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STUDY OF DRUG UTILISATION PATTERN IN OBSTETRICS AND GYNAECOLOGY DEPARTMENT OF A TERTIARY CARE HOSPITAL

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ABSTRACT

Disorders related to obstetrics and gynaecology are increasing, and the use of drugs is inevitable. Because of this, irrationality can occur using inappropriate prescribing, not enquiring about past medical and medication history, OTC medications, and polypharmacy. Drug utilisation study facilitates ADR minimisation and optimisation of health care resources. This prospective observational study aims to assess and understand the drug utilisation pattern in a tertiary care hospital using WHO core prescribing indicators. A total of 160 cases were enrolled over six months of the time. In pregnancy, general checkups were standard, and hypothyroidism was common in gynaecology. A total of 351 drugs were prescribed, including minerals and vitamins are majorly prescribed. The percentage of drugs from EDL was 80.9%, less than WHO standards. Antibiotics prescribed was 15.38%, which is within the limit; drugs by generic name were 28.49%, very much less than the standard, and the average number of drugs per prescription was 2.19%, which is higher than the standard, indicating the trend of polypharmacy. Most of the drugs were from the essential drug list of the National List of Essential Medicines (NLEM). Overall, the drug use pattern was found to be rational, with few exceptions of polypharmacy.

KEYWORDS: Obstetrics and Gynaecology, Drug Utilisation, OTC Medications, NLEM and FDA Category, ADR.

INTRODUCTION

Obstetrics and Gynaecology is a specialised branch of medicine concerned with women's reproductive health. Obstetrics is the medical care of women during and after pregnancy, and Gynaecology is the medical care of female genital conditions and reproductive health. This discipline provides extensive services ranging from parturition, puberty, menopause and beyond. This field is essential for reproductive health and addresses broader concerns about women's health and well-being.[1,2] Common gynaecological conditions include dysmenorrhea, a painful menstruation that commonly occurs in 50-90% of adolescent girls and women of reproductive ages. Secondary dysmenorrhea commonly occurs due to endometriosis and other aetiologies. Primary Dysmenorrhea occurs due to increased levels of prostaglandins and leukotrienes. NSAIDs and hormonal contraceptives are highly preferred in treating them.[3,4] Polycystic ovary syndrome (PCOS) is an endocrine disorder that is a group of symptoms affecting women of reproductive age. A fluid-filled cyst is formed in the ovaries due to an imbalance of sexual hormones. This leads to insulin resistance, and visible signs of morphological alterations can be seen in women. Metformin and hormonal therapy are usually recommended in this condition.[5,6] Uterine fibroids are benign tumours that commonly affect older women and women of reproductive ages. This can be asymptomatic in some individuals but usually causes abnormal uterine bleeding, increased urinary frequency, lower back pain, and bowel dysregulation. Tranexamic acid, NSAIDs, and hormonal contraceptives are used as a part of management.[7,8] Endometriosis is a condition in which the tissue resembling the endometrium grows outside of the uterus. It is a chronic disease that affects 10% of reproductive-aged women worldwide. Typically, it affects the ovaries and peritoneum, resulting in dysmenorrhea and discomfort before menstruation.[9,10] Irregular menstruation is very common in adult women and is associated with work-life imbalance and socio-economic status. Due to a stressful lifestyle, unhealthy eating habits, sleep disturbance, psychological imbalance, and other underlying causes such as thyroid disorders, endometriosis, and PCOS may also be the reason.[11,12] Hyperemesis gravidarum is the severe form of feeling nauseous and vomiting during pregnancy. Nausea and vomiting during the early stages of pregnancy are pretty familiar with a prevalence of 70% worldwide. At the same time, only one person describes severe symptoms leading to decreased oral intake and significant weight loss. The condition can be associated with vitamin B1 deficiency, bleeding

diathesis due to vitamin K deficiency, and oesophagal rupture impacts overall physiological and mental well-being.[13,15] Gestational diabetes mellitus is one of the most common pregnancy problems that affects around 7 to 10% of the pregnancy population worldwide. It usually appears in the second or third trimester, and the risk of mortality increases if the woman experiences diabetes in two or more pregnancies.[16,18]

According to the World Health Organization (WHO), Drug utilisation can be defined as the study of marketing, distribution, prescription, and use of medicines in a society, emphasising the resulting medical and socio-economic consequences.[19]

Disorders related to obstetrics and gynaecology are increasing, and the use of drugs is inevitable. With the increase in the burden of gynaecological diseases in lower-income countries like India, there is an increase in unrecognised morbidity with such conditions.[20] The value of the Indian pharmaceutical market grew by 14.1% by July 2022, with the fastest-growing disciplines of respiratory, gynaecology, chemotherapy, urology and so on. 24% growth was seen in gynaecology when compared to other categories. In February 2012, drugs from the gynaecology department ranked 8th as the strongest-selling medication with 16.4% growth among different categories of drugs, according to the data announced by AIOCD-AWACS (All Indian Origin Chemists and Distributors Ltd-Advanced Working, Action and Correction System).[21] In the OB-GYN department, the most used medications include Vitamins and minerals, hormones, antibiotics, contraceptives, analgesics, and antifungals. With this information, drugs are an essential part of the healthcare system. Irrational use of these drugs not only minimises the optimal therapeutic outcome but also maximises the chances of inducing adverse drug reactions, undesired interactions, and unwanted side effects. Besides, there is a loss of resources, increased socioeconomic burden, and chances of antimicrobial resistance. Irrationality can be caused by various aspects such as inappropriate prescribing, prescribing expensive medications, not enquiring about past medical and medication history, medication nonadherence, use of OTC medications, polypharmacy, and choosing newly introduced medicine due to over-promotion by pharmaceutical companies.[22,23] To improve the quality of life of patients and optimise the use of healthcare resources, following rational use of medicines is essential. This is possible by understanding individual patient conditions, medication adherence, proper monitoring, tailored therapeutic care, and periodic study of drug utilisation. Drug utilisation study facilitates the appropriate use of medications, minimises undesired side effects and ADR, and helps optimise healthcare

resources with desired patient therapeutic outcomes.[24] Thus, WHO and INRUD (International Network for Rational Use of Drugs) have developed a set of indicators called the core prescribing indicators, which help to measure the degree of polypharmacy, the tendency of prescribing generic medications over brand medications, average number of drugs per prescription, level of antibiotics and injections per prescription, and presence of drugs in essential drug list (EDL).[25] These core indicators can be a simple yet efficient tool to assess and analyse the utilisation of drugs in the healthcare system. Despite this, the data on drug utilisation patterns in the OB-GYN department is insufficient. Considering the above aspects, the present study examined the drug utilisation pattern using WHO core prescribing indicators and NLEM (National List of Essential Medicines) in the OB-GYN department of a tertiary care hospital in Chittoor district, Andhra Pradesh.

METHODOLOGY

A prospective observational study was conducted at Babu Hospital, Chittoor, Andhra Pradesh, and it had a time duration of 6 months with 160 patients. Patients satisfying the inclusive criteria of the OB-GYN department were selected. The data was obtained through direct interaction, patient case profiles, and prescriptions.

Inclusion criteria

Patients in the OB-GYN department within the age group of 10-45 years, pregnant patients with comorbidities of thyroid, diabetes, and hypertension.

Exclusion criteria

Patients of age >45 years, patients with neurological disorders, and emergency cases like eclampsia, pre-eclampsia, and shock in the OB-GYN department.

METHOD OF DATA COLLECTION

All the patients satisfying the inclusion criteria were selected from the OBGYN department in Babu Hospitals, Chittoor. The patient's data was collected using the patient profile form. Patient case profile includes demographic details, past medical and medication history, menstrual data, marital and obstetrics history, history of allergy to drug or food, Laboratory investigations, provisional diagnosis, and treatment chart. Data obtained through prescription includes medications prescribed, dosage and route of administration, brand or generic drug, number of drugs per prescription, pregnancy category of drugs, and drugs present in the essential drug list of NLEM.

Statistical analysis

Statistical analysis was primarily descriptive, and the data obtained will be expressed graphically using Microsoft Excel.

RESULTS

One hundred sixty cases were collected for six months, including 79 cases from obstetrics and 81 from the gynaecology department. The data was collected from the age group of 10-45 years, among whom patients of the age group of 21-25 years are higher in number, and the least is from the age group of 10-15 years. Table 1 shows the age categorisation of patients.

Table 1: Age categorisation of patients.

Age group (years)	No. of patients
10-15	2 (1.25%)
16-20	10 (6.2%)
21-25	58 (36.2%)
26-30	43 (26.8%)
31-35	28(17.5%)
36-40	9 (5.6%)
41-45	10 (6.2%)
Total	160

The conditions in gynaecology and obstetrics are divided as shown in Table 2 and Table 3. In the gynaecology department, compared to polycystic ovary syndrome and urinary tract infections, hypothyroidism cases are frequently obtained. In obstetrics, women visiting for general check-ups are more common than other pregnancy-related conditions. Pregnant women with gestational diabetes and thyroid disorders are quite less. During early pregnancy, morning sickness is highly prevalent, yet women do ignore this. Spotting can be seen in the first trimester of pregnancy. It is expected during the early stages, but treating the underlying cause is crucial in severe cases.

Table 2: Distribution of Gynaecological conditions.

Clinical conditions	No. of cases
PCOS	13 (16%)
UTI	14 (17.2%)
Menorrhagia	9 (11.1%)
Uterine fibroids	2 (2.4%)
Irregular menstruation	7 (8.6%)
Urinary incontinence	3 (3.7%)
Anemia	4 (4.9%)
Abdominal pain	4 (4.9%)

Dysmenorrhea	3 (3.7%)
Intermenstrual bleeding	2 (2.4%)
Vaginitis	2 (2.4%)
Dysfunctional uterine bleeding	1 (1.2%)
Hypothyroidism	17 (20.9%)
Total	81

Table 3: Distribution of pregnancy conditions.

Pregnancy conditions	No. of cases
General check-up	58 (73.4%)
Gestational diabetes	5 (6.3%)
Hypothyroidism	7 (8.8%)
Morning sickness	5 (6.3%)
Hookworm infestation	1 (1.2%)
Spotting	3 (3.7%)
Total	79

In Obstetrics, pregnancy patients were divided as per trimester. Out of 79 cases, most of them are in the third trimester (45), followed by the second (20) and then the first trimester (14). Figure 1 shows the pregnancy trimester-wise categorisation.

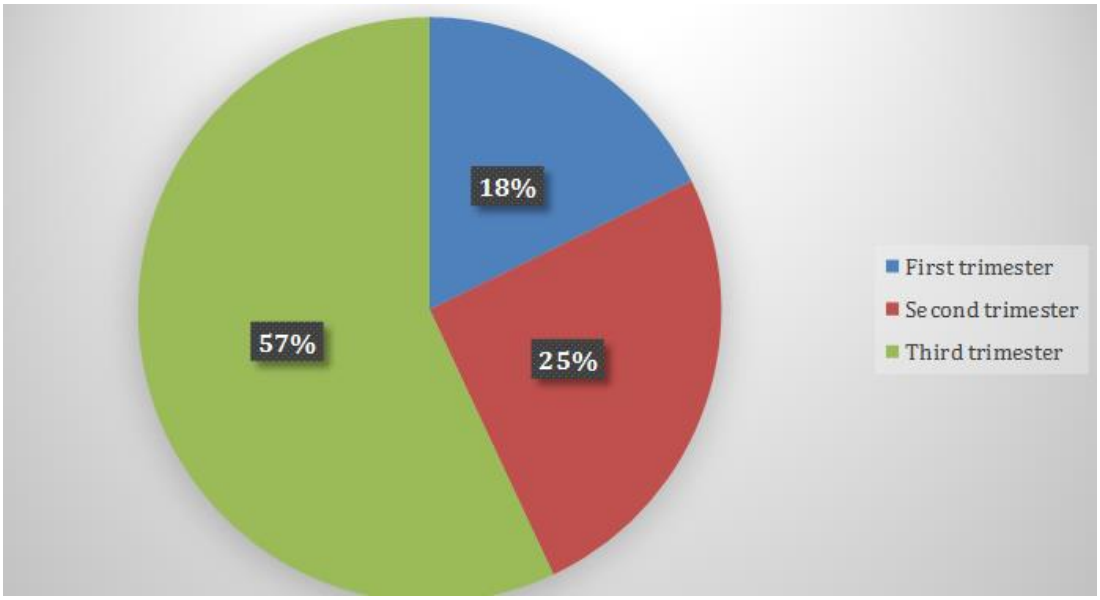

Figure 1: Pregnancy trimester-wise categorisation.

For 160 cases, 351 drugs were prescribed. Minerals and vitamins are the most prescribed as they are the most widely used medicine during pregnancy. Other categories include tetanus toxoid injection, cough syrup, ayurvedic/unani preparations, protein powder. Table 4 shows the Categorization of classes of drugs prescribed.

Table 4: Categorization of classes of drugs prescribed.

Prescription pattern	No. of cases	No. of drugs
Minerals and Vitamins	53	169
Antimicrobials	17	54
Analgesics and Antispasmodics	10	14
Gastric inhibitors	9	9
Antihypertensive	1	1
Antiemetics	11	11
Antidiabetics	10	12
Hormonal drugs	22	55
Antifibrinolytics	6	6
Others	12	20
Total	160	351

The prescription pattern was analysed, and individual classes of drugs were divided. Metronidazole, Nitrofurantoin, and Doxycycline as a combination therapy or individual drugs are highly prescribed for urinary tract infections. Figure 2 shows the individual antimicrobial drugs prescribed. Progesterone is commonly prescribed in the hormonal category out of 55 hormonal medications. Hormonal therapy is prescribed as contraceptives, replacement therapies, and to correct the menstrual cycle in women suffering from irregular menstruation. The hormonal category also includes thyroid drugs, levothyroxine and thyroxine sodium. Figure 3 shows the individual Hormone drugs prescribed. Metformin is commonly the preferred oral hypoglycaemic agent. Metformin is also prescribed for PCOS conditions. Insulin is preferred in uncontrolled blood glucose levels. Figure 4 shows the individual antidiabetic drug prescribed. A total of 14 pain management drugs were prescribed, most of which are used to treat abdominal cramps and dysmenorrhea, as shown in Table 5.

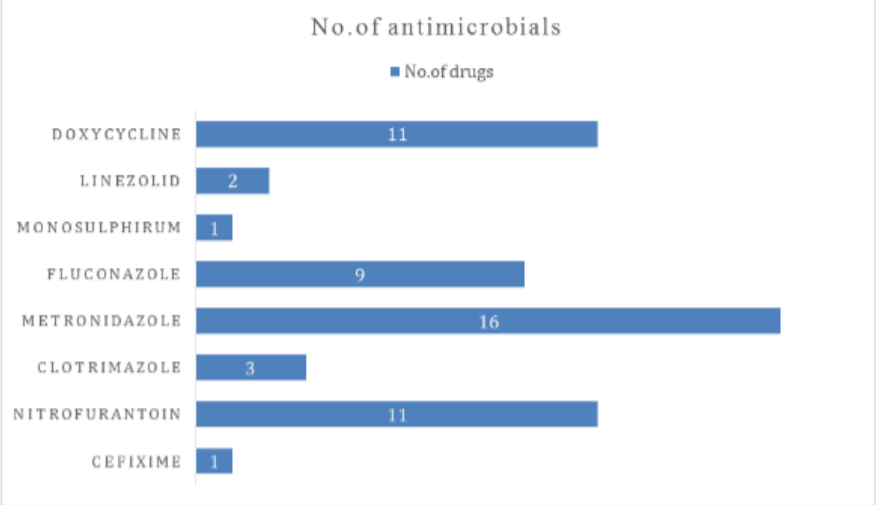

Figure 2: individual antimicrobial drugs prescribed.

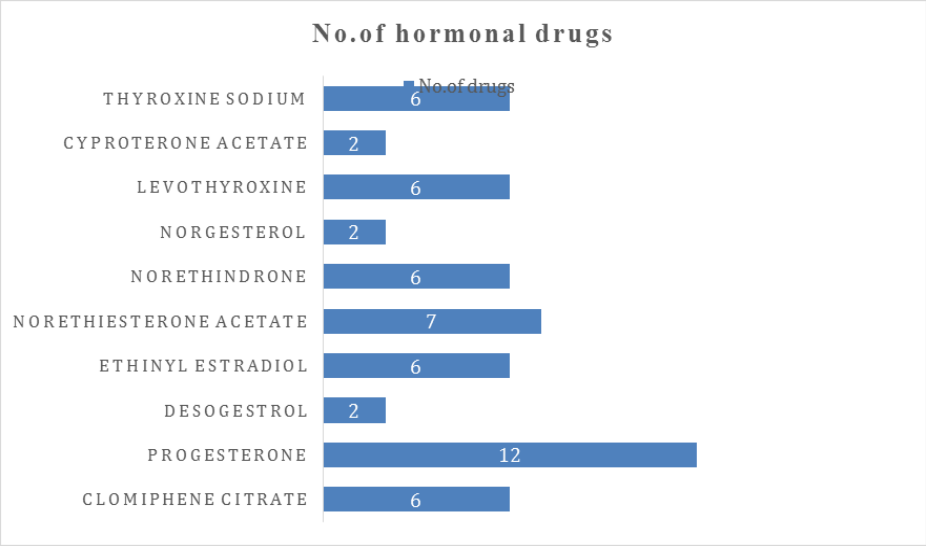

Figure 3: Individual Hormonal drugs prescribed.

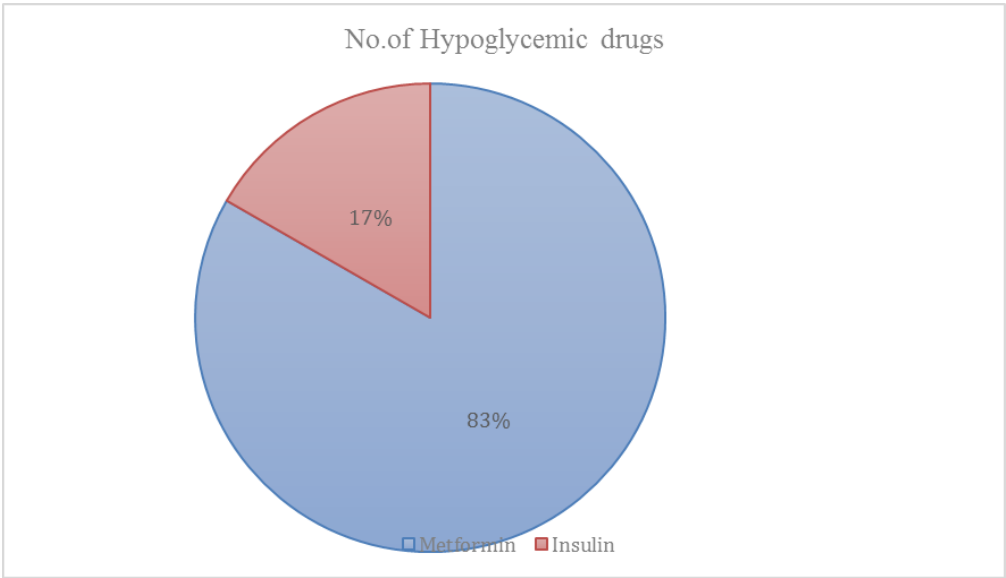

Figure 4: Individual Antidiabetic drug prescribed.

Table 5: Individual pain medications prescribed.

Individual pain medications	No. of drugs
Dicyclomine HCl	3 (21.4%)
Ibuprofen	2 (14.2%)
Acetaminophen	2 (14.2%)
Drotaverine	1 (7.1%)
Mefenamic acid	2 (14.2%)
Diclofenac sodium	2 (14.2%)
Serratiopeptidase	1(7.1%)
N-Acetyl cysteine	1 (7.1%)
Trypsin and Chymotrypsin	1(7.1%)
Total	14

Out of 351 drugs, most medications prescribed are brand 251 (72%) compared to generic medicines 100 (28%). Most medications prescribed are specified with a frequency of administration of 307 (87%), while some drugs, such as vitamins, minerals, and protein supplements, are not specified with a frequency of 44 (13%). The oral route of administration is commonly preferred 330 (94%) drugs over any other route of administration - Intramuscular 10 (2.8%), Topical 6 (1.7%), Intravenous 4 (1.1%), Subcutaneous 1(0.2%). Compared to capsules 21 (5.9%), tablets 301 (85.7%) are primarily available in dosage form, followed by injections 15 (4.2%), topical 6 (1.7%), powders 4 (1.1%) and syrups 4 (1.1%). Out of 351 drugs prescribed, most were specified, with a dose of 242 (68.9%). Some prescriptions for vitamins, minerals, ayurvedic supplements, gastric inhibitors, pain medications, were not specified with the dose 109 (31%). Most drugs were prescribed from the National List of Essential Medicines (NLEM) 2022, 284 drugs (80.9%). Some are not in this Essential Drug List (EDL) 67 (19%).

All the drugs prescribed were checked for the FDA pregnancy category, and the majority of the drugs were prescribed from category B. The medications under category X are provided to gynaecology patients, including Ethinyl estradiol, Cryproterone acetate, Clomiphene citrate, Norgesterol, HMG injection, Norethisterone and norethindrone acetate. These are prescribed to patients who are not pregnant and not planning for childbirth at the time.

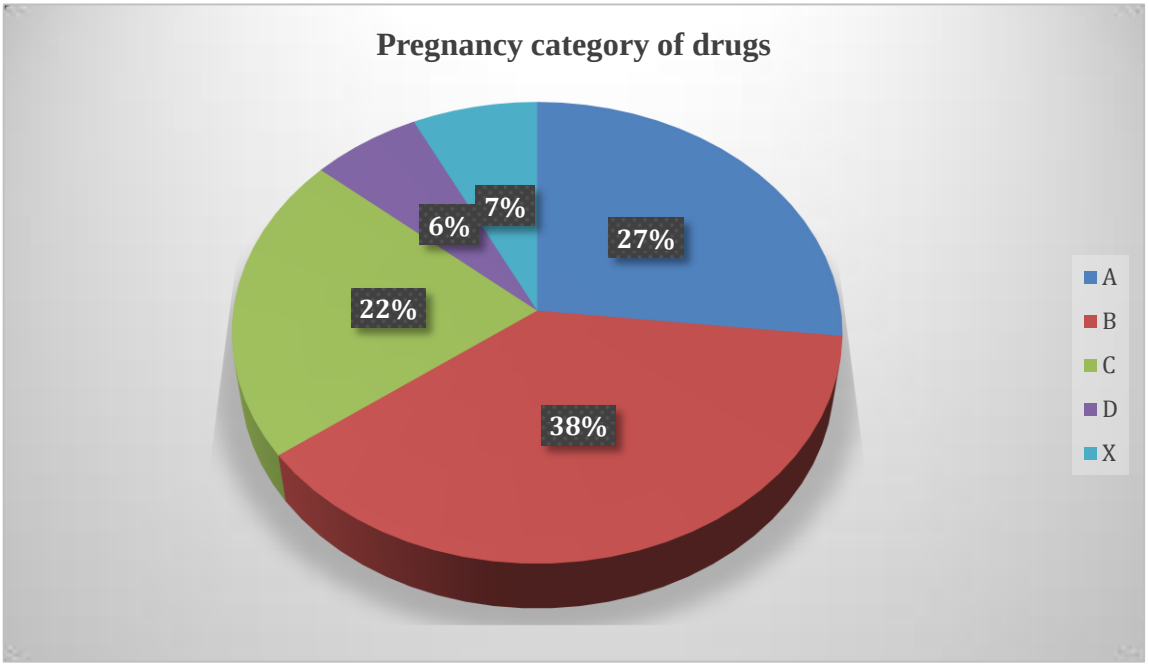

Figure 5: Pregnancy categorisation of drugs.

The core prescribing indicators are the measures used to assess and analyse the prescription pattern in healthcare settings. The trend of polypharmacy can be seen due to an increase in the average number of drugs per prescription than WHO's standard, and the number of medications prescribed from EDL is lower than the recommended standard.

Table 6: WHO Core Prescribing Indicators.

WHO core indicators	No. of drugs	Results	WHO standards
Average no. of drugs per prescription	351	2.19	1.6-1.8
Drugs prescribed by Generic name	100	28.49%	100%
No. of Antibiotics prescribed	54	15.38%	<30 (20.0-26.8%)
No. of injections prescribed	15	4.27%	<25 (13.4-24.1%)
No. of drugs from EDL	284	80.9%	100%

DISCUSSION

Our prospective observational study carried out among 160 patients and 351 drugs prescribed in the OB-GYN department, shows that most patients fall under the age group of 21-25 years. Of 160 patients, 81 were from the gynaecology department, and 79 were from the obstetrics department. In gynaecology, the majority of the conditions are Hypothyroidism, as per the study conducted by Somen Bhattacharjee et al.[26] then infections such as UTI, followed by other conditions such as PCOS, Menorrhagia and so on. In a study conducted by Manish B. Nandeshwar et al.[27] on obstetrics, most patients visited for general pregnancy checkups. Pregnant patients with thyroid disorders, diabetes, and morning sickness have a similar prevalence and require fewer hospital visits. Patients of the 3rd-trimester cases are more common than the first and second trimesters. According to the research conducted by Baig MS et al., among 351 drugs, the most common drugs prescribed in this department are vitamins and minerals such as iron, folic acid, calcium and D_3, multivitamins, followed by hormonal medications are utilised to manage irregular menstruation, PCOS, and as hormonal replacement therapy for middle-aged women experiencing hot flushes. Followed by antimicrobials are used for addressing infections. In the gynaecology department, urinary tract infections are more commonly reported than sexually transmitted and fungal infections. Pain management medicines not only treat menstrual cramps but also address other minor conditions like general body weakness. Metformin is the preferred medication in

gynaecology due to its favourable safety profile, while injectable insulin is much less prescribed as an antidiabetic agent. Antiemetics are utilised to treat morning sickness in the early stages of pregnancy and women. GI inhibitors such as pantoprazole, metoclopramide, and antacids are prescribed due to their safety profile in pregnancy. Tranexamic acid is often chosen as an antifibrinolytic agent to control excessive menstrual bleeding in women suffering from dysmenorrhea. Other categories of drugs were also prescribed, which included protein supplements, Tetanus toxoid injections, cough syrup, HMG-Human menopausal gonadotropin injection and ayurvedic/unani preparations. Lakde P Suresh et al.[28] conducted a study in which antimicrobials treated Infections, and among them, Metronidazole was the most prescribed, followed by nitrofurantoin and doxycycline. As per the study conducted by Perasani Umarani et al.,[29] many prescriptions are specified by frequency and dose. The predominant method of administration was oral, which offers greater convenience compared to other routes. Most of these were in tablet form, readily accessible and generally well-received by patients. Nearly 71.5% of drugs prescribed were brand, and only 28.4% of drugs were generic. All the drugs prescribed were checked for the FDA pregnancy category. Among these, category B drugs were frequently prescribed, which means there is insufficient evidence from human studies, but animal research did not show any risk to the developing fetus. Category X drugs - studies on pregnant women have revealed potential risks to the developing fetus. At the same time, human or animal research has indicated possible fetal abnormalities, thus suggesting the dangers associated with the medication exceed its potential advantages. Such drugs were prescribed for gynaecological conditions to patients who were not pregnant and not planning for pregnancy at that moment. WHO core prescribing indicators are used to assess and analyse the prescription pattern. This includes the average number of drugs per prescription, drugs prescribed by generic names, antibiotics prescribed, and the number of drugs prescribed from Essential Drug List (EDL). The percentage of drugs prescribed from EDL was 80.9%. The Percentage of injections present was 4.27%, less than WHO standards. Antibiotics prescribed were 15.38%, which is within the WHO standards. Drugs prescribed by generic names were 28.49%, much less than the standard range of WHO. According to the research conducted by Naresh Karki et al., the average number of drugs per prescription was 2.19%, higher than the WHO standard values, indicating the trend of polypharmacy.

CONCLUSION

The study concludes that the average number of drugs per prescription was slightly higher than the WHO standards, indicating polypharmacy. Iron, folic acid, B. complex vitamins, and calcium were mainly prescribed. Brand drugs were majorly preferred over generic drugs. Most drugs were from the essential list, and FDA category B drugs were frequently prescribed. Periodic drug utilisation studies are imperative to promote rational and optimal use of healthcare resources.

LIST OF ABBREVIATIONS

OBG: Obstetrics and Gynaecology; **WHO:** World Health Organisation; **OTC:** Over the Counter Drugs; **AIOCD-AWACS:** All Indian Organization of Chemists and Druggist – Airborne Warning and Control System; **INRUD:** International Network for Rational Use of Drugs; **NLEM:** National List of Essential Medicines; **EDL:** Essential Drug List; **UTI:** Urinary Tract Infection; **PCOS:** Polycystic Ovarian Syndrome; **OPD:** Outpatient Department

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