Drug Utilization Evaluation For Postoperative Patients In Obstetrics and Gynaecology Department In A Tertiary Care Teaching Hospital

T Lakshmi Suseela¹, S Jaya Jyothi², T Mahendra³, E Sam Jeeva Kumar⁴

ABSTRACT

A growing number of pharmaceutical products are available in the world market and there has been an increase both in the consumption of the drugs and in expenditure on them. The main aim of the study was to analyze drug use pattern in a post-operative patients in obstetrics and gynaecology ward and to assess the prescribing indicators (WHO: Core Drug Use Indicators). A prospective, concurrent and retrospective observational study was conducted over a period of six months, after getting approval by the Institutional Ethics committee. A well designed patient data collection proforma for collecting the required data from post-operative patients by using chart review method in Obstetrics and Gynaecology ward of a tertiary care teaching hospital. The data was analyzed using descriptive analysis with the help of SPSS software. The results shown are a total of 582 cases were analyzed during the following study period. Out of 582 patients, 559 (96%) were prescribed with parenteral Cefotaxime and Metronidazole. Post-operative pain was managed with Tramadol (87%). All patients were prescribed with an antibacterial agent and analgesic (100%). The percentage of encounters with an injection prescribed was 100% in our study. Out of 19 different drugs prescribed, 16 (84.21%) were from the Essential Medicines WHO Model List (2015) and 10 (52.63%) were prescribed by their generic name. Accordingly, the study can be concluded as it provides valuable insight about the overall pattern of drug used in postoperative patients. The study is useful in decreasing the irrational prescription, which helps to decrease the morbidity and health care burden in the society.

Key-words: Drug utilization, Post-operative, Obstetrics and Gynaecology

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¹ Associate Professor, Department of Obstetrics & Gynaecology, Rajiv Gandhi Institute of Medical Sciences, Kadapa.
² PharmD-Post Baccalaureate, P.Rami Reddy Memorial College of Pharmacy, Kadapa
³ Pharm.D, P.Rami Reddy Memorial College of Pharmacy, Kadapa
⁴ Associate Professor, P. Rami Reddy Memorial College of Pharmacy, Kadapa

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INTRODUCTION

Drug Utilization Reviews (DUR)

Drug Utilization Reviews (DUR), also referred to as Drug Utilization Evaluations (DUE) or Medication Utilization Evaluations (MUE), are defined as an authorized, structured, ongoing review of healthcare provider prescribing, pharmacist dispensing, and patient use of medication [3]. DURs involve a comprehensive review of patients’ prescription and medication data before, during, and after dispensing to ensure appropriate medication decision making and positive patient outcomes [8].

DURs are classified into three categories:
- Prospective
- Concurrent
- Retrospective

Why DUR Are Important:

DUR play a key role in helping managed health care systems understand, interpret, and improve the prescribing, administration, and use of medications. Pharmacists play a key role in this process because of their expertise in the area of pharmaceutical care. Pharmacists can collaborate with other members of the health care team, initiate action to improve drug therapy for both individual patients and covered populations. DURs serve as a means of improving the quality of patient care, enhancing therapeutic outcomes, and reducing inappropriate pharmaceutical expenditures, thus reduces the overall health care costs and length of stay in the hospital [8].

PROSPECTIVE DUR:

A Prospective DUR involves evaluating a patient’s planned drug therapy before a Medication is dispensed. Clinical Pharmacists routinely perform prospective reviews in their daily practice by assessing a prescription medication dosage and directions and reviewing patient information for possible drug interactions or duplicate therapy [9].

Issues Commonly Addressed by Prospective DUR:
- Drug-disease contraindications
- Generic substitution
- Inappropriate duration of drug treatment
- Clinical abuse/misuse
- Therapeutic interchange
- Incorrect drug dosage
- Drug-allergy interactions

CONCURRENT DUR:

A Concurrent DUR is performed during the course of treatment and involves the ongoing monitoring of drug therapy to ensure positive patient outcomes. It presents pharmacists with the opportunity to alert prescribers to potential problems and to intervene in areas such as drug-drug interactions, duplicate therapy, over or underutilization, and excessive or insufficient dosing [9][10][11].

Issues Commonly Addressed by Concurrent DUR:
- Drug-drug interactions
- Drug-gender precautions
- Over and underutilization
- Excessive doses
- High or low dosages
- Drug-disease interactions
- Duplicate therapy
- Drug-pregnancy precautions
- Drug-age precautions

Retrospective DUR:

A retrospective DUR is the simplest to perform since drug therapy is reviewed after the patient has received the medication. A retrospective review may detect patterns in prescribing, dispensing, or administering drugs to prevent recurrence of inappropriate use or abuse and serves as a means for developing prospective standards and target interventions. In retrospective DUR, patient medical charts or computerized records are screened to determine whether the drug therapy met approved criteria and aids prescribers in improving care for their patients, individually and within groups of patients, such as those with diabetes, asthma, or high blood pressure.
Issues Commonly Addressed by Retrospective DUR:

- Therapeutic appropriateness
- Appropriate generic use
- Drug-disease contraindications
- Incorrect drug dosage
- Clinical abuse/misuse
- Over and underutilization
- Therapeutic duplication
- Drug-drug interactions
- Inappropriate duration of treatment

The use of multiple medications may further increase the risk of drug-related problems, such as adverse drug reactions, interactions, patient noncompliance with treatment, and medication errors. Hence, the appropriate management of these patients is a challenge for treating post-operative patients in Obstetrics and Gynaecology ward healthcare professionals in a tertiary care teaching hospital.

CLINICAL PHARMACIST

Clinical pharmacist can be defined as 'the practice of pharmacy by the bedside of patients, in close association with doctors, nurses and other Health Care Professionals (HCP’s) with the objective of promoting rational and prudent use of medicines' [10] [11] [40] [41].

ROLES OF CLINICAL PHARMACISTS IN DUE [10] [11] [12] [13] [14] [15] :

- Program development, supervision and coordination.
- Education of hospital staff about DUE in conceptual and practical terms.
- Promotion of the goals and objectives of DUE.
- Development/review of audit criteria, guidelines, study protocols and educational material.
- Development of data collection instruments.
- Pilot testing, data collection, analysis and report writing.
- Documentation of program outcomes, effectiveness and cost benefits.
- Participation on hospital committees concerned with quality assurance in general and drug usage.
- Presentation of DUE results at meetings and conferences.
- Publication of results in peer-reviewed journals.

Figure 1.8: Clinical Pharmacist Roles and Responsibilities in ICU

Drug Related Problems (DRPS)

Role of pharmacist in Drug therapy Management (DTM) can prove to be the best to achieve therapeutic goals in patients and improves treatment outcomes by effective drug use and patient safety. Advancements in diagnostic testing, technological interventions and pharmacotherapy provides great benefits to patients with life-threatening acute illness. Clinicians are faced with making many important drug dosing decisions each day, even when the correct medication is chosen although, few drug related problems (DRPs) are not preventable as they are un-predictable because of their idiosyncratic nature [16] [42] [43].

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Complex pharmacotherapy, simultaneous use of drugs in post-operative patients in Obstetrics and Gynaecology ward often require close monitoring as their safety is of paramount importance. Raising healthcare costs, combined with decrease in medical care formulas for hospitalized patients have focused on transitions of care and preventing re-admission. Desired outcomes of DTM are appropriate drug use; enhanced patient understanding of appropriate drug use, increased patient adherence, reduced risk of adverse effects (AEs) associated with drugs, and reduced need for other costly medical services.

Hence, the current project was designed to monitor the current practice of clinicians for treatment of post-operative patients in Obstetrics and Gynaecology ward. The results also help to monitor the progress and to identify opportunities for strategic initiatives and policies to improve practice.

**Drug-Drug Interactions (DDI’S)**

Drug-drug interactions are an event that occurs when the effects of a drug are modified when another drug or food is taken concomitantly. This interaction can cause reduced, null or increased drug effect. Interactions can be classified, according to mechanisms by which drugs interact with each other, as physicochemical, pharmacokinetic and pharmacodynamic [17].

Physical-chemical or pharmaceutical interaction occurs when two or more drugs interact exclusively due to physical-chemical mechanisms. Pharmacodynamic interaction occurs when there is an added or antagonistic effect of drugs. Pharmacokinetic interaction occurs when a drug acts modifying absorption, distribution, biotransformation, and elimination of another drug.

Risk factors for drug interactions can be related to patient, drug and medical prescription. Patient-related factors include people that are more vulnerable to drug interactions such as the elderly, patients undergoing surgical procedures, and those receiving immune suppressed patients.

The main drug related risk factors are drug potency to cause effects of enzyme induction and inhibition, and drug therapeutic index.

Risk factors related to medical prescription include a large number of prescription drugs needed for patients admitted to the hospital with complex clinical conditions. As inpatients receive on average seven different drugs a day, drug interaction is evidently a significant concern, even more in surgical settings where patients receive care and a large range and quantity of drugs on a daily basis.

Although drug interactions have been widely addressed in medical and pharmaceutical books and journals, there have been scarce investigations in the nursing area, especially bearing in mind that the nursing team was responsible for the entire drug administration process.

**Adverse Drug Events (ADE’s):**

Adverse drug events (ADEs) involve "harm caused by a drug or the inappropriate use of a drug". ADEs can mimic diseases, decrease the confidence of patients in doctors, and delay both diagnosis and treatment. Moreover, ADEs can increase the length of hospital stay, raising hospital costs. Factors that predispose a patient to ADEs are age, gender, and polypharmacy. To assess the likelihood that a drug caused an ADE; and to identify the drugs, the ADEs themselves, and the risk factors associated with hospitalization.

WHO defines drug utilization as "the marketing, distribution, prescription and use of drug in a society with special emphasis on resulting medical, social and economic consequences." [1]

The principal aim of drug utilization research is to facilitate rational use of drugs in the population. A growing number of pharmaceutical products are available in the world market and there has been an increase both in the consumption of the drugs and in expenditure on them. [2] although rational use of drugs is quite a usual practice but sometimes certain factors may cause irrational practice. Monitoring of prescriptions and drug utilization studies could identify the associated problems and provide feedback to prescribers. [3] In most hospitals and clinics, conventional antibacterial therapy is given usually for 7-10 days to postnatal patients with episiotomy as well as post-surgical patients. It increases the cost for the patient, increases workload on hospital staff and results in emergence of antimicrobial resistance. [4] Surgical site infections are common complication of obstetric and gynecological surgeries; up to 10% of gynecological patients undergoing an operative procedure will develop a surgical site infection. [5] The principles of surgical prophylaxis have been established over years. Selection of antibacterial agent for prophylaxis should be based on its activity against anticipated bacteria at the specific surgical site. [6] Properly timed accurate dose of preoperative antibacterial agent reduces the incidence of surgical site infection. [7] Developing countries have limited funds available for
healthcare and drugs and it becomes very important to prescribe drug rationally so that the available funds can be utilized optimally.\(^8\) Postoperative utilization of drugs is very much marked. Drugs are prescribed for the purpose of analgesia, prevention of infection, nausea and vomiting, to maintain the hemodynamic status.\(^9\) since there are very few studies which describe the utilization of drugs postoperatively; this study was conducted to provide the drug utilization pattern in postoperative wards and to increase the rational use of drug to improve patient quality of life.

**AIM:**

The aim of the study is to perform the Clinical Pharmacist Role in Drug Utilization Review (DUR) for Obstetrics and Gynaecology Department patients in South Indian Tertiary Care Teaching Hospital (RIMS) Kadapa.

**OBJECTIVES:**

- To study the drug use pattern/prescribing pattern of drugs in Obstetrics and Gynaecology patients
- The collected data was used to find the prescribing indicators like
  - a) The average no. of drugs per prescription.
  - b) The percentages of the drugs which were prescribed by their generic names.
  - c) The percentages of the drugs with antibiotics which were prescribed.
  - d) The percentages of the drugs with different route of administration.
  - e) The percentages of the drugs which were prescribed from the Essential Drugs List or the formulary.
- To study about the various complications/morbidity patterns admitted in Obstetrics and Gynaecology and common drug groups prescribed for various morbidity patterns.
- To detect and help to prevent the drug related problems.
- To assess the reason for deaths and to find out the incidence of deaths.
- To study drug utilization metrics and their applications.

**RESEARCH METHODOLOGY**

**MATERIALS:**

1. Patient Data Collection Form ICU (Annexure -I)
2. Inform Consent Form (ICF) (Annexure -II)
3. Pharmacist Intervention Form (Annexure -III)

**METHODOLOGY:**

A prospective and concurrent observational study was carried out over a period of 6 months in the Obstetrics and Gynaecology department of RIMS after obtained approval by Institutional Review Board. Based on Inclusion and Exclusion criteria patients are included in the study. Written Informed Consent Form from the patient/legal guardian was taken prior to conduct the study. All the necessary and relevant baseline information are collected by using “Chart Review Method”, (which is well suited for DUE) in a patient data collection sheet which includes Patient demographic details, Past/Present medical history, Lab investigations, Diagnosis, Treatment/Physician medication order sheet (Agents, Doses, Dose intervals, Routes of Administration, Number of doses and Duration of Administration) and any other verbal communication data obtained from patients/patient caregivers. Confidentiality of the entire patient’s data will be maintained.

**Study design** : A Prospective, Concurrent and Retrospective observational study.

**Study site** : Rajiv Gandhi Institute of Medical Sciences, Kadapa.

**Study duration** : 6 - months.

**Sample size** : 250 Patients who are admitted in Obstetrics and Gynaecology Department.

**METHODS**

The study was conducted in department of Obstetrics and Gynaecology of a tertiary care teaching hospital. Case records of the patients admitted to Obstetrics and Gynaecological post-operative ward were collected after obtaining the approval of Institutional Ethics committee. Details of each case were recorded in separate
predesigned and pretested proforma. As per selection criteria, total 582 patients were enrolled in the study and demographic data, diagnosis, on-going treatment were recorded and analyzed.

**Inclusion criteria**
- The patients who underwent major operative procedure in the age group of 18 to 70 years were recruited in this study.

**Exclusion criteria**
- Patient who were not consenting for the study
- Patient discharged against medical advice
- Patient who were referred to higher centre were excluded from the study.

**Data analysis**
Rationality of prescription was analyzed by comparing with following WHO prescribing indicators –
- Average number of drugs per encounter.
- Percentage of drugs prescribed by generic name.
- Percentage of encounters with an antibiotic prescribed.
- Percentage of encounters with an injection prescribed.
- Percentage of drugs prescribed from essential drugs list or formulary.
Data were analyzed using descriptive statistics.

**RESULTS**
In the present study, total numbers of patients were 582. The patients had undergone different types of surgeries during the study. Lower segment caesarean section (LSCS) was the most common surgery (546 patients), followed by hysterectomy (36 patients). Among the Lower segment caesarean section, most common performed surgery was Emergency LSCS, followed by Elective LSCS. Different indication for lower segment caesarean section is shown in Figure 1.

![Figure 1: Indications for LSCS.](image)

Most commonly prescribed drugs in decreasing frequency are shown in Figure 2. The average number of drugs prescribed per patient was 9.8.
In our study, total patients with an antimicrobials prescribed were 582 and percentage of patients with an antibacterial prescribed was 100% (Table 1). Most commonly used antibacterial combination was metronidazole (582) along with cefotaxime (559) and piperacillin and tazobactam (21). An injection was prescribed in all the 582 patients either as an injectable antibacterial agent, or an injectable analgesic or intravenous fluid. Thus the percentage of patients with an injection prescribed was 100% in our study. The antibacterial agents were given for average duration of 3 to 5 days. In our study we found that out of 19 different drugs 10 drugs were prescribed by generic name (52.63%) and remaining 9 drugs were prescribed by brand name (47.3%) (Figure 3).

### Table 1: Percentage of antibiotic usage (n=582).

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Group of antibiotic</th>
<th>Frequency</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inj. Cefotaxime</td>
<td>Cephalosporin</td>
<td>559</td>
<td>96</td>
</tr>
<tr>
<td>Inj. Metronidazole</td>
<td>Antiamoebic</td>
<td>582</td>
<td>100</td>
</tr>
<tr>
<td>Inj. Piperacillin &amp; Tazobactam</td>
<td>Beta-Lactam</td>
<td>21</td>
<td>3.6</td>
</tr>
<tr>
<td>Inj. Ceftriaxone</td>
<td>Cephalosporin</td>
<td>2</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Figure 3: Percentage of drugs prescribed

<table>
<thead>
<tr>
<th>Pattern of Drugs Prescribed</th>
<th>Total (n=19)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. Of Generic Drugs</td>
<td>10</td>
<td>52.60</td>
</tr>
<tr>
<td>Total No. Of Branded Drugs</td>
<td>9</td>
<td>47.30</td>
</tr>
</tbody>
</table>

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Out of 19 different drugs prescribed, 16 (84.21%) were from the Essential Medicines WHO Model List (Figure 4). The post-operative pain was managed with Tramadol (87%) with average duration of 3-5 days, followed by Diclofenac sodium (9%) and Pentazocin (4%) (Figure 5).

**DISCUSSION**
Rational use of antimicrobial is extremely important as injudicious use can adversely affect the patient cause emergence of antimicrobial resistance and increase the cost.\textsuperscript{10-11} The use of antibacterial prophylaxis has been shown to prevent post-surgical wound infection. When employed rationally, significant reduction in the mortality and morbidity and saving in resources can be achieved.\textsuperscript{12-13} The purpose of antibacterial prophylaxis is to prevent postoperative infections, which are the primary cause of morbidity and mortality in patients undergoing surgery today. Aseptic techniques alone could decrease, but do not completely eliminate bacterial

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contamination of the surgical field. Therefore, the need for antibacterial agent to supplement aseptic technique becomes more widely accepted.14 In present study, surgery for LSCS was very common and accounted for a total of 546 patients which was 93.7% which is higher than the findings of Shah BK et al which was 45.5%.15 This difference is because, in our study most of the patients were from low socioeconomic status and rural area. Most of the cases were of emergency LSCS (56.5%), because trial labour was tried before taking any patient for surgery, unless there was an absolute indication. In our study major indication for emergency LSCS was oligohydramnios (24.9%), followed by history of previous LSCS (23.8%) and fetal distress (13.3%). The average number of drugs prescribed per patient was 9.8 with range of 5-19 which was lesser to findings of Agarwal JM et al (10.5) and Gyawali S et al (10.6).2,16 Most commonly used antibiotics in our study were Metronidazole (100%), Cefotaxime (96%), Piperacillin plus Tazobactam (3.6%), ceftriaxone (0.3%). Study of antimicrobial preference by Shah BK and Shah VN showed that Ciprofloxacin was maximally used (60.90%) followed by ampicillin (54.54%) and metronidazole (39.69%). This difference may be due to difference in the availability of drugs in different regions. In the study conducted by Heethal J et al most commonly used antibiotic combination was Cefotaxime plus metronidazole (35%), followed by ceftriaxone (25.3%) and ampicillin (17.2%).17 The current antimicrobial preference data provides that Cefotaxime was the most commonly given to the obstetrics and gynaecological post-operative patients to minimize the surgical site infections which has also been shown different similar studies. To prevent injection-associated infections, injection use needs to decrease and injection safety must be achieved. Several interventions were conducted world-wide to decrease injection overuse and/or to achieve safer practice. Some of them were very successful. Better communication between prescriber and patients and managerial approaches (i.e. restricting access to selected unnecessary and dangerous injectable drugs) can reduce overuse.18,19 In our study all the post-operative patients were given injection (100%) which was comparable to findings of Agrawal et al (88.13%) and higher to findings of Gyawali S et al (57.04%).2,16 Pain is an unpleasant sensation occurring in varying degrees of severity as a consequence of injury, disease, or emotional disorder. Poor pain control is unethical, clinically unsound and economically wasteful. Acute painful disorders are treated instantly; on the other hand severe post-operative pain and severe visceral pain are under diagnosed and under treated. Successful postoperative pain control was achieved by efficient use of health resources and patient's satisfaction. Large varieties of analgesics are available in the market which may lead to the problem of irrational prescription.20,21 The present study shows that Tramadol was the most frequently used opioid analgesic by intravenous route followed by pentazocine and diclofenac which was 96%, 84% and 4% respectively. Kolawole IK et al showed that Pentazocine was the most commonly used analgesic followed by tramadol which was 86.4% and 13.6% respectively.22 Like most part of the world opioid analgesic is the mainstay of post-operative pain control in our hospital. However potent opioids like morphine and pethidine which have been found useful and effective for pain control following major surgical procedure were not used in our hospital because of non-availability of these drugs. As prescribing by generic name will help for rational use of drugs with regard to cost, safety and efficacy by permitting the identification of the products by its scientific names, we wanted to analyze this parameter also. In our study we found that out of 19 different drugs 10 drugs were prescribed by generic name (52.6%) and remaining 9 drugs were prescribed by brand name (47.3%) which was similar to findings of Bhansali NB et al (48.7%).9 In study done by Kumarasingam T et al it was found that percentage of drugs prescribed by generic name was 39% which was lesser than the findings of our study.24 Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms and at a price that individuals and the community can afford. This concept is intended to be flexible and adaptable to many different situations; exactly which drugs are regarded as essential remains a national responsibility.25 Out of 19 different drugs prescribed, 16 (84.2%) were from the Essential Medicines WHO Model List which was similar to other studies like Agrawal et al (85.1%) and Falguni et al (92.8%).25,26

CONCLUSION

The present study provides valuable insight about the overall pattern of drug used in postoperative patients. The study is useful in decreasing the irrational prescription, which helps to decrease the morbidity and health care burden in the society.

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