Original Research Article

A Study of drug utilization pattern in gynaecology out-patient department of a tertiary care hospital

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ABSTRACT

Background: Gynaecological diseases are common in India because of socioeconomic, hygienic and literacy problems. 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. So, the present study was carried out to examine the patterns of drug prescription.

Methods: A retrospective, observational study was done by collecting the prescriptions of the patients who attended the Gynaecology out-patient department in our institute for the period of six months. Total 300 prescription were collected and analysed. Patient’s demographic data, total number and category of drugs prescribed, percentage of individual drug and their dosage forms, drugs prescribed by generic name, brand names and percentage of drugs prescribed from essential drug list were analysed.

Results: The mean age of presentation was 36.6±10.98 years. Among infective group breast abscess were common and among non-infective cases dysmenorrhea was most common. Out of 754 drugs prescribed, minerals were most commonly prescribed (42.70%) followed by antimicrobials (24.53%). Tablet form were prescribed more commonly (96.02%) followed by capsules (2%) and injections (1.06%). The average no. of drugs per prescription was 2.51±1.26 SD. Percentage of drugs prescribed by generic name were 98.01% and drugs prescribed from essential drug list were 85.41%.

Conclusions: The overall drug use pattern in our study correlates with various gynaecological diseases. Majority of the women from rural background depend on primary health services for gynaecological diseases in their areas so, strengthening of gynaecological health care services reduce the morbidity among the women from rural areas.

Keywords: Drug utilization, Essential drug list, Gynaecological diseases, Gynaecology out-patient department

INTRODUCTION

Drug utilization is defined as “the prescribing, dispensing, administering, and ingesting of drugs”. The World Health Organization (WHO) expands on this definition by including outcome variables in their definition. Drug utilization is defined by the WHO as the “marketing, distribution, prescription, and use of drugs in society, with special emphasis on the resulting medical, social, and economic consequences.” For clinical, educational and economic purpose the assessment of drug utilization is important. Periodic evaluation of prescribing patterns is necessary 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 drug use is responsible for reduction in the quality of drug therapy, wastage of resources, increased treatment cost, increased risk for adverse drug reactions and emergence of drug resistance.
Gynecological diseases are common in India because of socioeconomic, hygienic and literacy problems. Hospitals in most of the tribal regions of underdeveloped nations lack proper healthcare facilities.\textsuperscript{7}

But with the increasing awareness, the flow of patients visiting gynaecology OPD has increased. There are few comprehensive community-based studies in low income countries that express burden of gynecological 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 women.\textsuperscript{9} 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 2012.\textsuperscript{9} However very few studies had been carried out to evaluate the drug utilization pattern. The principal aim of this drug utilization research is to facilitate appropriate use of drugs as per WHO guidelines in patient population, minimize the adverse event and drug interactions leading to better patient outcome. Considering the flow of the gynaecology patients and scarcity of data regarding drug utilization study (DUS) the present study is carried out to examine the patterns of drug prescription in the gynaecology outpatient department (OPD).

**METHODS**

A retrospective, observational study was done by collecting the prescriptions of the patients who attended the gynaecology out-patient department of tertiary care teaching hospital. The study was conducted after getting approval from Institutional Ethical committee and permission of HMIS (hospital management information system) of the institute. Study period was 6 months from January 2016 to June 2016.

**Inclusion criteria**

- Prescription data of the patients with age >18 years who have attended the gynaecology OPD were included in the study.
- Prescription containing the patient related information like age, diagnosis and drug related information like number of drugs prescribed, indications for which various drugs were prescribed, drug doses, drug dosage form, route of administration, drugs prescribed by generic or brand names, fixed dose combinations of drugs were included in the study.

**Exclusion criteria**

- Prescription data of the patients with age <18 years.
- Prescription containing incomplete patient related and drug related information.

- Prescription data of in-door patients and emergency cases.

All the prescription given to the patients during January 2016 to June 2016 were screened and analyzed according to the inclusion and exclusion criteria. After screening, total 300 prescription which contains complete patient related and drug related information according to inclusion criteria were evaluated. Parameters that assessed were average number of drugs prescribed per prescription, relationship between patient demographics and prescription patterns, indications for which various drugs were prescribed, percentage usage of various drugs and dosage forms of the drugs, drugs prescribed by generic name and brand name, fixed drug combinations and polypharmacy.

Percentage usage of various category of drugs and various dosage forms of the drugs were calculated by dividing the variable by total number of drugs prescribed and multiplying it by 100. The average number of drugs prescribed per patient was calculated by dividing the number of drugs given to patient by the total number of patients.

**RESULTS**

Total of 300 prescriptions were analyzed. The mean age of presentation was 36.6±10.98 years. Among all the prescriptions, 226(75.3%) were issued to patients from rural area and 74(24.7%) to patients from urban area. The average no. of drugs given per prescription was 2.51±1.26 SD Out of 300 prescriptions, 100, 166 and 34 were in age group >18-30 years, >30-50 years and >50 years respectively. Out of 300 prescriptions, 91(30.29%) were infective cases and 209(69.66%) were non-infective. Among infective group, breast abscess was common followed by acute gastroenteritis. Distribution of infective diseases among patients visiting gynaecology OPD is given in Table 1.

Among non-infective cases, menstrual disorders were common, in which dysmenorrhea was most common followed by Dysfunctional uterine bleeding (DUB). There were 2 patients of Carcinoma breast, 2 patients of Carcinoma cervix and 1 patient of Carcinoma endometrium. In pelvic mass, ovarian cyst was common, there were 2 patients of polycystic ovarian disease and 8 patients of Primary infertility. Distribution of non-infective diseases among patients visiting gynaecology OPD is given in Table 2. Among the other diseases, acid peptic diseases were most common followed by anemia. There were 7 patients of Hypertension, 2 patients of Diabetes mellitus, 3 patients of hypothyroidism and 3 patients for Copper-T (Cu-T) insertion. Distribution of other diseases is given in table 3. Among all drugs, tablet form of drug was prescribed more commonly (96.02%) followed by capsules (2%) and injections (1.06%). Distribution of drugs according to various dosage forms is given in table 4.
Among all drugs, Minerals were most commonly prescribed 322(42.70%). In minerals, calcium 139(18.43%) were most common followed by iron 98(12.99%) and folic acid 36(4.77%) supplements. The second most common drugs prescribed were antimicrobials 185(24.53%), in which, Ciprofloxacin 88(11.67%) was common followed by Metronidazole 69(9.15%) and Amoxycillin 9(1.19%).

Table 1: Distribution of infective diseases according to age.

| Infective diseases       | (Age in years) | Number of patients | Percentage |
|--------------------------|----------------|--------------------|------------|
| Acute vestibulitis       | 18-30          | 2                  | 0.66       |
| Age                      | 30-50          | 0                  | 0          |
| Bacterial vaginosis      | >50            | 2                  | 0.66       |
| Breast abscess           |                | 0                  | 0          |
| Enteric fever            |                | 0                  | 0          |
| PID                      |                | 0                  | 0          |
| Scabies                  |                | 0                  | 0          |
| Tinea corporis           |                | 0                  | 0          |
| UTI                      |                | 0                  | 0          |
| Vaginal candidiasis      |                | 0                  | 0          |
| Viral fever              |                | 0                  | 0          |
| Infected mole            |                | 0                  | 0          |
| Total                    |                | 25                 | 30.29      |

AGE- Acute gastroenteritis, PID- Pelvic inflammatory disease, PTB- Pulmonary tuberculosis, UTI- Urinary tract infection

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

| Non infective diseases    | (Age in years) | Number of patients | Percentage |
|---------------------------|----------------|--------------------|------------|
| Bartholin cyst            | 18-30          | 1                  | 0.66       |
| Ca breast                 | 30-50          | 3                  | 0.66       |
| Ca cervix                 | >50            | 0                  | 0          |
| Cervicitis                |                | 0                  | 0          |
| Dub                       |                | 0                  | 0          |
| Dysmenorrhea              |                | 0                  | 0          |
| Early pregnancy           |                | 0                  | 0          |
| Ectopic pregnancy         |                | 0                  | 0          |
| Ca endometrium            |                | 0                  | 0          |
| Endometriosis             |                | 0                  | 0          |
| Endothelial dysfunction   |                | 0                  | 0          |
| Fibroadenoma breast       |                | 0                  | 0          |
| Fibroadenosis             |                | 0                  | 0          |
| Hyperemesis gravidarum    |                | 0                  | 0          |
| Mastalgia                 |                | 0                  | 0          |
| Menorrhagia               |                | 0                  | 0          |
| MTP                       |                | 0                  | 0          |
| Ovarian cyst              |                | 0                  | 0          |
| PCOD                      |                | 0                  | 0          |
| Preeclampsia              |                | 0                  | 0          |
| Primary infertility       |                | 0                  | 0          |
| Senile vaginitis          |                | 0                  | 0          |
| Uterine prolapse          |                | 0                  | 0          |
| Total                     |                | 56                 | 45.9       |

Ca- Carcinoma, DUB- Dysfunctional uterine bleeding, MTP- Medical termination of pregnancy, PCOD- Polycystic ovarian Disease
Table 3: Distribution of other diseases according to age.

| Other diseases       | (Age in years) | Number of patients | Total | Percentage |
|----------------------|----------------|--------------------|-------|------------|
| Anaemia              | 18-30          | 6                  | 3     | 3.66       |
|                      | 30-50          | 5                  | 11    | 11.33      |
|                      | >50            | 0                  | 2     | 0.66       |
| Acid peptic disease  | 18-30          | 9                  | 21    | 34         | 11.33     |
|                      | 30-50          | 2                  | 4     | 6          | 2.22      |
| Backache             | 18-30          | 0                  | 1     | 1          | 0.33      |
|                      | 30-50          | 0                  | 1     | 1          | 0.33      |
|                      | >50            | 2                  | 4     | 7          | 2.33      |
| Cu-t                 | 18-30          | 2                  | 1     | 3          | 1         |
|                      | 30-50          | 1                  | 0     | 1          | 0.33      |
| Diabetes melitus     | 18-30          | 0                  | 2     | 0          | 0.66      |
| External hemorrhoids | 18-30          | 0                  | 1     | 0          | 0.33      |
|                      | 30-50          | 1                  | 0     | 1          | 0.33      |
| Hypertension         | 18-30          | 1                  | 2     | 4          | 7         |
|                      | 30-50          | 2                  | 1     | 3          | 1         |
| Hypothyroidism       | 18-30          | 0                  | 2     | 0          | 0.33      |
|                      | 30-50          | 1                  | 0     | 1          | 0.33      |
|                      | >50            | 1                  | 0     | 1          | 0.33      |
| Total                | 18-30          | 19                 | 41    | 71         | 23.63     |
|                      | 30-50          | 41                 |       |            |           |
|                      | >50            | 11                 |       |            |           |

Cu-T: Copper T

The third group of drugs commonly prescribed were gastrointestinal drugs 105(13.92%) in which ranitidine 97(12.86%) most commonly was prescribed. Other group of drugs like Non-steroidal anti-inflammatory drugs (NSAIDS) 74(10.07%) in which Diclofenac 51(6.76%) was commonly prescribed followed by Paracetamol 19(2.51%). There were 16(2.12%) drugs from cardiovascular system (CVS) and 3 (0.39%) drugs from Central nervous system (CNS). In hormonal preparation, Norethisterone and thyroxine were prescribed. Other prescribed drugs classified according to pharmacological class are given in Figure 1.

Out of 754 drugs prescribed, 739(98.00%) were prescribed by generic name, 15(2.00%) by brand name (figure 2) and 70(9.28%) prescribed were fixed dose combination. Among the total drugs prescribed 644 (85.41%) were from NLEM. Prescription containing >2 drugs per prescriptions was observed in 115 (38.33%) prescriptions (Table 5).

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

| Sr. No. | Dosage forms | Total (drugs) | Percentage (%) |
|---------|--------------|---------------|----------------|
| 1       | Tablet       | 724           | 96.02          |
| 2       | Capsule      | 12            | 2              |
| 3       | Pessary      | 2             | 0.26           |
| 4       | Powder       | 3             | 0.39           |
| 5       | Topical      | 2             | 0.26           |
| 6       | Injection    | 8             | 1.06           |
| 7       | Syrup        | 3             | 0.39           |
| Total   |              | 754           | 100            |

Figure 1: Distribution of drugs according to pharmacological class.
Among the infectious diseases, breast abscess is most common in our study followed by acute gastroenteritis and PID. Breast abscess however is uncommon due to the early availability of antibiotic but breast infection (including infectious mastitis and breast abscess) more commonly affects lactating women aged 15-45 years. The WHO review of mastitis (2000) concluded that 11% of women with mastitis develop an abscess from the same study. More cases of breast abscess in our study might be due to poor hygiene, lack of awareness among the females of rural area and hesitancy in contacting the health care services. Kolasani BP et al, reported that vaginal discharge due to reproductive tract infection is common while Sharma et al found PID as most common infectious disease. Reproductive/Sexual tract infections (RTI/STI) are major cause of gynecological morbidity all over the world. NFHS-3 (National Family Health Survey), estimates that 11.1% of women were reported to have STI in India.

In this study, among all the drugs, 42.70% prescribed were minerals in which calcium and iron were commonly prescribed followed by folic acid. Considering the most common age group in our study, calcium supplements might be given as prophylaxis to prevent the osteoporosis. In India, 55% of the females have anemia and is more widespread among both women and children and it has risen almost 5% than NFHS-2. As per Bhatia et al, approximately one-third of all women in OPD reported symptoms of anaemia. In our study, there is a difference between diagnosed cases of anaemia and iron-folic acid drugs prescribed which indicates majority of these drugs prescribed were based on symptoms of anaemia. Many physicians prescribe these supplements considering the nutritional status and socioeconomic background of Indian women.

Second most common prescribed group was antimicrobials in which Ciprofloxacin was common followed by Metronidazole and Amoxicillin which is consistent with study conducted by Shah et al, in the study conducted by Baig et al metronidazole (6.97%) was commonly prescribed followed by ciprofloxacin (6.20%) and ampicillin (4.50%).

The third group of drugs commonly prescribed were gastrointestinal drugs (13.92%) in which ranitidine (12.86%) was most common. This is in contrast to the Baig et al, Sharma et al, and Vakharia et al where Non-steroidal anti-inflammatory drugs are the third most commonly prescribed drugs. This is because in our study, acid peptic diseases are most common in the category of other diseases.

As per Dhaubhadel et al, pain is the most distressing experience of human beings and pelvic pain is one of the most common reason for gynaecology consultation. In Non-steroidal anti-inflammatory drugs, Diclofenac (6.76%) was commonly prescribed which can be

DISCUSSION

The data in our study were accessed and collected from Hospital Management Information system, which has its advantages like minimizing the prescription errors, data safety and easy retrieval and analysis of data.

In our study, the mean age of presentation was 36.6±10.98 years and the most common age group was 30-50 years. This is in contrast to the Vakharia et al, and Misra et al where the mean age of presentation was 25.06±7.95 years and 26.39 years respectively while the most common age group was >18-30 years. This might be because majority of the patients in our study are from rural area 226(75.3%). As most of the females from this region are uneducated, their awareness to the diseases is less and so there is a delay in reaching the health care facility. Majority of the women from rural background depend on primary health services for gynecological diseases in their areas so this health care services should be strengthened to reduce the morbidity among the women from rural areas.

In our study the most common menstrual disorder was dysmenorrhea in 30-50 years age group. Baig MS et al, also found the dysmenorrhea as the most common among menstrual disorder but in >18-30 age group. Not only in India but worldwide dysmenorrhea is the most common menstrual disorder present in females. (Damhmare et al. 2011) (Harlow and Campbell 2004) (Unsal et al. 2010) (Grandi et al. 2012). Among the infectious diseases, breast abscess is most common in our study followed by acute gastroenteritis and PID. Breast abscess however is uncommon due to the early availability of antibiotic but breast infection (including infectious mastitis and breast abscess) more commonly affects lactating women aged 15-45 years. The WHO review of mastitis (2000) concluded that 11% of women with mastitis develop an abscess from the same study. More cases of breast abscess in our study might be due to poor hygiene, lack of awareness among the females of rural area and hesitancy in contacting the health care services. Kolasani BP et al, reported that vaginal discharge due to reproductive tract infection is common while Sharma et al found PID as most common infectious disease. Reproductive/Sexual tract infections (RTI/STI) are major cause of gynecological morbidity all over the world. NFHS-3 (National Family Health Survey), estimates that 11.1% of women were reported to have STI in India.

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explained as dysmenorrhea was most common in non-infectious diseases in our study.

The average number of drugs per prescription in present study was 2.51. Since, WHO has recommended that average number of drug per prescription should not be >2.0, because of increased risk of adverse drug reactions, drug interactions, dispensing errors and decrease adherence to drug regimens and unnecessary drug expenses.20 Lack of awareness about the gynecological diseases among the women of rural area leads to decrease in follow up visit which is a contributing factor for increase in drugs per prescription.

In our study majority of the drugs prescribed were generic which were from the essential medical list NLEM and WHO.21,22 The percentage of drugs prescribed from NLEM was found to be 85.41% which indicates a better trend of prescribing as these drugs are safer, efficacious and comparatively economical to the patients.

CONCLUSION

The overall drug use pattern in our study correlates with various gynecological diseases in the study. Average number of drugs per prescription was comparable with a standard given by WHO. Majority of the women from rural background depend on primary health services for gynecological diseases in their areas so, gynecological health care services should be strengthened to reduce the morbidity among the women from rural areas. Periodic evaluation of prescribing pattern should be carried out to ensure rational prescription practice.

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