Research Article

A STUDY TO ASSESS PATIENT SAFETY WITH CEFTRIAXONE AND METRONIDAZOLE IN POST-OPERATIVE LAPAROSCOPIC CHOLECYSTECTOMY PATIENTS

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ABSTRACT:

Objectives: To determine the incidence of antibiotic (ceftriaxone and metronidazole) resistance among patients undergoing laparoscopic cholecystectomy. To evaluate drug utilization pattern of post-operative laparoscopic cholecystectomy patients.

Methods: A total of 120 patients meeting the study criteria in surgery department will be enrolled in the study after obtaining the informed consent. All relevant data of the enrolled patients will be collected from various data sources and documented.

Results: A total of 120 study participants from Surgery department. The majority of patient belonged to the age group 36-45(32.5%) represented most of the patients in the study were males (45.8%) compared to females (54.16%)From the result, among 120 patients, (20.83%) were Smokers and (79.16%) were Non-smokers. (96.66%) were prescribed Ceftriaxone and (3.3%) patients were not prescribed Ceftriaxone. A culture sensitivity test was done only on 11 patients where 54.54% of the population were resistant to the drug ceftriaxone and 5 were not detected as resistant and there were no patients resistant to metronidazole. In this study, the most commonly prescribed class of drugs were Analgesics (19.8%), followed by Electrolytes (24.08%), Antibiotics (9.7%), PPI (8.02%), Antiparasitic (6.7%), Antiemetic (7.62%), Vitamin (24.08%) respectively.

Conclusion: In our study, antibiotics, PPI, vitamins and analgesics, drugs are most commonly used drug classes in treating post operative lap.Cholecystectomy. Average number of drugs per prescription was high reflecting polypharmacy. This study helps in evaluating the existing drug use pattern, Evaluating antibiotic resistance with ceftriaxone and metronidazole and to make appropriate interventions. This survey helps to estimate the drug utilisation evaluation of laparoscopic cholecystectomy patients and pattern of antibiotic resistance.

INTRODUCTION:

Cholelithiasis, also known as Gallstones, are calcified collections of digestive fluid that can develop in the gallbladder. Gall bladder is located underneath liver segments 4b and 5 on the inferior side of the hepatic bed. The gallbladder has a maximum length of 10 cm and a physiological capacity of 50 cc of bile(1). Gallstone disease affects more than 20 million Americans, and 80,000 patients are admitted to hospitals each year(4) Cholesterol gallstones, black pigment gallstones, and brown pigment gallstones are the three most prevalent forms. Gallstones made of cholesterol account for 90% of all cases.(1) Gallstones composition varies depending on the etiology These illnesses typically have biliary colic symptoms, such as intermittent attacks of persistent, acute stomach pain in the right upper quadrant (RUQ), which is frequently accompanied by nausea and vomiting, as well as normal physical examination findings and laboratory test results. Vomiting, nausea, and diaphoresis could also be present (1)

Laparoscopic cholecystectomy is a minimally invasive surgical operation performed to remove a damaged gallbladder. (5). A novel third-generation cephalosporin, ceftriaxone exhibits good activity against a wide variety of gram-negative bacteria and mediocre activity against the majority of gram-positive bacteria [7]. Metronidazole is one of the main drugs used to treat anaerobic, protozoal, and

microaerophilic bacterial infections. It is cytotoxic to facultatively anaerobic microorganisms.

MATERIALS AND METHOD:

Study site: The study was conducted in Krishna Rajendra hospital, Mysuru.

Study design: This is a Prospective observational study. The sample size of the study was 120 patients.

Study period: The study was carried out for a period of six months.

Ethical approval: Institutional Ethical Committee of Krishna Rajendra hospital Hospital, Mysore approved the study.

Study criteria:

Inclusion criteria:
1. Adult patients >/=18 years of age.
2. Patients of either gender
3. Participants undergone laparoscopic cholecystectomy and receiving ceftriaxone and metronidazole in their treatment regimen

Exclusion criteria:
1. Patients who are not willing to participate.

2. Patients with severe medical conditions that may interfere with the study or pose a safety risk.

3. Pregnant and lactating women

Source of data: Medical and Medication records of the patient. Interviewing patient and caretaker. Communicating with concerned clinicians and health care professionals. Telephonic contact with patients and/or physicians if necessary.

Study procedure: The study involved the following steps: -

1. Preparation of informed consent form (ICF): An informed consent form was suitably designed both in English (Annexure 1) as well as in Kannada (Annexure 2) to obtain consent from patients who volunteered for the study and fulfilled the study criteria. The ICF was reviewed and approved by the institutional ethics committee. The patient was explained about the study and consent was obtained after they voluntarily agreed after being aware of every important aspect regarding the study. For those patients who were illiterate, the study was discussed with them, and consent was obtained from caretakers.

2. Preparation of data collection form (DCF): A specially designed data collection form (Annexure 3) was designed for the study. The particulars included demographic details like name, age, gender, family history, social habits (smoking, tobacco chewing, and alcoholism), diet, weight, height, and body surface area. Clinical data such as diagnosis, past medical history, past medication history, Therapeutic data such as the name of the drug, dose, frequency, duration, route of administration, details on the supportive medication used, premedication, and discharge medications. It also contains the details of laboratory test results.

3. Patient enrollment: Patients fulfilling the study criteria were enrolled in the study after obtaining informed consent.

4. Data collection: All relevant details of the enrolled patients were obtained from various data sources and documented in the data collection form.

5. Statistical analysis: the collected data were entered and assembled in Microsoft excel. The data was analysed using descriptive statistical analysis with the help of Microsoft excel to calculate the quality of life in study population, to determine and divide the study population according to the demographic details and clinical characteristics. Frequency and percentage of Resistance in different demographic categories was calculated and expressed in suitable charts

RESULTS:

A total of 120 study participants from Surgery department who met our inclusion criteria and had been through laparoscopic cholecystectomy were enrolled in the study.

Demographic Data: The average age of the patient was found to be 41.01 . The majority of patient belonged to the age group 36-45(32.5%). Most of the patients in the study were males (45.8%) compared to females(54.16%) among 120 patients, 79.16% were Non-smokers and 81.6% were Non-alcoholic.

Ceftriaxone treatment: Among 120 patients, the antibiotic Ceftriaxone 1g IV was distributed; 96.66%

Ceftriaxone Treatment	No. of patients	Percentage
Prescribed	116	96.66%
Not Prescribed	4	3.3%
Total	120	100%

Table 1: Representation of the total Study population that received Ceftriaxone treatment

Distribution of ceftriaxone therapy based on age group categorization was found to be the majority of patients who received ceftriaxone therapy were under the age 36-45(32.5%)

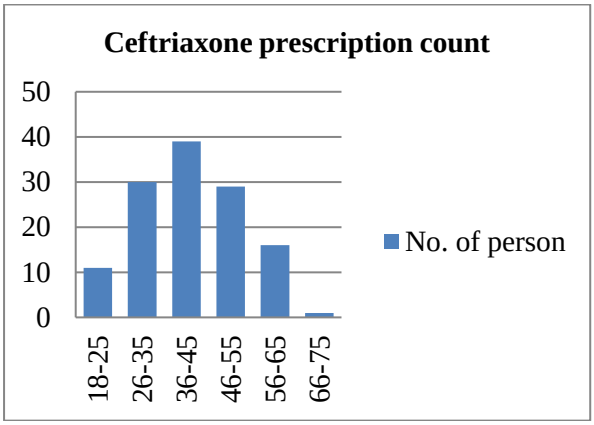

Figure 1: Representation of Ceftriaxone Prescription Count based on age group

Culture sensitivity test: From the result, among 120 patients, a Culture sensitivity test was done on 11 patients (9.16%)

Culture sensitivity test	No. of patients	Percentage
Wound culture conducted	11	9.16%
Wound culture not conducted	109	90.83 %
Total	120	100%

Table 2: Total study Population receiving Ceftriaxone treatment, undergone Culture sensitivity test count

Resistance to Ceftriaxone: Culture sensitivity test was done only on 11 patients where 54.54% (n=6) of the population were resistant to the drug ceftriaxone

Resistance	No. of patients	Percentage
Resistant to Ceftriaxone	6	54.54%
Not resistant to ceftriaxone	5	45.46%
Total	11	100%

Table 3: The study population underwent a Culture sensitivity test-detected to be resistant to Ceftriaxone count

Resistant to the drug Ceftriaxone based on Organism strains: The strains of organisms that exhibit Ceftriaxone resistance that is gram-negative bacteria *Escherichia coli* (n=4) and gram-negative bacteria *Pseudomonas aeruginosa* (n=2).

Metronidazole treatment: antibiotic Metronidazole500mg IV was distributed; 83.33% were prescribed

Metronidazole treatment	No. of patients	Percentage
Prescribed	100	83.33%
Not Prescribed	20	16.67%
Total	120	100%

Table 4: Representation of the total Study population that received Metronidazole treatment

Resistance to Metronidazole: A Culture sensitivity test was done only on 11 patients where there were no patients resistant to metronidazole

Drug Utilisation Pattern: From the study population total of 1495 drugs were prescribed the average number of drugs prescribed per prescription was found to be 12.45. commonly prescribed class of drugs were Analgesics (19.8%), followed by Electrolytes (24.08%), Antibiotics (9.7%), PPI (8.02%), Antiparasitic (6.7%), Antiemetic (7.62%), Vitamin (24.08%) respectively.

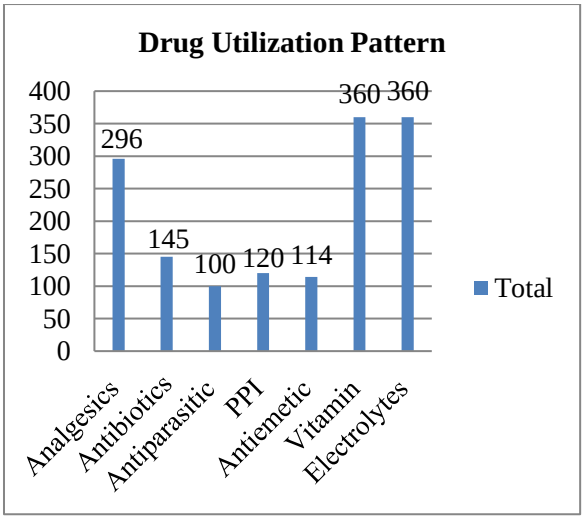

Figure 2: Representation of Distribution of drug utilization pattern

Conclusion:

In our study, antibiotics, PPI, vitamins and analgesics, drugs are most commonly used drug classes in Treating Post operative lap. Cholecystectomy. Evaluating antibiotic resistance with ceftriaxone and metronidazole, and to make appropriate interventions required to provide optimum healthcare services to the community. Ceftriaxone has broader and stronger gram-negative coverage then first or second-generation cephalosporins, and . Metronidazole is used to treat or prevent certain infections that may occur during surgery. Culture sensitivity test was done only on 11 patients 6 were resistant to the drug ceftriaxone and none of them were resistance to metronidazole since ceftriaxone is largely used than metronidazole. This survey helps to estimate the drug utilisation evaluation of laparoscopic cholecystectomy patients, And pattern of antibiotic resistance.

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