologists agreeing or disagreeing with various statements.

Statement	Strongly agree (%)	Agree (%)	Neutral (%)	Disagree (%)	Strongly disagree (%)
Liability is a concern if there were to be an adverse pregnancy outcome following the use of medications	48.3	38.3	13.3	-	-
There is a lack of sufficient information about the effects of medications on the fetus	21.7	41.7	16.7	13.3	6.7
It is difficult to interpret the information that is available about the effects of medications on the fetus	10	31.7	21.7	28.3	8.3
It is difficult to communicate the information that is available in a way that patients will understand	8.3	26.7	21.7	31.7	11.7
There is not enough time to adequately communicate the information that is available to patients	10	26.7	23.3	28.3	11.7
There is a lack of access to current information about the effects of medications on the fetus	15	31.7	10	26.7	16.7

Table 3

Obstetrician–gynecologists' rating of their training.

How well do you feel your training and experience qualify you to manage the following?			
	Well qualified	**Somewhat qualified**	**Not qualified**
Medication prescribing during pregnancy	58.3	36.7	5
Counseling regarding teratogenic exposure	46.7	45	8.3
Prenatal testing after teratogenic exposure	21.7	48.3	30

How would you rate your residency training regarding the teratogenic potential of?					
	Comprehensive	**Adequate**	**Barely adequate**	**Inadequate**	**Non-existent**
Prescription medications	26.7	58.3	10	5	0
OTC medications	21.7	45	25	3.3	5
Dietary supplements or herbal remedies	15	31.7	25	21.7	6.7

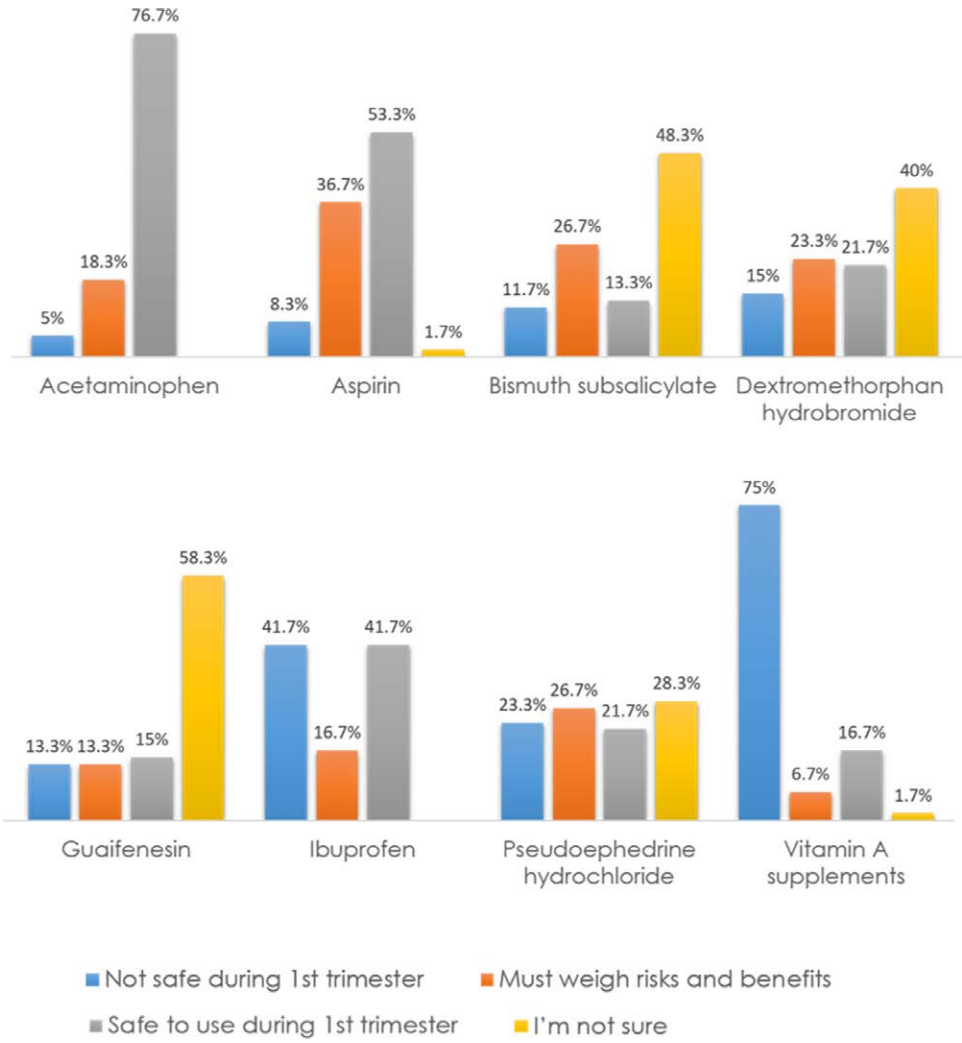

Figure 4. Assessment of nonprescription drug use during the first trimester of pregnancy.

Clinical pharmacists' contributions to the field were reported in the literature, highlighting their role in preventing the incidence of toxicity and death.[15] Their expertise allows them to help select appropriate medications and adequately counsel patients regarding the safety of different treatment modalities, dietary supplements, and herbals. That was supported by previous evidence, where they found clinical pharmacy services in Obstetrics and Gynaecology were associated with a high level of physician satisfaction and better patient care.[16]

When assessing participants' knowledge about the safety of medications in the first trimester, the vast majority reported that Isotretinoin is contraindicated and acetaminophen is safe, which is consistent with the published literature.[8,17–19] On the contrary, results varied with Alprazolam. That may be attributed to the weak level of evidence and lack of consensus on its effect on the fetus.[20,21] Nevertheless, since Alprazolam falls into Category D and may be detrimental to the fetus, prospective studies with a large sample size to assess its effect may be difficult to conduct.

Moreover, 75% of responders stated that Vitamin A dietary supplements are not safe in the first trimester, which is far higher than a study conducted amongst community pharmacists, in which 48.4% reported it unsafe.[22]

As for the safety of herbals, participants showed a lack of sufficient knowledge of their use in this patient population. This uncertainty is alarming as the use of herbal medicine prevalence in pregnant women in the Middle East ranges from 7% to 55%.[10] These medications may harm the mother and child; thus, healthcare practitioners' education is essential in this regard as it also contributes to proper patient education.

Several limitations exist in our study. The response rate remained low despite many reminders and visits to our participants. That may be justified by the Obstetrician–gynecologists' high-load nature of practice and busy service, hindering the data collection process. In addition, most responders were from the central region, affecting the results' generalizability. Since the study used self-administrated questionnaires, desirability bias may arise. It is also important to note that there was no way of determining whether or not responders used their actual knowledge or used reference sources when filling out the questionnaire. A nationwide, paper-based study is recommended to overcome the limitations mentioned above and confirm the results of this study.

5. Conclusions

Our study found that Obstetrician–gynecologists vary in their knowledge about medication and herbal remedies' teratogenicity risk. These findings highlighted the need to emphasize this during their training year and the importance of having this information readily available to health care providers in an updated form.

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Visualization: Mashael Alshebly and Abdullah M. Mubarak.
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Writing – review and editing: Bana Almadi and Abdulrahman Alwhaibi.

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