

Rationale Treatment of GERD During Pregnancy: A Prescription Audit Using WHO Core Drug use Indicators

GUL E NAZISH¹, MAHREEN AKHTAR², SUMETHA YASEEN², AYESHA NAZIR KHOKHAR³

¹Assistant professor Pharmacology, Amna Inayat Medical College

²Lecturer Pharmacology, University of Health Science, Lahore

³Student MBBS, Sheikh Zayed Medical College Rahim Yar Khan

Corresponding author: Gul e Nazish, Email: Gulnazish999@gmail.com, Cell: 03324642961

ABSTRACT

Background: GERD is a common condition worldwide. It is also frequently seen during pregnancy due to hormonal changes and increasing intra-abdominal pressure. Treatment is usually focused on resolving symptoms. In this regard life style modification and pharmacological interventions are done. But prescribing during pregnancy is a risk benefit condition. Irrational prescribing is a routine practice nowadays. Prescribing during pregnancy needs more care. To avoid hazards associated with irrational prescribing WHO has developed five indicators.

Aim and objective: This study was designed to find out prescription mistakes during pregnancy using WHO core drug use indicators. To provide clinicians with prescribing guidelines in order to avoid future discrepancies while prescribing.

Method: It was a cross sectional study. Data was obtained from outpatient obstetric departments and analyzed.

Result: Antacids, PPIs, Ranitidine and metoclopramide were frequently used drugs. All drug classes are present in essential drug list of Pakistan 2021. Only 8% of the total drugs were prescribed by generic name. Number of drugs per encounter was minimum 5%. Number of injections per encounter was also within standard range 23%. About 20% of prescription were expensive which is a high cost for an under developing country like Pakistan.

Practical implication: Good prescribing puts positive impact on patient's physical and mental health.

Conclusion: There should be a shift of prescription from brand name to generic name. Control of prescription cost is another issue highlighted. WHO core drug use indicators are only limited to outpatient Departments. These are of limited value for in doors patients where drug prescriptions are more complex.

Keywords: Drug use WHO Drug use, GRED, Pregnancy, Pakistani Women

INTRODUCTION

Gastroesophageal reflux disease or "Heartburn" is a common complaint during pregnancy. It can be seen in almost 80% of the pregnancies. GERD usually develops at the end of the first trimester and progress as pregnancy proceeds^{1,2}. Symptoms of GERD become worse with the passage of time until the end of 3rd trimester. Reason might be the hormonal changes during pregnancy and intra-abdominal pressure of growing uterus. Although symptoms usually resolve after delivery, about 20% of women continue to experience GERD symptoms even after the pregnancy. GERD is also linked with the severity of nausea and vomiting during pregnancy³. Effective management of GERD symptoms is important to improve quality of life. Some guidelines suggest diet and lifestyle modifications; and the use of medications to treat GERD symptoms⁴. Therefore, use of drugs to control GERD is an essential part of prescription in obstetrics settings. Most commonly used drugs in this situation are alginic acid, calcium- and magnesium-based antacids, ranitidine, and metoclopramide and proton pump inhibitors. However, drug prescription during pregnancy is an additional risk-benefit situation. According to reports published in literature more than 90% of the drugs approved by the FDA have insufficient data to determine safety of these drugs in pregnancy⁵. Irrational use of drugs is a serious problem worldwide. The overuse, underuse or misuse of drugs results in endless menace. These include poly-pharmacy, inadequate dosage, over-use of injections and a prescription not matching clinical guidelines⁶. Therefore, it is important to put special attention on writing a prescription for a pregnant woman. We designed this study to evaluate the prescription errors while prescribing for pregnant females using WHO core drug use indicators. Our aim was to identify the mistakes regarding use of drugs during pregnancy and to provide right information to clinicians in order to overcome future discrepancies.

MATERIALS AND METHODS

It was a cross sectional study based on retrospective data inclusion from November 2020 to September 2022. Data was obtained from Sir Ganga Ram Teaching Hospital Lahore and Kishwar fazal teaching hospital Sheikhpura. Sample size was 1996 pregnant female prescriptions from outpatient obstetric

department. Informed consent was taken. Confidentiality regarding patient's data was assured. Participants with history of acid peptic disease were also included in the study.

Participants were within age range of 18-42 years with mean age of 29 years. 45 % of participants were of 3rd trimester, 36% were 2nd trimester and 19% were of 1st trimester. WHO core drug use indicators were used to analyze prescription for GERD medications⁷. Indicators were

1. Average number of GERD medications per prescription
2. Percentage of GERD drugs prescribed by generic name
3. Percentage of injections per prescription
4. Percentage of drugs prescribed from the EDL⁸
5. Cost of drugs per prescription

Data analysis: Data was compiled in Microsoft excel. Descriptive analysis was done with the help of Graph Pad prism 6. Results of each parameter were expressed in terms of percentages.

RESULTS

1996 prescriptions were evaluated. Out of 1996 prescriptions 10% (n=200) were prescribed by professors, 22% (n=439) were prescribed by associate professors, 21% (n=419) by assistant professors, 25% (n=499) by Sr. registrar/registrar, 22% (n=437) by medical officers.

Treatment: 5% (n=100) of the participants were advised life style modifications only. 28% (n=558) were prescribed antacids salts of aluminum and magnesium, 40% (n=799) were prescribed PPIs, 16% (n=319) were prescribed ranitidine h2 receptor blocker, 11% (n=219) were prescribed metoclopramide a pro-kinetic agent.

Number of drugs per encounter: 85% (n=1700) participants were prescribed single agent to control GERD symptoms while 5 % (n=99) were given two drugs. 5% (n=103) were prescribed three drugs.

Prescription with generic name: Out of all drugs only 8 % (n=160) were prescribed with generic names.

Number of injections per prescription: 52% (n=1037) were prescribed with oral route. 23% (n=480) were given by IV route, 19% (n=380) were given IM, 6% (n=119) by transdermal patch.

Cost of prescription: 42% (n=839) of the drugs were low price. 38% of the drugs were medium price, 20 % drugs were of high cost.

Table 1: Patients Demographics

Mean Age of the pregnant females n=1996	Trimester		
	1st	2nd	3rd
29 years	20 %	30%	50%

Table 1 shows Demographic data of pregnant females with mean age and number of pregnancy trimester. Where n= 1996

Table 2: Prescribers detail

Prescriber	Percentage of Prescription n=1996
Professor	10% (n=200)
Associate professor	22% (n=439)
Assistant professor	21% (n=419)
Senior registrar	25% (n=499)
Medical officer	22% (n=437)

Table 2 shows prescriber's data where n = number of patients 1996

Table 3: Treatment t of GERD

Life style modifications	Antacids	PPIs	Ranitidine	Metoclopramide
5%	28%	40%	16%	11%
n=100	n=558	n=799	n=319	n=219

Table 3 shows percentage of the drugs prescribed where n=1996

Table 4: Number of drugs per encounter

Single drug	Two drugs	Three drugs	Standard	Generic name	Standard
85%	5%	5%	4 drugs per prescription	8 %	100%

Table 4 shows Number of GERD drugs per prescription where n = 1996

Table 5: Number of injections and prescription with generic name:

Oral	IV	Standard IV	IM	Transdermal	% from essential drug list	Standard
52%	23%	13.4 -24.1 %	19%	6%	8 %	100%

Table 5 shows percentage of route of administration used/number of injections used where n = 1996

Table 6: Cost of prescription

Low cost	Medium cost	High cost
42%	38%	20%

Table 6 shows cost of prescription

DISCUSSION

To investigate the drug use in health care settings, the WHO has established five core prescribing indicators. These indicators aim to measure the performance of health-care professionals in several important areas related to appropriate or rational use of drugs. These indicators have been developed by the WHO after observing prescribing practices at outpatient facilities for the treatment of acute and chronic illnesses.

According to data we obtained Patients were advised life style modifications and pharmacological interventions to control GERD symptoms. Antacids, Proton pump inhibitors, Histamine receptor blockers and pro-kinetic agent like metoclopramide were used.

Use of Antacids is said to be first line therapy after life style modification fails. Salts of aluminum and magnesium are beneficial to neutralize the acid produced by gastric parietal cells. However a pregnant woman must be aware of potential adverse effects regarding over dose of Antacids.⁹

Histamine receptor blockers like ranitidine are considered relatively safe drugs during pregnancy.¹⁰ Proton pump inhibitors were most frequently prescribed drugs in our data. PPIs are considered category B drugs while omeprazole is considered as category C drug. Although PPIs are reported to be associated with increased risk of preeclampsia no potential congenital defects have been seen with the use of PPIs during pregnancy as per literature review.¹¹ In a nutshell, All of these medications are safe and effective during pregnancy.²

Number of dugs per prescription is an important indicator of rational drug use. Increasing number of drugs per prescription can

increase cost of prescription and also results in drug –drug interactions. When pregnancy is in consideration more caution is required. In our study only 5% of subjects were prescribed two or three drugs for GERD respectively which is closely related to standard 1.6 -1.8 per encounter/Four drugs per prescription.^{12,13,14}

According to WHO core drug use indicators prescribing with generic name should be 100%. In this study we find out only 8% of the drugs were prescribed drugs by generic names. Prescription by brand name has been strictly forbidden in 1976 Drug Act of Pakistan. Prescribing drugs with generic name needs to be brought in practice. It will promote local manufacturing rather than imported drugs ultimately lower down cost of prescription. But quality of drug is still a question mark by local manufacturers.¹⁵

High percentage of injections per prescription is also an irrational use of drugs. Percentage of injections used was 23% which is within the standard range of 13.4% -24%. All drugs were prescribed from National essential drug list 2021 of Pakistan except Antacids.⁸

Pakistan has almost more than 600 drug manufacturing units and 88,000 registered medicinal products. It is the huge number of drug products among underdeveloped countries. Because number of pharmaceutical companies is large, the competition is severe and many companies use unethical promotional tools and activities to gain a market share. To get maximum financial benefit from pharmaceutical companies, doctors prescribe the maximum number of drug products and sometimes expensive medicines, which is another contributing factor to increases the cost of prescription.¹⁶⁻¹⁷ We find 20 % of the prescription expensive which is high rate for an under developing country like Pakistan.

CONCLUSION

We concluded that drugs used to control GERD symptoms in pregnant females were safe and effective. However only 8% of these drugs were prescribed by generic name which is an attempt to promote specific brands. Drugs were chosen from essential drug list generated by Pakistan drug regulatory authority except Antacids. Number of injection use was also limited but cost of prescription rate was slightly high. We use WHO core drug indicators to pick out prescribing mistakes. Good prescribing always puts a healthy physical and mental impact on patients. But these indicators are limited to outpatient departments only. They are not useful for in doors where use of drugs is more complex.

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