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ORIGINAL ARTICLE

Identification of At-risk Pregnant Population for Over-the-Counter Drug Usage in Low-Resource Settings

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Abstract

Objective Nearly 1.5 billion people of an Asian country are living their lives without a country-specific over-the-counter (OTC) drug list. A study was planned to assess the understanding and practice of OTC medication consumption in the pregnant population.

Methods A questionnaire-based cross-sectional study evaluating different perspectives on OTC drug consumption was planned in around 500 pregnant women attending tertiary care outpatient antenatal clinics. The association of knowledge, attitude and practice versus indications, knowledge regarding harmful effects possible, reasons for choosing OTC medication, the practice of consulting nonmedical persons and drug interactions with the disease or prescription medications was determined. Regression analysis was performed in statistical software R.

Results Seven percent (36/516) of pregnant women were found to consume oral antimicrobials without prescription. Local chemist consultation was the most common channel (72.48%) to procure the OTC medicines. Participants with good knowledge score showed an odds ratio (OR) of 1.87 (95% C.I.; 1.28–2.73), 1.6 (95% C.I.; 0.99–2.63), 1.66 (95% C.I.; 1.14–2.42) and 2.66 (95% C.I.; 1.49–4.89) for self-medication encouragement tendency possible, restricting sale of OTC medications, the habit of reading drug leaflets and understanding the potentially harmful effects, with OTC drugs, respectively. Right-attitude participants showed an OR of 1.89 (95% C.I.; 1.29–2.80) and 1.8 (95% C.I.; 1.19–2.76) for identifying knowledge of acetaminophen overdose and liver damage link as well as the disease symptom masking possibility with OTC, respectively. Participants with insufficient knowledge and attitude scores showed an association with more OTC antacid-antiemetics and analgesic use, respectively.

Conclusion Antenatal pregnant women need to be guided on avoiding OTC antimicrobial usage. Both obstetricians and regulators have to play an active role in educating pregnant women and contributing to developing country-specific OTC drug lists with the guidelines.

Keywords Over-the-counter medicines · Pregnancy · Pharmacoepidemiology · Knowledge · Attitude · Practice · Developing country

Introduction

Are all nonsteroidal anti-inflammatory drugs (NSAIDs) completely harmful during pregnancy? Do all of them have any association with fetal organogenesis? Questions such as these remain unanswered to date. The reason may be the near-absence of randomized controlled trials, of over-the-counter (OTC) medications or other prescription medicines, in pregnant women. Furthermore, drug safety and efficacy results are primarily extrapolated from studies conducted on nonpregnant populations [1–3]. The patients and physicians often refer to health information websites for drug use or prescription, where

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usage in pregnancy and lactation information remains varied [4, 5]. Till recently, more than 60% of all available drugs were classified as Pregnancy Category C, with inadequate detailing on medication safety. It led to the Pregnancy Lactation Labelling Rule (PLLR) formulation and development in the USA in the last five years while the topic is still unattended by Indian regulatory [1].

During pregnancy, common medical complaints remain heartburn, nausea, vomiting, backache and constipation, requiring careful selection of medicines. Analgesics and drugs used to treat skin, respiratory and gastrointestinal disorders form a significant chunk of OTC drugs consumed during pregnancy [6]. It has been observed that over 90% of women take medications during pregnancy [7], and the fact that India does not have its own OTC drug list and regulatory guidance creates a potentially risky scenario [8]. Moreover, the communication gap between the central and state drug licensing authorities, coupled with patients' preference to obtain cheaper drugs from chemist consultation, further worsens this situation [9, 10]. Implementing a short bridge course for pharmacists is underway in India, leading to a possible increase in pharmacist consultations and OTC drug consumption [11]. Developed countries such as the USA maintain yearly data on OTC drug sales and consumption rate, which is not standard practice in India [12]. Hence, a study was planned to assess current perceptions regarding OTC usage in pregnant women visiting antenatal clinics.

Materials and Methods

The current study presents a cross-sectional analysis of pregnant women who visited antenatal clinics at the Department of Obstetrics and Gynaecology, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India. Institutional Ethics Committee with permission No. INT/IEC/2019/001,760 dated August 28, 2019. Written informed consent was obtained from the study participants. First-trimester pregnant women visiting antenatal outpatient clinics on all weekdays between 8 AM and 2 PM were included without any specific exclusion criteria. The study was conducted within three months, from September 1, 2019, to November 30, 2019. Each interview, on average, lasted for 10 min.

The participants were interviewed using a self-designed knowledge attitude and practice questionnaire. In the questionnaire, section 'A' had the necessary details regarding the 'participants' age and obstetric history, such as gravida, parity, abortion and living children. Sections B, C and D contained four, five and two questions pertaining to knowledge, attitude and practice, respectively: knowledge questions were assessing participants understanding about the meaning of OTC medications, understanding of critical timing regarding usage of OTC in pregnant women, population in which OTC should be used carefully, awareness regarding potential of paracetamol to cause liver damage; attitude questions were assessing opinion regarding the requirement of oral antimicrobials to be made available without prescription, statement regarding the link of drug intake in pregnancy to fetal malformations, idea regarding the propensity of OTC to encourage self-administration, opinion regarding the safety of OTC drugs during pregnancy, statement regarding placement of restriction for buying OTC drugs during pregnancy; practice questions were assessing about the practice of reading accompanying drug leaflets with medicines, practice with relation to OTC intake when confronted with illness during pregnancy. Section E presented four practice-related exploratory questions. It assessed the information regarding the personnel consulted for making decisions on OTC drug dosage, common reasons for taking OTC without a 'doctor's prescription, awareness regarding potentially harmful effects with OTC usage, and understanding the class of drugs used during pregnancy. Sections B, C and D allowed the participants to select only one option, whereas section E allowed multiple options. The full details of the questions with their respective options are available in Supplementary Table 1. The same questionnaire was later built in Epicollect 5 (https://five.epicollect.net/) software [15].

Data Collection and Coding

The responses to the questions based on knowledge, attitude and practice were coded as 0 or 1, wherein a higher value was assigned to the better/right answer. The coding pattern for each question is mentioned in supplementary Table 1. KSum, ASum and PSum were planned intermediate variables calculated by summing up the responses to the questions on knowledge, attitude and practice. Since the number of items varied between the three categories of knowledge, attitude and practice, we divided KSum, ASum and PSum by the total number of questions in the respective categories to determine each category's unit value. The same was referred to as average KSum, average ASum and average PSum, respectively. Antenatal women were divided into two groups, namely women with a score greater than or equal to the average denoted as 'GENA' and women with a score less than the average denoted as 'LNA'.

Since the questions concerning knowledge were used to classify the same antenatal women into GENA and LNA, we omitted the knowledge domain questions during the knowledge association model development. A similar methodology was adopted for the other models as well.

Statistical Analysis

Keeping the population size as one crore with a 4.5% error, 95% confidence interval and 10% dropout rate, we computed a sample size of 523 participants using SurveyMonkey online sample size calculator (https://www.surveymonkey.com/mp/sample-size-calculator/). The formula used by the software for the calculation is

$$\text{sample size} = \left[z^2 * p * (1-p)/e^2\right] \Big/ \left[1 + \left(z^2 * p * (1-p)/e^2 * N\right)\right],$$

where N stands for the population size, e stands for the margin of error (in percentage) and, z stands for the z-score.

The statistical analysis was performed using the *R* statistical software (version 3.6.1) [13]. Other than the base package, ggplot2, sjPlot, reshape2 and ez were used as well [16–19]. Continuous variables have been expressed as mean ± S.D., while categorical variables have been expressed as the number and percentages. The Chi-square test was employed to compare the categorical variable. The variables that turned significant in the univariate analysis were included to construct the binomial logistic regression model. For all the analyses, the p value of < 0.05 was considered as statistically significant.

Results

Five hundred sixteen agreed for the interview out of 560 women asked for the study participation and included in the final analysis. The reasons for not agreeing to participate were lack of time, household works, childcare and unwillingness to participate.

The summary of the recorded responses is presented in Table 1. The mean ± S.D. of average knowledge, attitude and practice of the women participating in the study was 0.36 ± 0.22, 0.78 ± 0.23 and 0.44 ± 0.38, respectively. We divided the study population into GENA and LNA groups based on the value of 0.36 for knowledge, 0.78 for attitude and 0.44 for practice.

A significant number of participants (47.1%) opted not to go for OTC medications during pregnancy. Analgesics were the OTC medications with the highest consumption rate (26.6%). Antimicrobials, herbal medicines and anticough drugs were consumed at 7%, 5% and 5% frequencies, respectively. The description of practice-related exploratory questions can be found in Table 2.

The univariate analysis results of attitude with practice against the knowledge domain, practice with knowledge against attitude domain and knowledge with attitude against the practice domain are presented in supplementary Table XXX2. Additionally, the univariate analyses of indications for OTC medication use, knowledge regarding harmful effects possible with OTC medication, reasons for choosing OTC medication and consulting persons for taking OTC drugs against the knowledge and attitude domains are presented in supplementary Table 3. The nonmedical person here referred to family, friends and chemists related to the study participants.

Association of Knowledge

The participants who felt that OTC drugs could encourage self-medication had 1.87 (95% C.I.; 1.28–2.73) times association with GENA in knowledge. The participants who felt that there should be a restriction on OTC drugs' sale showed 1.6 (95% C.I.; 0.99–2.64) times association with GENA in knowledge compared to those who felt that there should not be a restriction on OTC sale. However, the odds ratio remained statistically insignificant. The participants who had a regular habit of reading the drug leaflet while taking OTC drugs from chemist shops demonstrated 1.66 (95% C.I.; 1.14–2.42) times association with GENA in knowledge. The participants who understood different ways of manifestation of OTC drugs' harmful effects had 2.66 (95% C.I.; 1.49–4.89) times association with GENA in knowledge compared to those who could not understand the same. The study participants' multigravida status showed 0.49 times (95% C.I.; 0.29 – 0.82) times association with LNA in the knowledge domain compared to the primigravida (Fig. 1a).

The participants who consulted their families had 1.76 (95% C.I.; 1.14–2.75) times association with GENA in knowledge compared to those who did not consult their families. The participants who knew facts, such as OTC drugs can lead to overdose, change the effect of already prescribed medications and mask the symptoms of the disease, had 1.76 (95% C.I.; 1.21–2.56), 1.85 (95% C.I.; 1.26–2.72) and 1.72 (95% C.I.; 1.18–2.52) times association with GENA in knowledge compared to those who did not know, respectively. Participants who were taking OTC antacids and antiemetics demonstrated 0.3 (95% C.I.; 0.15–0.56) times negative association with GENA in knowledge in comparison with those who were not taking these drugs (Fig. 2a).

Association of Attitude

Similar to the results noted for the knowledge domain, the participants who understood the harmful effects of OTC drugs had 2.28 (95% C.I.; 1.16–4.89) times association with GENA in attitude. The participants who could identify liver

Table 1 Description of the recoded responses

Category	Recoded variables			
	0	1	2	3
General question				
Time period	–	216 (41.86%)	194 (37.60%)	106 (20.54%)
Knowledge domain				
KQ1	474 (91.86%)	42 (8.14%)	–	–
KQ2	256 (49.61%)	260 (50.39%)	–	–
KQ3	347 (67.25%)	169 (32.75%)	–	–
KQ4	239 (46.32%)	277 (53.68%)	–	–
Attitude domain				
AQ1	104 (20.16%)	412 (79.84%)	–	–
AQ2	85 (16.47%)	431 (83.53%)	–	–
AQ3	239 (46.32%)	277 (53.68%)	–	–
AQ4	41 (7.95%)	475 (92.05%)	–	–
AQ5	94 (18.22%)	422 (81.78%)	–	–
Practice domain				
PQ1	271 (52.52%)	245 (47.48%)	–	–
PQ2	305 (59.11%)	211 (40.89%)	–	–
Practice-related questions				
Consultation	486 (94.19%)	30 (5.81%)	–	–
Reasons	486 (94.19%)	30 (5.81%)	–	–
Harmful effects	451 (87.40%)	65 (12.60%)	–	–
Indications	429 (83.14%)	78 (15.12%)	9 (1.74%)	–

Table 2 Descriptive of the practice-related exploratory questions

Options	Response	
	No	Yes
Consultation		
Chemist	142 (27.52%)	374 (72.48%)
Family	397 (76.94%)	119 (23.06%)
Drug leaflet	364 (70.54%)	152 (29.46%)
Friends	492 (95.35%)	24 (4.65%)
Reasons		
Convenience	286 (55.43%)	230 (44.57%)
Cause less side effects	346 (67.05%)	170 (32.95%)
Distance	312 (60.47%)	204 (39.53%)
Finances	452 (87.60%)	64 (12.40%)
Harmful effects		
OTC drugs can lead to overdose	271 (52.52%)	245 (47.48%)
OTC drugs produce may not produce therapeutic effect	413 (80.04%)	103 (19.96%)
OTC drugs can change the effect of already prescribed drugs	314 (60.85%)	202 (39.15%)
OTC drugs can mask the symptoms of the disease	310 (60.08%)	206 (39.92%)
Indications		
Anti-cough	446 (86.43%)	70 (13.57%)
Multivitamin and herbal	462 (89.53%)	54 (10.47%)
Antibiotics	436 (84.50%)	80 (15.50%)
Antacids and antiemetics	457 (88.57%)	59 (11.43%)
Pain killers	379 (73.45%)	137 (26.55%)
No medicine if your pregnancy is first time	273 (52.91%)	243 (47.09%)

damage as a possible side effect of acetaminophen showed 1.89 (95% C.I.; 1.29–2.80) times association with GENA in attitude compared to those unaware of its side effects. Only these two features were included in the final developed model of attitude (Fig. 1b).

The participants who knew that OTC drugs could mask the disease's symptoms had 1.8 (95% C.I.; 1.19–2.76) times association with GENA in attitude. The participants who were taking analgesics as OTC had 0.46 (95% C.I.; 0.30–0.70) times negative association with GENA in the attitude domain than those who were not taking these drugs (Fig. 2b).

Association of Practice

The participants who felt that OTC drugs could lead to self-medication encouragement had 1.94 (95% C.I.; 1.30–2.92) times association with GENA in practice. The participants who could identify populations vulnerable to OTC drugs'

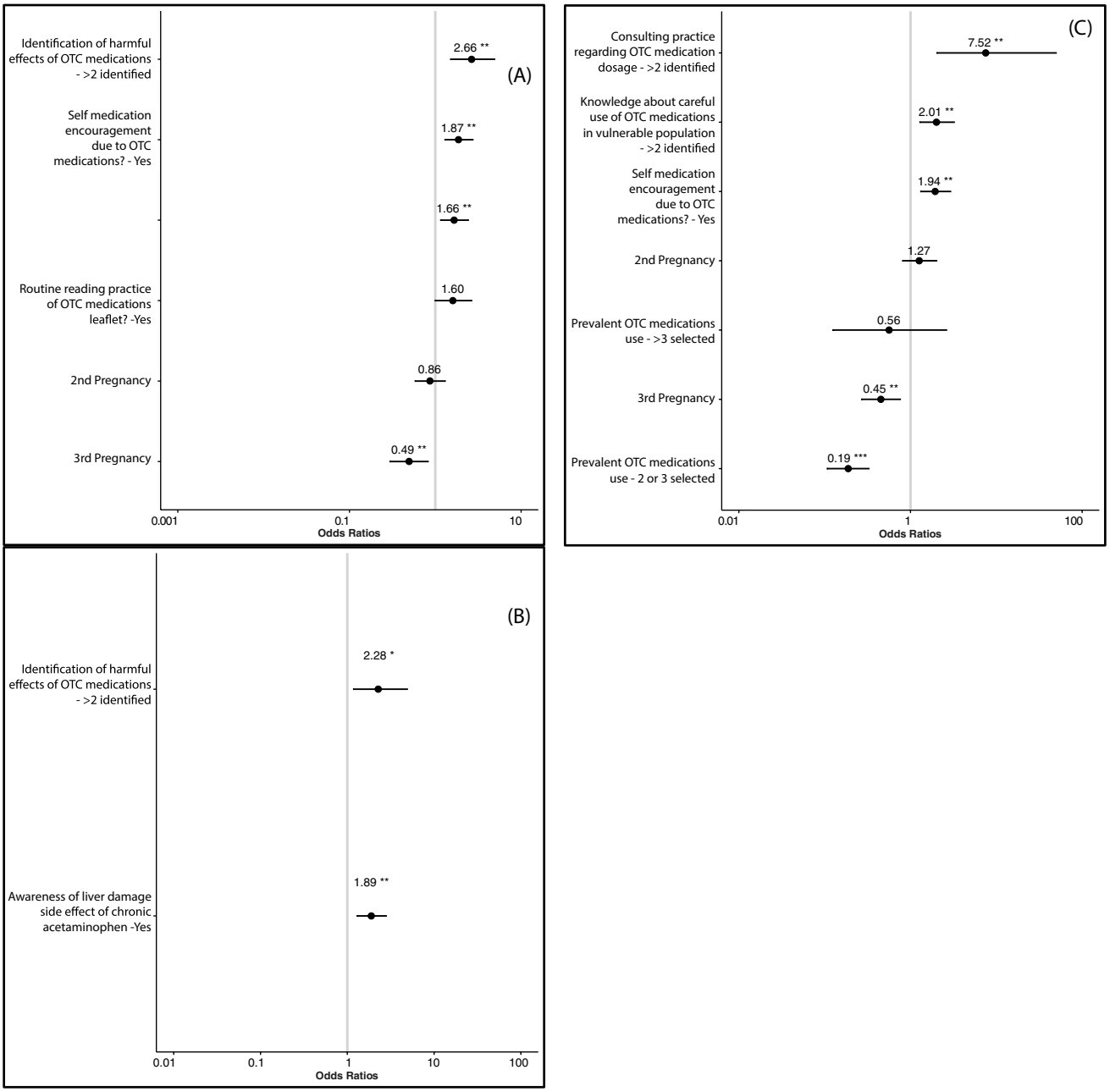

Fig. 1 Pictorial representation of the odds of the binomial logistic regression of knowledge, attitude and practice domains. *$p < .05$. **$p < .01$, ***$p < .001$

side effects showed 2.01 (95% C.I.; 1.27–3.22) times association with GENA in practice compared to those who could not. The participants who had the habit of consulting > 2 nonmedical persons for OTC drug usage demonstrated 7.52 (95% C.I.; 2.02–49.53) times association with GENA in practice. Moreover, the participants using OTC medications for 2–3 indications had 0.19 (95% C.I.; 0.11–0.33) times negative association with GENA in practice compared to those using a single OTC medication. Similarly, the participants using OTC medications for ≥ three indications had 0.56 (95% C.I.; 0.12–2.62) times negative association with GENA in practice compared to those using a single OTC medication and the odds did not turn statistically significant in this regard (Fig. 1c).

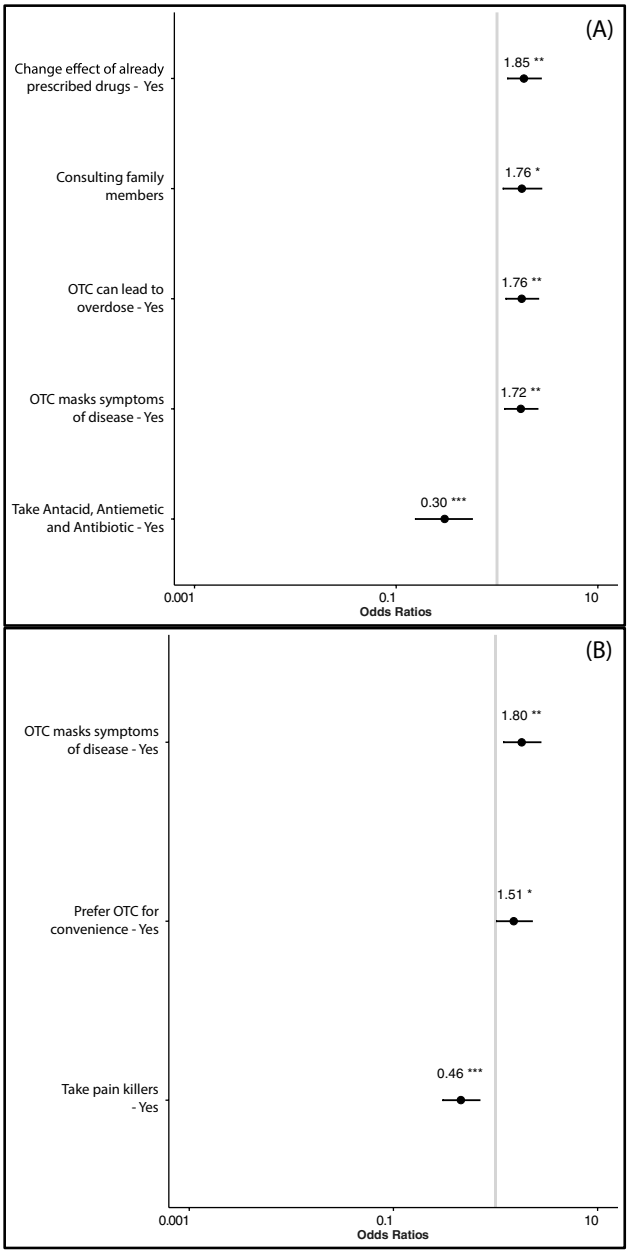

Fig. 2 Pictorial representation of the odds of the binomial logistic regression of knowledge, attitude and, practice against the practice-related exploratory questions. *$p < .05$. **$p < .01$, ***$p < .001$

Discussion

The study was carried out to understand the over-the-counter (OTC) medication consumption practices and educational interventions possible with simple select questions in the future [8]. According to a recent newspaper survey, 52% of Indians self-medicate using oral antimicrobials. Common antimicrobials found in current survey were ciprofloxacin, erythromycin and azithromycin. Wide antimicrobial use without prescription was reported for dermatological indications in a recent Indian survey [8]. There exists absolutely no check on the number of prescription-only drugs or the OTC drugs being sold daily in India [20]. The results go hand in hand with the results of the UAE and Italian study [21, 22]. The general purpose of OTC drugs is to self-medicate for common ailments. Our research showed that a significant proportion of pregnant women (47.1%) were not inclined toward taking OTC drugs. It indicates that the women are well aware of the effects of these subsets of drugs and know their responsibilities during pregnancy. Similar findings were reported by Navaro et al. in Italy, where only 50 percent of pregnant women consume OTC medications [22]. Present study women opted for analgesics as the commonest OTC drug consumed. Simultaneously, there were 5–7% of the population opting for oral antimicrobials and anti-cough medications without prescriptions. The study observed a lower analgesic consumption rate (55%) than a study by Abdulkarem et al. conducted in Sharjah UAE. The UAE study did not evaluate OTC antimicrobials during pregnancy [21].

The present study's novelty lies in collecting the reasons for opting the OTC drugs. The results showed that distance and finance were the common reasons. The choices presented were convenience, distance, financial aspects and fewer side effects of OTC drugs. In India, people do consult a pharmacist at the chemist shop while taking medicines without a prescription. Pharmacies (chemist shops) in India are either private or affiliated to hospitals and sell the medication at varied rates [22]. On the other hand, India's government is proposing a short bridge course for pharmacists to train them to prescribe drugs [23].

The population with a good knowledge score agreed that OTC drugs could encourage self-medication. A cough syrup used by one family member may not suit the other, or a different dose may be required [24]. It may lead to repetitive behavior of health-related decision making, worsening the underlying clinical condition or adverse drug-related events [25]. With a particular focus on cold and cough

syrups, almost 340 Indian fixed-dose combinations (FDC) medicines had come under legal ambit, thereby banned [7]. The effects of cough syrups on the fetus are unclear. Respiratory depression and the fetoplacental vasculature's constriction are mentioned in the literature with codeine and pseudoephedrine [26]. Debatable evidence exists for the development of fetal gastroschisis with pseudoephedrine during pregnancy [27].

With the evidence suggesting an average intake of 2.5 OTC drugs by a pregnant woman, the study shows that pregnant women with a good knowledge score believed in government restrictions on OTC drug sales. [27] Also, the habit of reading the drug leaflet or the cover information was found to be associated with good knowledge and practice scores. This habit of reading accompanying drug leaflets was earlier reported in 70% of his study population by Abdulkarem et al. [2] The link between absorption of clay from a antidiarrheal drug into the systemic circulation and iron deficiency anemia is well established. Reading the package leaflet information may alert pregnant women using antidiarrheal like kaolin.[29].

Participants identifying the link between chronic acetaminophen consumption and hepatotoxicity bore a good attitude score. Acetaminophen was the most commonly used NSAID during pregnancy for pain relief [21, 30]. Despite its commonness, a study by Kasaaw and Wabe in Ethiopia observed that the knowledge of the study population regarding such analgesics was significantly low [30]. Paracetamol is the analgesic of choice among NSAIDs, followed by Ibuprofen [21]. In the present study, participants with a good attitude score could identify self-medication encouragement as a possibility with OTC drug use and the vulnerable population subgroups to the adverse effects of OTC medications. Almost 98% of the existing drugs are not tested on pregnant women before drug approval leading to inaccurate dosage and consequences possible [31, 32].

Consulting more than two nonmedical individuals before taking an OTC drug was significantly associated with a good practice score in the present study. The study further tried to dissect the types and the role of a nonmedical person in OTC consultation and found that the family member consultation was strongly linked with OTC drug use. It can be justified as family member commonly renders caregiving [33]. A similar finding by Kline et al. in the USA saw consultation from friends and family for OTC drug information [34]. Cognizance of the OTC drug effects on other concurrent medicines and ongoing illnesses was strongly linked with adequate knowledge, attitude and practice scores. It can be considered a representative question of all three domains and can be utilized by clinicians in their practice and researchers in their future studies. The habit of taking oral antacids and antiemetics from the chemist shop without a prescription was strongly linked to lesser knowledge.

Limitations

The OTC antimicrobial use was not stratified further. The present questionnaire, as well as the results, needs to be validated in other healthcare settings. The questionnaire used here in the present study was lucid and straightforward. Thus, we did not feel the necessity of reliability study on questionnaire instrument.

Conclusion

Antimicrobial use without a prescription that too in vulnerable section of population is a grave concern identified by this study. A simple, cost-effective pharmacoepidemiological tool in the form of a questionnaire can help obstetrician colleagues strengthen their patient care quality. Clinical pharmacology, community medicine and obstetric departments need to attend this call. In short, a road map for educational intervention among antenatal women and regulatory decision making is built herewith. A combined roundtable conference between the obstetricians, regulatory and the population representation can help the OTC medication list and guidance document development.

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Declarations

Conflict of interest The authors declare no conflict of interest.

Human or Animal Rights Yes. The study received approval from the Institutional Ethics Committee with permission No. INT/IEC/2019/001760 dated August 28, 2019.

Informed Consent Written informed consent was obtained from the study participants.

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