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Research Article

Postoperative

A prospective, randomized controlled trial of single dose of Cefepime and tazobactum as the sole prophylactic preoperative antibiotics in Laparoscopic cholecystectomies

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Introduction: Anti microbial prophylaxis before any elective surgery is a preferred deterrent to post operative surgical site infection now. Many regimes with different antimicrobial agents are tried and most of the institutions have developed their own regime or philosophy to address postoperative surgical site infection. Most of standard textbook of surgery suggests a single dose of Intravenous antibiotic dose, preferably tird generation cephalosporin, at appropriate time before surgery, Most preferably at induction of anaesthesia or within half hour of starting a surgery. Aim was to find out how combination of cefepime, a fourth generation cephalosporin combined with Tazobactum fare in preventing post operative SSI in laparoscopic cholecystectomies. **Methods:** A total of 138 patients (above 16 years) were taken for study. It was a randomized and blind study. Patients were prospectively analysed. First, patients were divided into two groups. Different antibiotics combinations were studied to understand efficacy of those prophylaxis in preventing the SSI in Laparoscopic cholecystectomies. We are reporting experience with Cefepime and tazobactum combination in this work in prevention of SSI in cases undergoing Laparoscopic Cholecystectomies in our hospital setting. **Results:** Keeping outcome of the study in mind all materials was analysed and statistical analysis done and confidence intervals were noted. The study revealed interesting observations. Single dose pre operative prophylaxis scored over three doses regime in all cases for lap surgery. **Conclusion:** Multiday and antibiotics use for a prolonged period is not advisable these days after a routine elective abdominal surgery. Single dose injection of Cefepime+ Tazobactum at incision is good enough to prevent SSI after laparoscopic cholecystectomies.

Keywords: Postoperative, Surgical site infections, Antibiotics

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Introduction

Soft Tissue Infection is dreaded complication of surgery. Although considerde to a nightmare for plastic, reconstructive and cosmetic surgeries, it is nonetheless a serious condition for all surgical interventions. It was Joseph Lister who revolutionized the infection free practice of surgery by his understanding of "germs" and spraying Phenol in and around the operating environment. He is aptly recognized as the father of modern surgery [1]. However surgical site infections still are important complications. Some deaths are also reported due to post-operative SSI. Many procedures are applied to prevent it like laminar airflow, sterile environment, procedures of sterilization of instruments and necessities, Operation room behaviour, using of proper clean/ sterilized attires, Hand washing as well as avoiding entering O.Ts if ill etc. are all applied to prevent the SSI. Prophylactic antibiotics and its concept, Operating under normothermia, creating a cleaner O.T air by installing HEPA filtration and operating in a positive pressure environment also help in reducing the post-operative SSI. At present various studies suggest that the rate is stabilized at 2% for extra abdominal surgeries and over 20% for intra-abdominal procedures [2]. Surgical site infection or SSI is defined by the centre for disease control and prevention, Atlanta, as a proliferation of micro-organism in the incision site either within the skin ad subcutaneous tissue, muskulofascial layers,or in an organ and a cavity [3].

The CDC also has a recommended guideline for antimicrobial prophylaxis [4, 5].

01. To use Anti-Microbial Prophylaxis (AMP) in those procedures, which carry a risk of infection, when the consequences of such infection is great and have evidence that using AMP reducing the incidence of SSIs.
02. To select an agent which is safe, inexpensive, preferably bactericidal and most narrowly covers the anticipated SSI in that particular procedure..
03. Time the administration so that it reaches the maximum serum and tissue concentration at the time of incision.
04. Maintain adequate level/ therapeutic level of the antibiotics at the closure of the incision.

There is widespread evidence of using AMP before all surgical procedures that is it is beneficial and prevent SSIs [6, 7]. A meta-analysis on AMP in biliary surgery suggests that increase of SSIs over 9 times if compared to those cases where no AMP was use with 95% confidence Interval [8].

Single dose cephalosporins were found to be effective in Biliary, genitor-urinary and gynaecological procedures was found to be efficacious in preventing SSIs in these procedures [9]. A sudy was undertaken in Germany to find out the efficacy of AMP in both open and laparoscopic cholecystectomies. It was found to be beneficial equally in both the open and laparoscopic groups over no AMP group and was found to be statistically significant (p=<05) [10]. Development of SSI leads to increase in hospital stay, Expenditures, Morbidity as well as deaths. [11, 12].

Basing on NNIS report it can be said that SSI is an important nosocomial problem in all the countries. The world wide experience suggests that SSI is a major health care as well financial problems in all the countries [13, 14].

Table-1: World wide experience of SSI

Country	Setting	Period	Design	SSI No.	SSI (%)
Australia[15]	28 Hospitals	1992	Retrospective	5432	8
France[16]	UniversityHospital	1993-1998	Retrospective	9422	7
US of A[17]	NNIS Hospitals	1992-1998	Prospective	738398	3
Thailand[18]	UniversityHospital	2003-2004	Prospective	4764	1
Vietnam[17]	Tertiary careHospitals	1992-1998	Prospective	697	11
Italy[18]	PublicHospitals(31)	1 month	Prospective	617	3

Table 1 clearly suggests that it is indeed a global problem.

SSI can be caused by two different kinds of spreads. Exogenous and endogenous. Most common cause of exogenous route is the Operating environment and the most common endogenous route is from the GIT or Genital in females. The environmental factors are tackled by standard operation theatre conditions as well as regular surveillance by the team of microbiologists as well as the preoperative preparation for surgery and is dependent on the institutional philosophy. Control of endogenous infection is best tackled by Preoperative use of antibiotics. Keeping these factors in mind the study was undertaken to evaluate the combination of cefepime

And tazobactum as prophylactic antibiotics regime in Cases undergoing Laparoscopic Cholecystectomies and to see the result.

Materials and Methods

A total of 138 patients were taken for the study. Inclusion criteria were above 16 years of age and no history of allergy to cephalosporins, imidazoline derivatives, beta lactamase inhibitors, fluoroxoquinolones and history of seizures. Excluded are the emergency procedures and history of seizures and hypersensitivity towards the chemicals to be used. Out of all those we selected 21 patients who will receive a single Intravenous injection of a combination of Cefepime and Tazobactum. The patients were divided into the study groups in a randomized and blinded method. Cheat picking was applied to select patients in the various groups.

Antimicrobial agents used-

1. Cefipime: Fourth-generation cephalosporins, such as cefepime, have an extended spectrum of activity compared with the third generation and have increased stability from hydrolysis by plasmid and chromosomally mediated b-lactamases. Fourthgeneration agents are particularly useful for the empirical treatment of serious infections in hospitalized patients when gram-positive microorganisms, Enterobacteriaceae, and Pseudomonas all are potential etiologies [20].

2. Tazobactum: Tazobactam is a penicillanic acid sulfone b-lactamase inhibitor. In common with the other available inhibitors, it has poor activity against the inducible chromosomal b-lactamases of Enterobacteriaceae but has good activity against many of the plasmid b-lactamases, including some of the extended-spectrum class. It has been combined with piperacillin and Cefepime as a parenteral preparation [21]. The operation time and other details were noted. Most of the surgeries were done by a particular surgeon. Patients undergoing both open as well as Laparoscopic Cholecystectomy received Cefepime and tazobactum as a single dose prophylaxis only and the results were analysed. Data were analysed by SPSS 16.5 Statistical package. Graph and prism version 5.04 and excel 2007. RATES OF ssiwere extracted, 2x2 tables were prepared and odds ratio (OR), relative risk (RR) with 95% confidence interval (95% CI) calculated. All categories were verified by chi-square test with Y ates correction (with 95% CI).

Results

Over the period from sept 2010 to May 2011, 39 patients of lap chole fitted with the inclusion criteria and taken in the group who received only single dose of Cefipime and Tazobactum were analysed and no difference between the open and laparoscopic groups were noted.

Table 2: The cefipime + Tazobactum single dose group composition

Surgery	Nos. Of Pts.	Males	Females	Median age
Lap	11	5	6	35
Open	10	4	6	39
Total	21	9	12	37

Table 2 shows the composition of two groups. One group received single Intravenous dose of weight corrected Cefepime and Tazobactum at the induction of Anaesthesia. The open surgery group and Laparoscopic groups underwent surgery in same environment and by the same surgeon.

Table 3: Cefipime+ Tazobactum SSI rates in the study

Surgery	Nos. Of Pts.	SSI
Lap	11	0
Open	10	2
Total	21	2

When analyzed it was evident that there were no SSI in the group who underwent Laparoscopic Cholecystectomiy. But there were two SSI in the open surgery group. This finding is though not statistically Significant was an important finding.

Discussion

Fourth generation cephalosporins has a wider spectrum of coverage over the third generation antibiotics. Although many text books suggest that third generation antibiotics be used to prevent SSI, we tried with a fourth generation antibiotics. Tazobactum was added to extend the coverage to beta lactum producers. Commonest exogenous organisms found in most studies related to post-operative SSI are gram positive cocci, Ecoli and Klebsiella species long with sprinkling of some other microorganisms [19, 23]. While choosing to study a cephalosporin, we have taken Cefepime because it is readily available in the market, It does not have a prohibitive price, It is quite stable at the temperature range in the locality as well

As the coverage is adequate for the study [20]. Tazobactum is added as the resistance reports are alarming here too. It extends support to the cephalosporin for its action and increases
the efficacy. Such a combination was found to be ideal in the local scenario [21, 24, 25].

The result was a good one. Not a single patient who underwent laparoscopic Cholecystectomy developed SSI. However as we also had an open group to compare the Laparoscopic group, developed SSI. Both the groups were operated in the same O.T as well by the single surgeon. Analysing these two groups we came to the conclusion of the study. Although the study groups were small, it served its purpose well and we hereby produce our result and this also shows that Laparoscopic surgery probably safer than open surgery so far as acquiring post-operative SSI.

Conclusion

A single dose of the combination of cefepime and tazobactum at the incision is good enough to control the post-operative SSI in patients undergoing lap chole. We had SSI in patients undergoing Open Cholecystectomies but not in those undergaoing lap chole. We could conclude that the fourth generation antibiotic in combination with tazobactum is a preferable choice as an AMP for lap chole. After this study we recommend the use of the combination of Cefepime and Tazobactum as the single dose preoperative prophylactic antibiotics in lap chole cases.

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