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RESEARCH ARTICLE
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STUDY OF ANTIMICROBIAL PROPHYLAXIS, PRESCRIPTION PATTERN AND ASSOCIATED ADVERSE DRUG REACTIONS PROFILE AMONG PATIENTS UNDERGOING FOR CESAREAN SECTION IN OBSTETRICS AND GYNECOLOGY DEPARTMENT OF A TERTIARY CARE TEACHING HOSPITAL

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Abstract

Introduction: Caesarean section (C-section) procedures are becoming increasingly common worldwide. Preoperative strategies include administering prophylactic antibiotics within an hour before surgery, optimizing maternal health by treating infections during pregnancy, and ensuring proper antiseptic preparation of the surgical site. This study is planned with aims to evaluate the prescription pattern and adverse drug reaction associated with antimicrobial prophylaxis for Caesarean section.

Materials: This prospective observational study was conducted among 200 patients who visited and underwent cesarean section in department of Obstetrics and Gynaecology department at G.S.V.M. Medical College, Kanpur.

Results: All 200 preoperative prescriptions included exactly two drugs, resulting in an average of two drugs per prescription. The study observed 100% antibiotic usage across all phases. In the preoperative phase, third-generation cephalosporins (ceftriaxone) and nitroimidazoles (metronidazole) were each prescribed in 50% of cases. On postoperative day 1, aminoglycosides (gentamicin), piperacillin+ tazobactam were added in 9.99% of cases, and by day 5, penicillin-class antibiotics with beta-lactamase inhibitors (amoxicillin-clavulanic acid) were introduced in 12.48% of cases.

Conclusions: These findings highlight the need for rational antibiotic use, reduced polypharmacy, increased generic prescribing, and stronger antibiotic stewardship to minimize ADRs, and improve patient safety in Caesarean section management.

Keywords: Prescription pattern, Adverse drug reaction, Antimicrobials prophylaxis, Cesarean Section

INTRODUCTION

Caesarean section (C-section) procedures are becoming increasingly common worldwide. This rise reflects advancements in medical care, changing obstetric practices, and patient preferences. Globally, approximately 21% of all deliveries are now performed via C-section, a significant increase from earlier decades. However, the prevalence varies greatly across regions. In high-income countries, rates often exceed 30%, with some nations reporting over 50%, driven by factors such as higher maternal age, obesity, and a growing preference for elective procedures. In contrast, low-income countries generally report much lower rates, often under 10%, due to limited access to healthcare facilities and trained professionals **[1].**

In the current practice, C-sections are performed for a range of medical and non-medical reasons. Elective C-sections, requested by some patients, are more common in high-income settings where access and resources permit. These are often influenced by convenience, prior traumatic deliveries, or fear of labor-related complications. Emergencies such as umbilical cord prolapse or acute fetal distress may also require immediate surgical intervention to save the lives of the mother and baby **[2].**

Infection prevention is a critical component of ensuring the safety of C-sections, which are classified as major surgeries. Infections such as surgical site infections (SSIs), endometritis, and sepsis are among the most common complications following the procedure, particularly in low-resource settings where sterilization practices and access to antibiotics may be limited. Preoperative strategies include administering prophylactic antibiotics within an hour before surgery, optimizing maternal health by treating infections during pregnancy, and ensuring proper antiseptic preparation of the surgical site **[3].**

Unlike therapeutic antibiotic use, which aims to treat existing infections, prophylaxis focuses on prevention. The primary objective of antimicrobial prophylaxis is to reduce the risk of infections, especially surgical site infections that can arise during or after medical interventions**[4].**

The prescription pattern of prophylactic antimicrobials in cesarean sections is designed to reduce maternal and neonatal infectious complications effectively. Beta-lactams, particularly cefazolin, are commonly used due to their broad-spectrum activity against gram-positive and some gram-negative organisms. In some cases, other cephalosporins like cefuroxime or ceftriaxone may be chosen for their extended coverage. Metronidazole is frequently combined with cephalosporins to ensure anaerobic coverage, especially in emergency caesarean sections or when there has been a prolonged rupture of membranes. Alternatives such as clindamycin and gentamicin are prescribed in patients with beta-lactam allergies or when additional spectrum coverage is required. Ampicillin-sulbactam is another option that provides comprehensive gram-negative and anaerobic coverage when needed **[5].**

The use of antibiotics, a standard practice to prevent infections, can also lead to adverse effects. Allergic reactions are common, ranging from mild skin rashes to severe anaphylaxis. Gastrointestinal disturbances such as diarrhea and nausea are often reported, while long-term use can disrupt normal gut flora, potentially leading to dysbiosis or antibiotic resistance. Similarly, uterotonics, which are administered to manage postpartum bleeding, may have side effects. Oxytocin, for example, can cause nausea, vomiting, and headache, while prostaglandins like misoprostol are associated with fever, shivering, and diarrhea. **[6].**

So, this study is planned with aims to evaluate the prescription pattern and adverse drug reaction associated with antimicrobial prophylaxis for Caesarean section in the Obstetrics and Gynaecology department of a tertiary care hospital, GSVM Medical College, Kanpur (UP).

MATERIALS AND METHODS

Study Design and Setting

This study was a prospective observational study conducted in the the Department of Pharmacology in collaboration with Department of Obstetrics and Gynecology at G.S.V.M. Medical College, Kanpur.

Study Population

The study population comprised pregnant women undergoing elective or emergency cesarean section. The patients were included after taking written informed consent and consideration of inclusion and exclusion criteria.

Inclusion Criteria:

- Women undergoing elective or emergency cesarean section.
- Patients willing to provide written informed consent.

Exclusion Criteria:

- Patients unwilling to participate.
- Women with known hypersensitivity to prescribed antimicrobials.
- Patients with severe pre-existing infections requiring prolonged antibiotic therapy.
- Patients with pre-existing chronic illnesses that might confound ADR evaluation.

Methodology

A pre-structured case report form (CRF) was used to collect relevant data before undergoing surgery, post-surgery on day 1 and post-surgery on day 5 which has included the Patient demographics (age, socioeconomic status), medical history, type of cesarean section (elective or emergency, antimicrobial prescription details and adverse drug reactions. Prescription patterns were analyzed in each patients by using WHO core drug use indicators and ADR reported were recorded.

Sample size calculation and analysis

The sample size was calculated based on the estimated prevalence of antimicrobial prophylaxis use in CS cases, using the formula:

$n = [DEFF*Np(1-p)]/ [(d2/Z21-\alpha/2*(N-1)+p*(1-p)]$

where:

- n = required sample size,
- DEFF = design effect,
- N = population size,
- p = estimated proportion,
- d = desired precision,
- Z = standard normal variate at 95% confidence level.

Based on these calculations, a total of 200 patients were included in the study.

Data Collection & Analysis:

- Data were entered in Microsoft Excel. The entered data were checked for any missing values, error and later on analysed using SPSS version 25.0.
- Descriptive statistics (mean, frequency and percentages) were used for categorical and continuous variables.

RESULTS

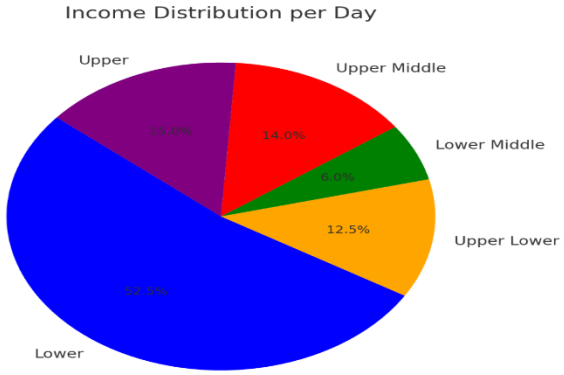
Most patients were 26-32 years old (47.5%), followed by 18-25 years (35.5%). The least represented group was 33-40 years (17%), the mean age is found to be 27.6 years, with a standard deviation of 5.3 years, indicating a predominantly young adult population with moderate age variability.

Table 1: Distribution of patients by age

Age interval in years	Frequency (n =200)	%
18-25	71	35.5
26-32	95	47.5
33-40	34	17
Total	200	100

The income distribution among the 200 patients studied showed that the majority, 52.5%, fell into the "Lower" income category, earning the least per day. Additionally, 12.5% were classified as "Upper Lower," 6% as "Lower Middle," 14% as "Upper Middle," and 15% as "Upper," representing the highest income group. This distribution indicates that a significant proportion of the patient population (65%) belonged to the lower income brackets (Lower and Upper Lower), while a smaller percentage (35%) were in the middle to upper income categories

Fig:1 Distribution by socioeconomic Status



Preoperative -All 200 prescriptions (100%) included exactly 2 drugs, resulting in an average of 2 drugs per prescription. This aligns closely with WHO recommendations for outpatient settings (1.6–1.8 drugs per prescription), though, in the context of a hospital setting for Caesarean section patients, a slightly higher average may be anticipated due to the need for prophylactic antimicrobials to prevent surgical site infections (SSIs).

Table 2: Preoperative - Average Number of Drugs per Prescription

Metric	Value	Percentage (%)
Total Number of Prescriptions	200	-
Total Number of Drugs Prescribed	400	-
Average Number of Drugs per Prescription	2	-
Prescriptions with 2 Drugs	200	100%
Percentage of drugs prescribed from the Essential Drug List	400	100%
Percentage of encounters with an injection	200	100%
Percentage of drugs prescribed by generic name	200	50%
Percentage of drugs prescribed by branded name	200	50%

Of the 400 drugs prescribed, (50%) were generic, specifically Injection Ceftriaxone, while the remaining (50%) were branded. All 200 prescriptions (100%) included antibiotics, specifically Injection Ceftriaxone (a third-generation cephalosporin) and Injection Metronidazole (a nitroimidazole). All 400

drugs prescribed (100%) were from the EDL, including Injection Ceftriaxone and Injection Metronidazole, aligning perfectly with WHO recommendations for rational drug use. 50% of the drugs were prescribed using their generic names and 50% of the drugs were prescribed by brand names.

Table 3: Postoperative Day 1 - Average Number of Drugs per Prescription

Metric	Value	Percentage (%)
Total Number of Prescriptions	200	-
Total Number of Drugs Prescribed	1111	-
Average Number of Drugs per Prescription	5.56	-
Prescriptions with 4 Drugs	89	44.5%
Prescriptions with 5 Drugs	109	54.5%
Prescriptions with 6 Drugs	2	1%
Total Number of Drugs from essential drug list	911	82.00%
Percentage of drugs prescribed by generic name	311	27.99%
Percentage of drugs prescribed by branded name	800	72.01%

Postoperative Day 1 -The total number of drugs prescribed was 1111, yielding an average of 5.56 drugs per prescription. Specifically, 44.5% prescriptions included 4 drugs, 54.5% included 5 drugs (due to the addition of Gentamycin), and 1% included 6 drugs (due to Piperacillin+ Tazobactam). Out of all the drugs prescribed, 82% were from the Essential Drug List. Only 27.99% were prescribed by their generic names, while a much larger portion 72.01% were prescribed by brand names. This high average indicates potential polypharmacy in the immediate postoperative period, which may be justified by the need for comprehensive prophylaxis and management of postoperative complications in CS, such as infection, bleeding, and nausea, aligning with the thesis focus on prophylactic antimicrobials. However, the increased number of drugs raises concerns about the risk of ADRs, necessitating careful monitoring and causality assessment of ADRs associated with this regimen.
Of the 1111 drugs prescribed, only 27.99% were generic (Ceftriaxone, Gentamycin, Piperacillin+ Tazobactam), while 72.01% were branded. All 200 prescriptions (100%) included antibiotics (Ceftriaxone, Metronidazole, Gentamycin, and Piperacillin+ Tazobactam), a continuation of the high usage observed in the preoperative phase. All 200 prescriptions (100%) included injections, consistent with the preoperative phase but significantly higher than the WHO-recommended range of 13.4–24.1%. Of the 1111 drugs prescribed, 82% were from the EDL, including Ceftriaxone, Metronidazole, Gentamycin, Piperacillin + Tazobactam, Tranexamic acid, and Ondansetron.

Table 4: Postoperative Day 1 - Prescribing Patterns by Therapeutic Class

Therapeutic Class	Number of Drugs	Percentage (%)
Third Gen Cephalosporin	200	18.00%
Nitroimidazole	200	18.00%
Aminoglycosides	111	9.99%
H2 Blocker	200	18.00%
Antifibrinolytic	200	18.00%
5-HT3 Antagonist	200	18.00%

Antibiotics dominated, with third-generation cephalosporins (Ceftriaxone, 18%), nitroimidazoles (Metronidazole, 18%), and aminoglycosides (Gentamycin and Piperacillin + Tazobactam, 9.99%) comprising a significant portion of the 1111 drugs prescribed. Additional classes included H2 blockers

(Rantitidine,18%), antifibrinolytics (Tranexamic acid, 18%), and 5-HT3 antagonists (Ondansetron, 18%), reflecting a comprehensive postoperative regimen to manage infection, bleeding, and nausea.

Table 5: Postoperative Day 5 - Average Number of Drugs per Prescription

Metric	Value	Percentage (%)
Total Number of Prescriptions	200	100%
Total Number of Drugs Prescribed	1602	-
Average Number of Drugs per Prescription	8.01	-
Prescriptions with 8 Drugs	198	99%
Prescriptions with 9 Drugs	2	1%
Total Number of Drugs from essential drug list	1202	75.03%

Postoperative Day 5 -The total number of drugs prescribed was 1602, resulting in an average of 8.01 drugs per prescription. Specifically, 99% prescriptions included 8 drugs, while 1% prescriptions included 9 drugs due to the addition of Cefixime. only 75.03% prescribed drugs were from the Essential Drug List. This high average indicates significant polypharmacy by day 5, which may be attributed to the comprehensive management of CS patients, including continued antimicrobial prophylaxis, pain management, and nutritional support.

The most commonly reported ADR is dry mouth, affecting 10.45% of patients, followed by nausea and vomiting, each occurring in 4.48%. Fever was reported in 1.49%, while cough, headache, and itching were the least frequent ADRs, each affecting 1.00%.

Table 6: Distribution of Reported ADRs Due to Prescribed Drugs

ADR Type	Frequency	Percentage (%)
Dry mouth	21	10.45%
Nausea	9	4.48%
Vomiting	9	4.48%
Fever	3	1.49%
Cough	2	1.00%
Headache	2	1.00%
Itching	2	1.00%

DISCUSSION

The study found an average of 2 drugs per prescription in the preoperative phase, increasing to 5.56 on postoperative day 1 and 8.01 by postoperative day 5, indicating significant polypharmacy by the later phase. A 2016 study by Liu et al.,[7] published in *Experimental and Therapeutic Medicine*, reported an average of 3.2 drugs per prescription in CS patients across all phases, which is lower than the postoperative averages in this study. Liu et al. attributed their lower average to a more conservative approach to postoperative care, focusing primarily on antibiotics and analgesics, whereas this study included additional drugs like nutritional supplements (e.g., Optineuron, Limcee) by day 5, potentially contributing to the higher average. Similarly, a 2010 study by Islam et al.,[8] found an average of 4.5 drugs per prescription in CS patients, aligning more closely with the postoperative day 1 findings but still lower than day 5.

This study observed 100% antibiotic usage across all phases, exceeding the WHO-recommended range of 20–26.8% for general settings. A 2014 Cochrane review by Smaill and Grivell [9], published in *Cochrane Database of Systematic Reviews*, reported that 85% of CS patients received prophylactic antibiotics, a high but slightly lower rate than this study.

The generic prescribing rate decreased from 50% in the preoperative phase to 27.99% on postoperative day 1 and 0.12% by postoperative day 5, far below WHO recommendations. A 2002 study by Liabsuetrakul et al.,[10] published in *International Journal for Quality in Health Care*, reported a generic prescribing rate of 65% in CS patients in Thailand, higher than this study's preoperative rate but still below WHO ideals. Liabsuetrakul et al. noted that cost considerations drove higher generic use, a factor that appears less influential in this study, where branded drugs like Augmentin/Amoxyclav dominated by day 5.

Similarly, a 2018 study by Abubakar et al.,[11] cited in a Sudanese study at Elqutainah Teaching Hospital, reported a 40% generic prescribing rate, closer to this study's preoperative phase but highlighting a regional preference for generics that was not sustained in this study's later phases. The low generic prescribing rate in this study may increase treatment costs for CS patients, potentially affecting access to care.

This study found 100% injection use in the preoperative and postoperative day 1 phases, dropping to 0% by day 5. A 2016 study by Nabhan et al., [12] published in *Cochrane Database of Systematic Reviews*, reported that 90% of CS patients received injections for antibiotic prophylaxis, slightly lower than this study's early phases but confirming the preference for injections in immediate perioperative care. Nabhan et al. noted that injections ensure rapid drug delivery, a justification mirrored in this study for the early phases. However, a 2013 study by Osman et al., [13] published in *BMC Research Notes*, found only 60% injection use in elective CS in Sudan, suggesting that the 100% rate in this study may reflect an overly aggressive approach to prophylaxis, potentially increasing the risk of injection-related ADRs.

Adherence to the Essential Drugs List (EDL) decreased from 100% in the preoperative phase to 82% on postoperative day 1 and 75.03% by day 5. A 2010 study at Elqutainah Teaching Hospital in Sudan [14] reported 95% EDL adherence in CS patients, higher than this study's later phases but lower than the preoperative phase.

CONCLUSION

This study highlights a consistent use of prophylactic antibiotics in all phases of cesarean section care, with a notable trend toward polypharmacy and declining rates of generic prescribing by postoperative day 5. While the high adherence to infection prevention protocols is commendable, the findings underscore the urgent need for rational antibiotic use, promotion of generic prescribing, and strict antibiotic stewardship to minimize adverse drug reactions, antimicrobial resistance, and ensure safe, cost-effective care for cesarean patients.

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