Assessment of Health Disorders and Drug Use Pattern Among Pregnant Women at Tribhuvan University Teaching Hospital, Nepal

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Abstract

To assess the different types of health disorders that are more frequent during the pregnancy and drugs prescribed for the management of those disorders are of the safest category and in practice considering the risk to benefit ratio. Also, to find out the extent to which the drugs prescribed are adhered to WHO prescribing indicators. It was an observational cross-sectional study. Data collection sheets were filled by the direct questionnaire and the prescription paper. The drugs were evaluated from WHO core prescribing indicators. Among the total of 141 pregnant women, the maximum number were from the age group 20-25 years. The average number of drugs received during pregnancy is 3.25 per prescription. Whereas the percentage of the drug prescribed by generic name and essential drug list were found to be 26.1 and 56.64, respectively. The most frequently prescribed drug was from the USFDA safe category i.e. category B (53%) and only 2% of drugs were prescribed from category X. Most of the medicine was prescribed listed in the National essential drug list. Deviation was observed in terms of prescription of injection and drugs with a generic name. Contraindicated medicines during pregnancy were almost absent in this study. Pregnant women who appeared during the duration of the study with the health disorder were treated with the appropriate drugs considering the risk to the benefit ratio. However, to assure the rational drug prescription the prescription audit should be carried out at regular intervals.

1 Introduction

The presence of antigen (HCG) in the urine or serum either polyclonal or monoclonal available commercially by 8-11 days after conception ensures pregnancy1. The physiological changes in the body and the safety concern of the fetus challenges clinicians managing disease states during pregnancy in the selection of medications. Drug use during pregnancy may lead to the teratogenic risk to the fetus2.

The pregnancy is measured in terms of trimester counting from the first day of the last menstrual period. The first trimester consists of the first 1-12 weeks of pregnancy. The second trimester consists of 13-28 weeks of pregnancy. The Third trimester consists of 29-40 weeks of pregnancy. During the first trimester, morning sickness is inconsistently present in about the maximum of the cases. In the second trimester, an active fetal movement is felt by women and due to the growing uterus, the lower abdomen enlarges progressively3.

In 1979, The U.S. Food and Drug Administration established five letter risk categories – A, B, C, D and X to indicate the potential of a drug to cause birth defects if used during pregnancy. Category A is considered the safest category and category X is contraindicated in the pregnancy4.

The world health prescribing indicators are assessed as 1) An average number of drugs per prescription 2) Percentage of drug prescribed by generic name 3) Percentage of prescriptions with antimicrobial(s) prescribed, 4) Percentage of prescription with injection(s) prescribed and 5) Percentage of the drugs prescribed from an essential drug list5. National list of essential medicines, Nepal (2016), was used to find out the percentages of drugs prescribed from the lists6.
Nearly 18.5% of the diseases among women of reproductive age are related to pregnancy-related complications and deaths due to those complications are higher in developing nations. Nepal has a maternal mortality ratio of 170 per 100,000 live births which is one of the worst figures in South Asia. In 2013, complications of pregnancy resulted globally in 293,000 deaths, down from 377,000 deaths in 1990.

The most common causes of maternal mortality are maternal bleeding, maternal sepsis, hypertensive disease of pregnancy, obstructed labor, and pregnancy with abortive outcome. Approximately 2.4% of newly born babies have some form of birth defects. Less than 1% is linked to exposure to medications during pregnancy. There is the absence of adequate studies on the safety and effectiveness of the prescription drugs for pregnant women and the evidence available shows that physicians prescribe, and pregnant women take drugs surprisingly in large amounts. So, our study aims to find out the pattern of health disorder and evaluate the safety of the drugs prescribed.

2 Materials and Methods

2.1 Study design

It was an observational cross-sectional study that was conducted in the Department of Obstetrics and Gynecology of Tribhuvan University Teaching Hospital (TUTH), Maharajgunj, Kathmandu, Nepal for 2 months i.e. from February to March 2018. Demographic profiles along with the parity, present, and history of pregnant women were recorded from prescription.

2.2 Inclusion and Exclusion criteria

The pregnant women who visited the hospital during the study duration and presented with at least one newly diagnosed complication were included in the study with written consent. Any patient coming for follow up weren’t included in this study to avoid the repetition of prescription.

2.3 Ethical Clearance

The study was approved by the Institutional Review Committee (IRC) of Institute of Medicine (IOM), Tribhuvan University.

2.4 Study tool

Prescription obtained was sorted and classified in accordance with USFDA risk classification for pregnancy. The drug was evaluated from WHO core prescribing indicators. A Pre-structured questionnaire was asked to the patients during the data collection method from the datasheet.

2.5 Statistical Analysis

Data analysis was done in a statistical package for social sciences (SPSS) software version 20.0.

3 Result

3.1 Demographic Data

3.1.1 Age

Table 1 shows that the pregnant women who were at the age group of 20-25 years were maximum i.e. 37.6% and (36-40) years were minimum.

Table 1: Age group of pregnant women

| Age group (yrs) | Percentage % |
|----------------|--------------|
| 15-19          | 8.5          |
| 20-25          | 37.6         |
| 26-30          | 36.2         |
| 31-35          | 15.6         |
| 36-40          | 2.1          |

3.1.2 Education status of the patient

The majority of the pregnant women were literate (97.2%) and only 2.8% were illiterate as shown in Table 2.

Table 2: Education status of pregnant women

| Education      | Percentage (%) |
|----------------|----------------|
| Illiterate     | 2.8            |
| Below SEE      | 36.2           |
| SEE            | 28.4           |
| Intermediate   | 17.7           |
| Bachelor       | 10.6           |
| Masters        | 4.3            |

3.2 Trimester of pregnancy

Of the total 141 pregnant women, 40.4% were at their 2nd trimester followed by 30.5% at the 3rd trimester as shown in Table 3.

Table 3: Trimester of pregnancy

| Trimester     | Percent (%) |
|---------------|-------------|
| (1-3) mths    | 29.1        |
| (4-6) mths    | 40.4        |
| (7-9) mths    | 30.5        |

3.3 Obstetrics history of the patient

It was observed that 47.5% were primigravidae followed by second, third, and fourth gravida accounting for 32.6%, 19.1%, and 0.7% respectively. Similarly, more than half of the patients were nulliparous comprising 58.9% of the total cases whereas...
31.9%, 8.5%, 0.7% of patients were of first, second and third parity respectively. The detail of gravida and parity are shown in table 4.

Table 4: Obstetrics history of the patient

| Gravida | Percent (%) |
|---------|-------------|
| Primigravida | 47.5 |
| Second | 32.6 |
| Third | 19.1 |
| Fourth | 0.7 |

| Parity | Percent (%) |
|---------|-------------|
| Nulliparous | 58.9 |
| First | 31.9 |
| Second | 8.5 |
| Third | 0.7 |

3.4 Health disorder among pregnant women

Among the various complication, the most common are Hyperemesis gravidarum and Gastritis during 1st trimester, Urinary tract infection during 2nd trimester, and Itching during the 3rd trimester of the pregnancy. Different types of health disorder complaints and their distribution according to the trimester are given below in Table 5.

Table 5: Health disorder among pregnant women

| Complication          | 1st (n) | 2nd (n) | 3rd (n) | Total (n) |
|-----------------------|---------|---------|---------|-----------|
| Hyperemesis gravidarum | 10      | 1       | 2       | 13        |
| Loss of appetite      | 2       | 2       | 1       | 5         |
| Irritable bowel disease | 1     | 2       | 0       | 3         |
| Anemia                | 3       | 2       | 2       | 7         |
| Thrombocytopenia      | 0       | 1       | 1       | 2         |
| PV bleeding           | 1       | 1       | 2       | 4         |
| Itching               | 1       | 3       | 6       | 10        |
| Gastritis             | 10      | 8       | 1       | 19        |
| Hypothyroidism        | 3       | 2       | 3       | 8         |
| GDM                   | 0       | 1       | 3       | 4         |
| Hypertension          | 2       | 1       | 4       | 7         |
| Preeclampsia          | 0       | 0       | 1       | 1         |
| Hypotension           | 0       | 1       | 0       | 1         |
| Rheumatic heart disease | 1     | 1       | 3       | 5         |
| UTI                   | 4       | 12      | 5       | 21        |
| Candidiasis           | 1       | 3       | 0       | 4         |
| Pain (Back & Abdomen) | 4       | 6       | 4       | 14        |
| Edema                 | 3       | 5       | 1       | 9         |
| Diarrhea              | 1       | 5       | 3       | 9         |
| Depression            | 0       | 3       | 0       | 3         |
| Jaundice              | 0       | 3       | 1       | 4         |
| Others                | 0       | 5       | 2       | 7         |
| **Total**             | **47**  | **68**  | **45**  | **160**   |

In Nepal, most of the women conceive in their early twenties due to the fact that women get married at this age group as shown by data of Nepal demographic and Health survey. Among the women of advanced age category two of them were presented with the hypertensive disorder during the course of our study. There is an increased risk of complications with advanced maternal age like increase risk of hypertensive disorder and breech presentation.

3.5 Drug prescribed and their respective FDA category

The most frequently prescribed drugs were from FDA category B and least prescribed drug was from FDA category X. All the drugs except iron, calcium and TT injection and their respective FDA categorization are listed below in Table 6 and the percentage distribution of FDA categories of the drug is presented in the pie-chart in Fig 1.

Total 459 drugs were prescribed which comprises of the commonly prescribed drug like Iron in combination with folic acid, Calcium in combination with Vitamin D, Tetanus toxoid injection, and other drugs listed in Table 6. The average number of drugs per encounter was 3.25, with 120 drugs being prescribed in the generic name was 26.1%. The antibiotics were prescribed in 41 encounters hence the percentage of encounters with an antibiotic prescribed was 29.07%. 46 prescriptions had injections amounting to 32.62% of encounters. Among 459 products, 260 were listed in the essential drug list which was accounted for 56.64%. The data are summarized below in table 7.

4 Discussion

The result of the present study showed that the maximum number of pregnant women was from the age group 20-25 i.e. 37.6% which was similar to the study done by Gaidhankar SL et.al., in a tertiary care hospital in India (74.82%) of age group 20-30 years.
conducted by Shrestha P et al., in Nepal and Yadav S et al., in India. It shows that the Physician prescribes the safest drug of the USFDA category to the women which have no risk to the fetus growth and development.

Table 6: Drug prescribed and their respective FDA category

| Drugs             | FDA Categ. | 1st Trimester | 2nd Trimester | 3rd Trimester | Total (n) |
|--------------------|------------|---------------|---------------|---------------|-----------|
| Ondansetron        | B          | 10            | 2             | 1             | 13        |
| Levothyroxine      | A          | 2             | 0             | 0             | 2         |
| Drotaverine        | C          | 2             | 2             | 1             | 5         |
| Paracetamol        | B          | 1             | 2             | 0             | 3         |
| Progesterone       | B          | 3             | 0             | 0             | 3         |
| Ranitidine         | A          | 0             | 1             | 1             | 2         |
| Nitrofurantoin     | B          | 1             | 1             | 2             | 4         |
| Amoxicillin        | B          | 1             | 3             | 6             | 10        |
| Cephalosporin      | C          | 1             | 8             | 1             | 10        |
| Proton pump inhibitor | B       | 3             | 2             | 3             | 8         |
| Metronidazole      | B          | 0             | 0             | 1             | 1         |
| Ursodeoxycholic acid | B        | 0             | 2             | 2             | 4         |
| Hyoscine butyl bromide | B       | 1             | 2             | 1             | 4         |
| Phenoxyethyl penicillin | B      | 1             | 1             | 3             | 5         |
| Ketoconazole       | C          | 0             | 1             | 6             | 7         |
| Methylidopa        | C          | 2             | 0             | 4             | 6         |
| Corticosteroid (topical) | C   | 0             | 1             | 7             | 8         |
| Clotrimazole       | C          | 1             | 3             | 0             | 4         |
| Heparin            | C          | 2             | 0             | 2             | 4         |
| Warfarin           | X          | 0             | 1             | 0             | 1         |
| Insulin            | B          | 0             | 0             | 1             | 1         |
| Other drugs        | -          | 5             | 13            | 9             | 27        |

The average number of drugs per prescription in this study 3.25, which was similar to the study done by Agrawal M et al., Abubakar K et al., Uchenna J. Eze et al., and the result were found to be 3.31, 3.0, 3.1 respectively. The number of drugs is comparatively higher than the WHO reference range (1.6-1.8) for prescribing indicators because in the pregnant women Iron, Calcium with Vitamin D combination and Tetanus Toxoid injection are commonly prescribed medications.

Fig 1: Percentage distribution of drug prescribed according to the USFDA category

Percentage of the patients prescribed with injection was 32.62%, which is also higher as compared with the WHO range for the percentage of injection prescribed (20-26.8) because most of the pregnant women received Tetanus toxoid injection two times during the gestation period in which the first dose was given during the 4th and 6th months of pregnancy.

The percentage of generic drugs prescribed 53 % shows that most of the drugs are prescribed in their brand name. Only a few drugs like Nitrofurantoin, Calcium, and antibiotic like amoxicillin are mostly prescribed in their generic name. The probable reason behind the brand prescription might be due to the impressive and continuous appointment with the doctor by the medical representative of the pharmaceutical companies. Emphasis should be given more towards the Generic drug prescription.

In TUTH antiemetic drug i.e., Ondansetron during the first trimester whereas antibiotic during the second trimester was the most frequently prescribed medication. In a study conducted at Manipal Teaching Hospital antiemetic were prescribed mostly in the first trimester and antacid during the second trimester.

Most commonly prescribed analgesic was paracetamol, proton pump inhibitor for gastritis, ceftriaxone was mostly prescribed for the UTI patient, metronidazole as an antidiarrheal drug whereas the study conducted by Prasanand S et al., at the tertiary care hospital of south India, the most commonly prescribed antimicrobial agents were metronidazole and mebendazole.

the antiulcer drug was ranitidine, analgesic was paracetamol and tetanus toxoid was the only vaccine prescribed.

5 Conclusion

The study shows that WHO indicators of good prescription behavior were followed by the prescribers to some extent however deviation was observed in terms of prescription of...
injection, and drugs with the generic name. Contraindicated medicines during pregnancy were almost absent in this study.

Table 7: WHO prescribing indicators

| Prescribing indicators                                      | Findings | Optimal value\(^\text{OPT}\) |
|-------------------------------------------------------------|----------|-------------------------------|
| The average number of drugs per encounter                   | 3.25     | 1.6-1.8                       |
| Percentage of drug prescribed by generic name               | 26.10    | 100                           |
| Percentage of encounter with antibiotics prescribed         | 29.07    | 20.0-26.8                     |
| Percentage of encounter with injection prescribed           | 32.62    | 13.4-24.1                     |
| Percentage of drug prescribed from essential drug list      | 56.64    | 100                           |

Very fewer women were prescribed with the drug of category X and there was no prescription with category D of the drug. Pregnant women who appeared during the duration of the study with the health disorder were treated with the appropriate drugs considering the risk to the benefit ratio. To assure the rational drug prescription the prescription audit should be carried out at regular intervals.

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7 Conflict of Interest

The authors have no conflict of interest.

8 Author’s contributions

SK carried out the collection of data and arranged in tabular form, literature review, and draft the manuscript. NM supervised, revised, and edited the final version of the manuscript.

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