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## Original article

### DRUG UTILIZATION STUDY OF GYNECOLOGY OPD: IN A TERTIARY CARE HOSPITAL.

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## ABSTRACT

**Background:** The treatment of diseases by use of essential medicines, prescribed by generic names, has been emphasized by WHO and National Health Policy of India. Drugs used in gynaecology are one of the top selling drugs in India; however they are least studied with respect to drug utilization. Thus present study was undertaken to analyze drug utilization pattern of gynecology OPD in a tertiary care hospital. **Materials and Methods:** A retrospective, cross sectional, observational study of prescriptions in Gynecology OPD. Data was obtained from an electronic medical record database of patients that attended Gynecology OPD during the study period. Prescription records of patients were screened as per inclusion and exclusion criteria and 300 prescriptions were randomly selected by Openepi software. Patient related and drug related information was collected on a customized data collection sheet. **Results:** The mean age of patients was 30.19±9.83 years and common age of presentation was >18-30 years. In infective cases, vaginal discharge (10.33%) was common, and in non-infective cases, menstrual disorders (24%) were common. The average number of drugs per prescription was 3.47±1.53. In drug category, minerals (30.94%) were most commonly prescribed, followed by antimicrobials (24.98%), and NSAIDs (13.37%). Polypharmacy was observed in 96.33% of the prescriptions. **Conclusion:** It is only by drug utilization studies that burden of diseases and corresponding utilization of drugs in gynecology can be measured. In our study majority of the drugs prescribed were generic which were from the essential medical list NLEM and WHO.

**Keywords:** Drug utilization, Gynecology, Outpatient department.

## INTRODUCTION

Maternal health gives importance because life of not only the mother but the child is also at stake. There are only a few comprehensive community-

based studies in low income countries that quantify burden of gynecological disease in order to influence health policy with respect to

gynecology. These studies have shown a high prevalence of previously unrecognized morbidity that places a heavy burden on women.<sup>1,2</sup>

As per data by All India Origin Chemists and Distributors-Advanced Working, Action & Correction System (AIOCD-AWACS) market research firm, gynecology drugs are one of the strong selling drugs in pharmaceutical market; they rank as the 8<sup>th</sup> in all the super groups with 16.4% growth in the month of February 2012.<sup>3</sup> However they are the least studied drugs in terms of drug utilization studies.

The principal aim of drug utilization research is to facilitate appropriate use of drugs in patient populations, minimize the adverse event and drug interactions leading to better patient outcome.<sup>4</sup> Considering the flow of the gynecology patients and scarcity of data with respect to drug utilization study (DUS) the present study was planned to examine the patterns of drug prescription in the gynecology outpatient department (OPD) of Government Medical College and Hospital, Aurangabad a biggest tertiary care hospital covering eight districts of Marathwada Maharashtra state.

## MATERIALS AND METHODS

**Study Design :** A retrospective, cross sectional, observational study.

**Study Duration:** 1 year from 01 Dec 2010 – 30 Nov 2011

**Study Population:** The Electronic Medical Record (EMR) data was obtained; consisting of prescription records of 7762 patients that attended the Gynecology OPD at Government Medical College & Hospital, Aurangabad, Maharashtra.

**Procedure:** The study was conducted after obtaining the permission from the Institutional Ethics Committee, and from the Local HMIS (hospital management information system) project implementation committee of the institute. All Ethical issues pertaining to the study was taken into consideration. The 7762 patient's data was screened and analyzed as per the inclusion and exclusion criteria. After screening data, 300

patients were randomly selected using Openepi software version 2.3. Patient related information like age, gender, number of visits, diagnosis, month of presentation, urban/rural, drug related information like number of drugs prescribed, drug doses, drug dosage form, route of administration, fixed dose combinations of drugs, drugs prescription by generic or brand names were collected on a customized data collection sheet.

**Inclusion criteria:** Data of patients with age >18 years after screening having details of parameters under study were included.

**Exclusion criteria for screening:** Data of Gynecology In-door patients during the study duration, emergency patients, Incomplete data.

**Parameters studied :** The World Health Organization (WHO) indicators that were selected to analyze the prescription pattern included.

1. Average number of drugs prescribed per prescription per encounter
2. Relationship between patient demographics and prescription pattern
3. Indications for which various drugs were prescribed
4. Percentage usage of various drugs, various dosage forms of the drugs
5. Drugs prescribed by generic name and brand name, drugs prescribed from Indian National List of Essential Medicine (NLEM) 2011 & WHO list of essential medicines 2011, fixed drug combinations and polypharmacy.<sup>5,6</sup>

## RESULTS

Total 300 gynecology prescriptions were analyzed. The mean age of presentation was 30.19 ± 9.83 years ranging from >18 to 72 years of age. Among all the prescriptions 276 (92%) were from urban area and 24 (8%) were from rural area. The average number of visits was 2.22±1.42. The average number of drugs per prescription was 3.49±1.53.

Out of 300 patients, 180 (60%), 105 (35%) and 15 (5%) patients were in the age group >18-30, >30-50 and >50 years respectively. 85 (28.33%) were infective cases and 215 (71.67%) were non-

infective cases. In 31 cases of vaginal discharge 28 were cases of white vaginal discharge. Distribution of infective diseases is given in table I

Among non-infective group, menstrual disorders were common, in which dysmenorrhea, followed by Dysfunctional Uterine Bleeding (DUB). There were 3 patients of Polycystic Ovarian Disease (PCOD). In pelvic mass ovarian cyst was common, there were two patients of Carcinoma (Ca) Cervix and one patient of carcinoma endometrium. Distribution of non-infective gynaecological diseases are given in table II.

Among other diseases infertility was common; there were 13 patients for Copper-T (Cu-t) insertion, 4 cases of Diabetes Mellitus (DM) and 3 cases of Hypertension (HTN). Distribution of other diseases are given in table III.

A total of 1047 drugs was prescribed. Out of these 649 (61.99%), 354 (33.81%) and 44 (4.20%) were prescribed in >18-30 years, >30-50 years and >50 years of age group respectively. Among all drugs, minerals 324 (30%) were most commonly prescribed. In minerals anti-anemic drugs were commonly prescribed 192 (18.33%) followed by calcium supplements 132 (12.60%).

The second most commonly prescribed group of drugs was antimicrobial drugs 260(24.83%), in which metronidazole 73 (6.97%) was commonly

prescribed followed by ciprofloxacin 65 (6.20%) and ampicillin 47(4.50%).

The third group of drugs commonly prescribed was Nonsteroidal Anti-inflammatory Drugs (NSAIDs) 140 (13.37%), in which ibuprofen 73 (6.7%) was commonly prescribed followed by paracetamol 37(3.50%) and other NSAIDs (3.17%).

Others group of drugs like antihistamines 119 (11.37%) in which ranitidine 88 (8.40%) was commonly prescribed followed by cetirizine 22 (2.10%). In hormonal preparations 40 (3.82%) Oral Contraceptive Pills (OCP) 13 (1.2%) was commonly prescribed followed by cyclical progesterone 6 (0.57%). There were 12 (1.15%) drugs from Central Nervous System (CNS) class and 11 from cardiovascular system (CVS) and DM. Other prescribed drugs classified according to pharmacological class are given in graph 1.

Out of 1047 drugs prescribed, 996 (95.13%) were prescribed by generic name, 51 (4.87%) by brand name and 437 (41.73%) prescribed were fixed dose combination. Among the total drugs prescribed 986 (94.17%) were from NLEM and 880 (84.05%) were prescribed from WHO list. Polypharmacy (containing  $\geq 2$  drugs per prescriptions) was observed in 289 (96.33%) prescriptions. Distribution of drugs according to various dosage forms is given in table IV.

**Table 1: Distribution of infective diseases according to age.**

Infective Diseases	Number of patients				
	Age >18-30 yrs	Age >30-50 yrs	Age >50 yrs	Total	Percentage*
Vaginal discharge	15	11	5	31	10.33
PID	14	6	0	20	6.67
UTI	4	6	0	10	3.33
Abscess	5	2	0	7	2.33
Episiotomy wound	3	0	0	3	1.00
Cough fever	4	0	0	4	1.33
Diarrhea	2	1	0	3	1.00
TineaCorporis	3	1	0	4	1.33
Scabies	2	0	0	2	0.67
Tuberculosis	1	0	0	1	0.33
<b>TOTAL</b>	<b>53</b>	<b>27</b>	<b>5</b>	<b>85</b>	<b>28.33</b>

**Table 2: Distribution of non-infective gynaecological diseases according to age.**

Non infective Diseases	Age in years (Number of patients)				
	Age >18-30 yrs	Age >30-50 yrs	Age >50 yrs	Total	Percentage*
<b>Menstrual Disorders</b>					
Dysmenorrhea	19	12	2	33	11.00
DUB	4	11	1	16	4.33
Menorrhagia	6	6	1	13	5.33
Bleeding per vaginum	2	2	0	4	1.33
PCOD	3	0	0	3	1.00
Irregular menses	2	0	0	2	0.67
Amenorrhea	1	0	0	1	0.33
<b>Pelvic Mass</b>					
Ovarian cyst	5	9	0	14	4.67
Fibroid uterus	2	5	0	7	2.33
Prolapse	0	3	4	7	2.33
Adenomyosis	0	2	0	2	0.67
Ca Cervix	0	1	1	2	0.67
Ca Endometrium	0	0	1	1	0.33
Fibroadenosis	1	0	0	1	0.33
Vesicular mole	0	1	0	1	0.33
<b>TOTAL</b>	<b>45</b>	<b>52</b>	<b>10</b>	<b>107</b>	<b>35.65</b>

**Table 3: Distribution of other diseases according to age.**

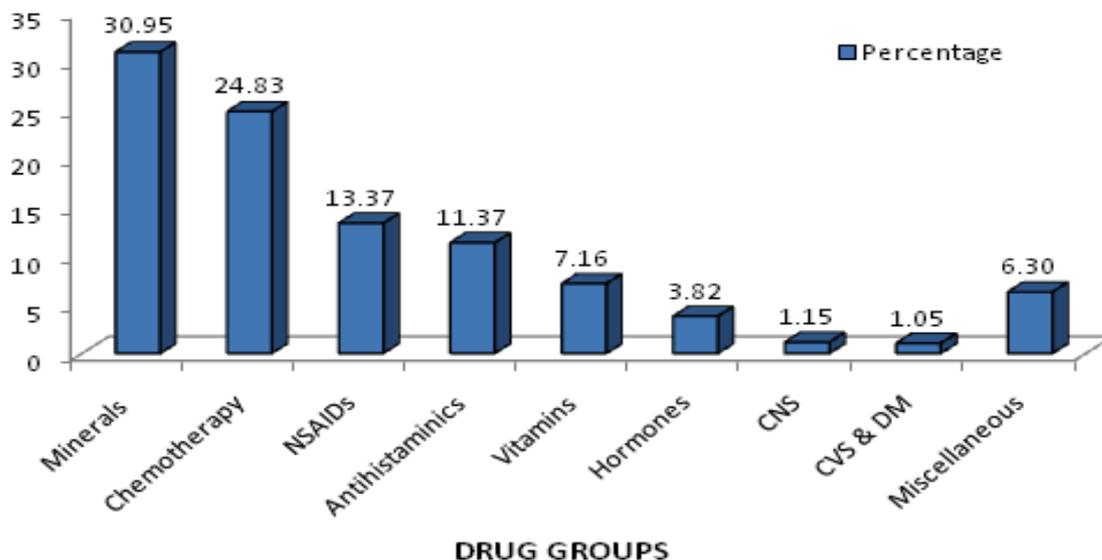
Other Diseases	Age in years (Number of patients)				
	Age >18-30 yrs	Age >30-50 yrs	Age >50 yrs	Total	Percentage*
Post Natal Cases	30	4	0	34	11.33
Postpartum psychosis	3	0	0	3	1.00
Cu-t	11	2	0	13	4.33
Lump in breast	3	0	0	3	1.00
Anemia	7	2	0	9	3.00
Backache	1	3	0	4	1.33
Headache	2	0	0	2	0.67
Hypothyroid	1	1	0	2	0.67
Diabetes mellitus (DM)	0	2	2	4	1.33
Hypertension (HTN)	1	2	0	3	1.00
<b>TOTAL</b>	<b>88</b>	<b>18</b>	<b>2</b>	<b>108</b>	<b>35.99</b>

*\*Note: In table 1-3, percentages are out of 300.*

**Table 4: Distribution of drugs according to various dosage forms.**

Sr.No	Dosage forms	Total (Drugs)	Percentage (%)
1	Tablet	854	81.57
2	Capsule	135	12.90
3	Pessary	27	2.58
4	Topical	15	1.43
5	Injection	9	0.86
6	Syrup	7	0.67
	<b>TOTAL</b>	1047	100

**Drug Use as per Category (%)**



\*Percentage calculated out of 1047

**Fig. 1: Distribution of drugs according to pharmacological class.**

## DISCUSSION

The data in our study were accessed by EMR managed by the Hospital Management information system. It has several advantages like data safety, reduced prescription errors and easy retrieval at one-click for records analysis.<sup>7</sup>

In our study mean age of presentation was  $30.19 \pm 9.83$  years and the most common age group was >18-30 years. In studies carried out by Kaur et al mean age of women attending

Gynecology OPD was  $29.80 \pm 6.293$  years.<sup>8</sup> Similarly, Shalini et al reported 70% patients were between 20-29 years.<sup>9</sup> In our study 92% patients were from urban areas and 8% were from rural area. This indicates that majority of the rural patients depend on the peripheral health services for gynecological diseases.

Reproductive/Sexual tract infections (RTI/STI) are major cause of gynecological morbidity all over the world.<sup>9</sup> NFHS-3, estimates that 11.1% of women were reported to have STI in India.

<sup>10</sup>Thapa et al reported that commonest age group of STI is 20-29 years and the most common symptoms are vaginal discharge. <sup>11</sup> According to Patel et al, Pelvic Inflammatory Disease (PID) is one of the most serious infections and is a common problem encountered in gynecological clinics in India and abroad. <sup>12</sup> In our study urinary tract infection (UTI) was seen in >30-50 years of age group. As per Gupta et al, more than half of the females with lower urinary tract symptoms were middle aged between 31-55 years of age. <sup>13</sup> Among menstrual disorders in our study in >18-30 years of age group dysmenorrhea was common. As per Harlow et al menstrual disturbances are between first and fourth most common reported gynecological complaints in India. <sup>14</sup> According to Adamson et al infertility varies across regions of the world and is estimated to affect 8 to 12 per cent of couples worldwide. <sup>15</sup> There were 10.33% cases of infertility, 4 patients of ovarian cyst, 7 fibroid uterus and 7 of prolapse in our study. The results of our study are consistent with Walraven et al, <sup>1</sup>Shalini et al, <sup>9</sup> and Bhatia et al <sup>16</sup> with regards to distribution of gynecological diseases. The distribution of gynecological diseases in our study correlates with the distribution in other studies. This study has shown the distribution of the majority of gynaecological diseases across various age groups which very few studies have reported. Among all the drugs, 30% prescribed were minerals in which anti-anemic drugs were commonly prescribed. In India 55% of the females have anemia and is more widespread among both women and children and it has risen almost 5% points than NFHS-2. <sup>17</sup> As per Bhatia et al approximately one-third of all women in OPD reported symptoms of anemia. <sup>18</sup> In our study diagnosed cases of anemia was less compared to anti-anemic drugs prescribed as majority of anti-anemic drugs prescribed were based on symptoms of anemia. The second commonly prescribed group in our study was antimicrobial drugs, in which metronidazole was common followed by

ciprofloxacin and ampicillin. In a study by Shah et al in indoor patients ciprofloxacin (60.90%) was commonly used followed by ampicillin (54.54%) and metronidazole (39.69%). A number of Indian studies have recorded a high level of use of ampicillin, metronidazole, ciprofloxacin, gentamicin, cefazolin in gynecological department. <sup>19</sup> As per Sihavong et al, recommended drugs for the treatment of vaginal discharge and lower abdominal pain syndromes include metronidazole orally or vaginal suppository. <sup>20,21</sup> Metronidazole is effective for the management of anaerobic infections, such as intra-abdominal infections, gynecologic infections and for mixed, aerobic and anaerobic infection. <sup>22</sup> As metronidazole was commonly prescribed for anaerobic infections in gynecological diseases along with combination with other antimicrobial agents, metronidazole topped list of antimicrobial drugs in our study.

The third commonly prescribed drugs in our study was NSAIDs. As per Dhaubhadel et al pain is the most distressing experience of human beings and pelvic pain is one of the most common reasons for gynecology consultation. <sup>23</sup>

The average number of drugs per prescription in our study was 3.49±1.53. It is recommended to limit the number of drugs prescribed per prescription should be 2, because of increased risk of drug interactions. <sup>24</sup> Around 40% of the women have STI at a given point in time and only 1% completes full treatment of both the partners. <sup>20</sup> Due to unawareness of the gynecological diseases there is less follow-up which is a contributing factor for the increase in drugs per prescription.

The drugs utilized in our study correlates with the pattern of various gynecological diseases observed in our study, however there were no DUS that shows the utilization of minerals, hormones, NSAIDs and antihistamines which were the other commonly used drugs in our study. In our study majority of the drugs prescribed were generic which were from the essential medical list NLEM and WHO.

## CONCLUSION

Our study focused on understanding drug prescription and prescription trends with respect to Gynecology OPD. It is only by drug utilization studies that burden of diseases and corresponding utilization of drugs in gynecology can be measured.

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