



“DRUG UTILIZATION STUDY IN PATIENTS VISITING GYNAECOLOGY OPD AT TERTIARY CARE HOSPITAL”

Pharma

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ABSTRACT

Gynaecological diseases are common in India because of socio-economic conditions, hygiene literacy problems. Women health is one of most neglected issues in developing countries like India. With the increasing awareness, the flow of patients visiting gynaecology outpatient department (OPD) has increased. Gynaecological drugs are one of the strong selling drugs in pharmaceutical market. Drug utilization research facilitate appropriate use of drugs in patient, minimize the adverse event and lead to better patient outcome. This study revisits the utilization patterns of drugs used in the gynaecology OPD. A prospective, observational and cross-sectional study was conducted in Department of Pharmacology in collaboration with Department of Obstetrics and Gynaecology of tertiary healthcare hospital. Total 360 prescriptions were analysed, most of them belonged to the age group of 31-50 years. The Average number of drugs per prescription is 3.2. 38.33% were found to be infective while 61.66% were non-infective. Total 1876 drugs were prescribed. Among all drugs, Hematopoietic agents were most commonly prescribed (46.69%) followed by antimicrobials (29.16%). 98.40% drugs were prescribed by generic name and by 1.60% brand name. 91.95% drugs prescribed were included in WHO essential drugs list 2021. 96.69% drugs prescribed were included in National list of essential medicines (NLEM) 2015. In this study it was observed that majority of patients visiting the OPD were from urban areas, as the women from rural areas depend on peripheral health services, so it is crucial to strengthen the peripheral health services, to reduce the mortality and morbidity amongst the population.

KEYWORDS

Drug Utilization; Gynaecology; Outpatient Department

INTRODUCTION

The term gynaecology (from the Greek, 'gynae' meaning 'woman' and 'logos' means 'discourse') is a branch of science which deals with diseases and conditions of the female reproductive system that includes breasts, uterus, fallopian tube, ovaries and external genitalia. Women health is one of most neglected issues in developing countries like India. Around 92% of all women were found to have one or more gynaecological or sexual diseases, and the average number of these diseases per woman was 3.6. Infections of the genital tract contributed half of this morbidity. Only 8% of the women had undergone gynaecological examination and treatment in the past¹.

Gynaecological diseases are common in India because of socio-economic conditions, hygiene literacy problems. Most Common Gynaecological Problems include: Menstrual Disorders, Polycystic Ovarian Syndrome, Pelvic Floor Prolapse, Pelvic Pain, Uterine Fibroids, Cervical Dysplasia, etc. Depending on the nature of the problem, medical or surgical interventions can be implemented by the gynaecologist. Drug therapy including Hematopoietic agents, Hormone Replacement Therapy, Antibiotics, Nonsteroidal Anti-inflammatory Disease (NSAIDs), and others Depending on the comorbid conditions are prescribed. Early detection and treatment of problems and taking the necessary precautions against the problems improve both the health level and life quality of women. Healthy women can contribute to community health by increasing women's health.

With the increasing awareness, the flow of patients visiting gynaecology outpatient department (OPD) has increased. There are only a few comprehensive community-based studies in low-socioeconomic countries that quantify burden of gynaecological disease in order to influence health policy with respect to gynaecology. These studies have shown a high prevalence of previously unrecognized morbidity that places a heavy burden on women².

As per data by All India Origin Chemists and Distributors –Advanced Working, Action and Correction System (AIOCD-AWACS) market

research firm, gynaecology drugs are one of the strong selling drugs in pharmaceutical market; they rank as the 8th in all the super groups with 16.4% growth in the month of February 2012³.

Drug utilization pattern study is a powerful exploratory tool to evaluate present trends of drug use and appropriateness of prescriptions. Drug utilization is defined by World Health Organization (WHO) in 1977 as “marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences”⁴. It is a descriptive and analytical method of collection, quantification, understanding and evaluation of the prescribing pattern, as well as dispensing and consumption for the advancement of existing therapy and enhancement of patient safety⁵. The assessment of drug utilization is important for clinical, educational and economic purposes. Prescribing patterns need to be evaluated periodically to increase the therapeutic efficacy, decrease adverse effects and provide feedback to prescribers. Inappropriate drug prescribing is a global problem, particularly in developing and transitional countries. Irrational use of drugs leads to emergence of drug resistance, increased risk for adverse drug reactions, increased treatment cost, wastage of resources, and reduction in the quality of drug therapy⁶.

Generic drugs are approved by the US Food and Drug Administration based on testing demonstrating the drugs' safety, purity, and effectiveness. The advantage of using generic drugs is the cost effectiveness, which can be reduced significantly to 85% and less than that of the brand-name drug. Lower-cost generic drugs have been shown to increase the likelihood that patients take essential medications prescribed by their doctors and to improve patients' health outcomes⁷. Thus, the physician should concentrate on prescribing drugs with their generic names to the maximum in order to minimize the cost-burden on the patients.

Though rational use of drugs is a usual practice, but certain factors may lead to irrational practice. Irrational use of drugs was observed with multivitamins, where those were prescribed to women having no nutritional deficiencies or antibiotics were prescribed in patients

without signs of bacterial illness⁸. According to WHO, 5 criteria for rational use of drugs are: correct diagnosis, accurate prescribing, right dispensing, appropriate packing and patient compliance. The main purpose of National List of Essential Medicines (NLEM) and WHO model list of essential medicines is to promote the rational use of drugs based on 3 aspects, i.e., cost, safety and efficacy of the drugs⁹.

This study revisits the utilization patterns of drugs used in the gynaecology OPD.

Aim:

To assess the utilization patterns of drugs used in the gynaecology OPD of tertiary care hospital.

Objectives:

1. To assess drug utilization pattern
2. To assess the adherence of prescription to WHO core prescribing indicators-
 - a. Name, dose, dosage regimen of all drugs
 - b. Occurrence of Polypharmacy.
 - c. To see the percentage of drugs prescribed by generic names / brand names.
 - d. To see the percentage of drugs, present in the WHO essential drug list.
 - e. To see the percentage of drugs, present in the NLEM.

MATERIALS AND METHODS

Study- Design:

It was a hospital based Prospective, cross-sectional and observational study.

Study- Centre:

This Study was carried out in Department of Pharmacology in collaboration with Department of Obstetrics and Gynaecology of Tertiary health care hospital.

Study- Period:

This study was conducted over a period of 3 months from October 2021 to December 2021 at Shri Chhatrapati Shivaji Maharaj Sarvopchar Rugnalay, Solapur, Maharashtra.

Sampling:

Total 360 prescriptions were collected from HMIS (Hospital Management Information System) as per inclusion and exclusion criteria.

Inclusion Criteria:

- Patients Visiting Gynaecology OPD will be included in the study.
- Sex- Females.
- Age > 18 years
- Patients willing to give written informed consent

Exclusion Criteria:

- Patients of age < 18 years.
- All IPD Patients
- Patient who refuses to participate in the study

MATERIAL AND METHODS:

- Patients Visiting Gynaecology OPD were included in the study.
- The sampling frame will be fixed as 10 prescriptions per day, 3 days a week during the given sampling period. In case of OPD holidays or non-fulfilment of our target of 10 prescriptions per day, the prescriptions of that day will be done on the next working day.

The following data was collected and analysed:

- Demographic information: Age
- Diagnosis and associated co-morbidities
- Drugs categorized into different classes, their doses, frequency and dosage form.
- Prevalence of Polypharmacy
- Percentage of Fixed-dose combination (FDC) and off-label

Ethical Approval: The protocol of the present study was approved by the Institutional Ethical Committee.

Statistical Analysis: Data was collected and entered into Microsoft Excel 2019. Descriptive statistics such as frequencies and percentage will be calculated for categorical variables.

RESULTS

In this study, Prescription of 360 patients attending Gynaecology OPD over a period of 3 months were assessed.

Demographics:

In this study, patients were divided into 3 groups based on their age. (Figure 1). It is observed that the maximum number of patients were between the age group of 31-50 years.

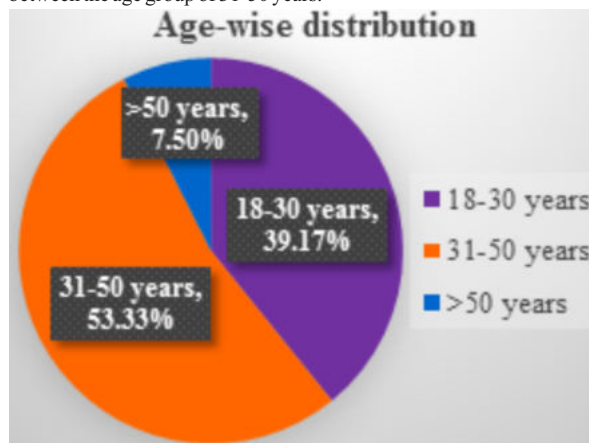


Figure 1. Age-wise Distribution

Among all the prescriptions, 286 (79.44%) were issued to patients from urban area and 74 (20.55%) to patients from rural areas.

In the assessment of 360 patients, 138 (38.33%) were found to be infective while 222 (61.66%) were non-infective.

Age-distribution Of The Infective Cases: Table 1

Among infective cases, Vaginal discharge was the most common, followed by Pelvic Inflammatory Disease (PID).

Table 1. Age-wise Distribution Of The Infective Cases

Infective Disease	No. of Patients (N=360)			Total	Percentage (%)
	18-30	31-50	>50		
Vaginal Discharge	31	25	06	62	17.22%
Pelvic Inflammatory Disease (PID)	25	18	00	43	11.94%
Urinary Tract Infection (UTI)	17	06	00	23	6.39%
Abscess	02	01	00	03	0.83%
Episiotomy wound	05	02	00	07	1.94%
Total	80	52	06	138	38.33%

Age-distribution Of The Non-infective Cases: Table 2

Among non-infective cases, Menstrual disorders were the most common, in which dysmenorrhoea was common followed by menorrhagia.

Table 2. Age-wise Distribution Of The Non-infective Cases

Non-infective Disease	No. of Patients (N=360)			Total	Percentage (%)
	18-30	31-50	>50		
Menstrual Disorders					
Dysmenorrhoea	12	32	05	49	13.61%
Menorrhagia	17	21	00	38	10.56%
Amenorrhoea	11	19	00	30	8.33%
Irregular menses	06	15	00	21	5.83%
Bleeding PV	00	12	08	20	5.56%
DUB	05	08	00	13	3.61%
PCOD	08	05	00	13	3.61%
Pelvic Mass					
Prolapse	00	12	04	16	4.44%
Fibroid uterus	00	08	03	11	3.05%
Ovarian cyst	02	07	00	09	2.5%
Ca Cervix	00	01	00	01	0.28%
Ca Endometrium	00	00	01	01	0.28%
Total	61	140	21	222	61.66%

Age-wise Distribution Of Other Associated Conditions: Table 3

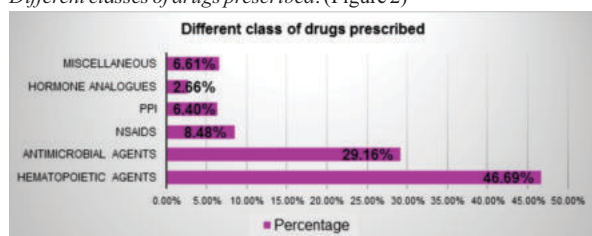
Out of 360 patients, 18.06% were anaemic, 46 were PNC cases, 19 patients came for Copper-T (Cu-T) insertion. 2.77% and 5.83% patients were associated with Diabetes and Hypertension respectively. 9 patients were Hysterectomized, while 12 patients underwent Bilateral Tubal Ligation.

Table 3: Age-wise Distribution Of The Other Associated Conditions.

Other	No. of Patients (N=360)			Total	Percentage (%)
	18-30	31-50	>50		
Anaemia	39	24	02	65	18.06%
Postnatal cases	42	04	00	46	12.77%
(Copper-T) Cu-T	16	3	00	19	5.28%
Diabetes Mellitus	01	06	03	10	2.77%
Hypertension	02	15	04	21	5.83%
Hysterectomy	00	03	06	09	2.5%
Bilateral Tubal Ligation	00	12	00	12	3.33%

Assessment of prescription:

Total 1876 drugs were prescribed in 360 prescriptions.

Different classes of drugs prescribed: (Figure 2)**Figure 2: Different Class Of Drugs Prescribed**

Out of 1876 drugs, Hematopoietic agents were most commonly prescribed (46.69%), where iron and folic acid supplements were most common (25.43%) followed by 11.35% Multivitamin B-complex (MVBC) and 9.91% Calcium.

Antimicrobials were the second most commonly prescribed group of drugs (29.16%). Metronidazole (15.35%) were the most commonly prescribed antibiotic, followed by Amoxicillin + Clavulanic Acid (Augmentin- 9.65%), Ciprofloxacin (3.52%), while Antifungal agent Clotrimazole (0.64%) was prescribed.

The third group of drugs prescribed were NSAIDs 8.48%, among which 5.76% were Diclofenac Sodium and 2.72 % were Paracetamol.

Pantoprazole (6.08%) were the most commonly prescribed Proton Pump Inhibitor, followed by Omeprazole (0.85%)

In hormonal therapy, Oral Contraceptive Pills were most commonly prescribed (1.97%), followed by cyclic progesterone therapy (0.69%). *Drug distribution based on dosage forms:* (Table 4)

Tablets were the most commonly preferred dosage form (68.66%).

Table 4: Distribution Of Drugs Based On Dosage Forms

Dosage forms	Total drugs (n=1876)	Percentage (%)
Tablet	1288	68.66%
Capsules	457	24.36%
Syrups	62	3.30%
Injections	42	2.24%
Pessaries	19	1.01%
Topical	8	0.43%
Total	1876	100%

Details of the studied prescription: (Table 5)

Table 5: Details Of The Prescription Studied.

Details Of The Prescriptions	Number Of Drugs
Total number of patient's prescription analysed	360
Total number of drugs prescribed	1876
Average number of drugs per prescription	3.2

Number of drugs prescribed by generic name	1846
Number of drugs prescribed by brand name	30
Drugs prescribed by FDCs (%)	52.61%
Drugs included in WHO essential drugs list 2021 (%)	91.95%
Drugs included in National list of essential medicines 2015 (%)	96.69%

DISCUSSION

This study was conducted to analyse the usage of different drugs in tertiary care hospital. Prescriptions of 360 patients visiting gynaecology OPD over a period of 3 months were analysed.

In our study, it was observed that the maximum number of patients were between the age group of 31-50 years (53.33%), which was similar to the study conducted by Nandeshwar MB et al where the maximum number of patients were between 30-50 years of age (55.33%)¹⁰.

In this study, 79.44% patients were from urban area and 20.55% patients were from rural area. This may be due to lack of awareness and literacy among the rural community. This problem could be addressed by emphasizing more on the facilities of Peripheral Health services to be more readily available as majority of rural population is dependent on them.

In our study, most of the patients came with the chief complaints of vaginal discharge (17.22%) of which majority of patients belonged to age group of 18-30 years. Thappa et al. reported that the Sexually Transmitted infections were most common among the age group 20-29 years¹¹, as women are more sexually active during this age.

Among the infectious disease, PID was the most common 11.94 % followed by UTI 6.39%. Similar results were observed in the study conducted by Mukesh et al, where PID (64.11%) was most common among women followed by UTI (24.70%)¹².

In India, menstrual disturbances were between the first and fourth most commonly reported gynaecological complaints. In our study, Dysmenorrhoea was the most common menstrual disorder among 31-50 years of age. Our findings correspond with the study conducted by Nandeshwar MB et al.¹⁰. Among non-menstrual disorders, majority of women presented with the complaints of something coming out of Vagina (Prolapse) followed by Fibroid & Ovarian Cyst 16%, 11%, 9% respectively.

Among all the classes of drugs prescribed, 46.69% were Hematopoietic agents, among which 25.43% were Iron and Folic acid supplements. According to the WHO, it was seen that the prevalence of anaemia in women of reproductive age in India was 53% in 2019, the fifth-highest globally¹³. In our study 18.06% patients were diagnosed cases of anaemia. Anti-anaemic drugs prescribed were more compared to diagnosed cases of anaemia as majority of anti-anaemic drugs prescribed were based on symptoms of anaemia.

The second commonly prescribed group was antimicrobial drugs (29.16%). Antimicrobials are grouped as antibiotics, antifungal, microbical, etc based on the microorganisms on which they act. Shah BK et al, recorded the major use of Ciprofloxacin followed by Ampicillin, Metronidazole, Gentamicin, Cefotaxime, Cephalixin, in the department of gynaecology¹⁴. As per Sihavong et al, recommended drugs for the treatment of vaginal discharge and lower abdominal pain syndromes include metronidazole orally or vaginal suppository¹⁵. Metronidazole is effective for the management of anaerobic infections, such as intra-abdominal infections, gynaecologic infections and for mixed, aerobic and anaerobic infection¹⁶.

NSAIDs were the third commonly prescribed group of drugs. This finding is consistent with various other study conducted by Baig et al, Sharma et al, where NSAIDs are the third commonly prescribed drugs^{2,17}. Diclofenac sodium was commonly prescribed NSAID as Dysmenorrhoea was most commonly noticed non-infectious disease in this study, as pain is the most distressing experience of human beings and pelvic pain is one if the common symptom for which patient opt-in for gynaecological consultation.

Tablets were the most preferred dosage form followed by capsules, which replicated the study conducted by Baig et al.³

The Average number of drugs per prescription is 3.2, the results of this study reflect polypharmacy. Since, WHO has recommended that average number of drugs per prescription should not be 2, due to increased risk of drug interactions, adverse drug reactions, dispensing errors, decrease adherence to drug regimens and unnecessary drug expenses¹⁸.

Majority of the prescribed drugs were generic which are included in the WHO model list of Essential medicines and NLEM^{19,20}. This indicates a better trend of prescribing, as these drugs are safer, efficacious & comparatively economical to the patients.

No serious side effects were noticed during the course of observation.

Limitations:

The results of this study cannot be extrapolated to the entire population of that region as it was conducted only in one tertiary care teaching hospital and did not include the patients visiting other tertiary care teaching hospitals of that region. Small sample size, single centred and short study duration are the main limitations of our study. A larger population size could give a better result if other tertiary care hospitals of the city were included and more reliable outcomes which could be generalize for the entire community.

CONCLUSIONS

This study provides an overview of utilization of drugs in patients visiting gynaecology OPD in one of the tertiary care hospitals in Maharashtra. In this study it was observed that majority of patients visiting the OPD were from urban areas, as the women from rural areas depend on peripheral health services, so it is crucial to strengthen the peripheral health services, to reduce the mortality and morbidity amongst the population. Most commonly prescribed drugs belonged to Haematopoietic agents like iron and folic acid supplements as anaemia is prevalent in women amongst the reproductive age group followed by antimicrobial agents due to increased risk of sexually transmitted infection prevalent in the similar population. This study revealed deviation from rational drug prescribing pattern, as the incidence of polypharmacy was higher as per WHO recommendations. Most of the prescribed drugs were available free of cost in the central pharmacy of the hospital, which is favourable for reducing the cost of health care facilities. Generic drugs were prescribed majorly, which promotes awareness amongst prescribers, supporting WHO policies. Despite the limitations, it was our sincere efforts to provide insight into the prescription pattern of drugs used amongst the women population in a government tertiary care hospital. Studies on drug prescribing patterns will, definitely, help the physician to improve the prescribing patterns and efficient management will delay the progression of disease and improve the quality of life. Further studies from time to time are required in drug prescription pattern and standard treatment guidelines should be circulated amongst practicing physicians to encourage rational prescription.

Abbreviations Used

NSAIDs- Nonsteroidal Anti-inflammatory Drugs, OPD- Outpatient department, AIOCD-AWACS- All India Origin Chemists and Distributors –Advanced Working, Action and Correction System, WHO- World health organization, NLEM- National List of Essential Medicines, HMIS- Hospital Management Information, IPD- inpatient department, FDC- Fixed-dose combination, PID- Pelvic Inflammatory Disease, UTI- Urinary Tract Infection, DUB- Dysfunctional Uterine Bleeding, PCOD- Polycystic Ovarian Syndrome, PNC- Postnatal Care, Cu-T- Copper-T, PPI- Proton Pump Inhibitors, MVBC- Multivitamin B-complex.

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Conflict Of Interest- None to declare

Ethical Approval- Approved by the Institutional Ethical Committee.

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