Study Comparing Effect of Single Dose Antibiotic Prophylaxis versus Conventional Antibiotic Coverage in Clean, Elective Surgeries – A Randomized Controlled Clinical Trial

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ABSTRACT

BACKGROUND
Postoperative wound infection remains the most common complication of surgery. With the fear of developing wound infection after surgery, many surgeons administer antibiotics for 7 -10 days even in clean uncontaminated cases. This practice is not only expensive to the patients but also can lead to hospital-acquired infections. We wanted to assess the effectiveness and efficacy of single-dose antibiotics in clean elective surgical cases in this study.

METHODS
A prospective interventional study was conducted in the General Surgery department, SRM Medical College Research Centre, Kattankulathur for a period of 18 months between May 2018 and October 2019. In this study, 143 patients were selected according to the inclusion criteria. All the data findings were recorded and analysed.

RESULTS
Out of 143 patients presented with clean cases, 72 cases were included in the study group and 71 cases in the control group as per the inclusion criteria. In the present study, the incidence of postoperative infection was equal i.e., 6 % in both groups. However, the grade of infection varied. The difference was not statistically significant.

CONCLUSIONS
Based on my study I would like to conclude that it is recommendable to use single-dose antibiotic prophylaxis for clean surgical cases, as per the study results there is not much difference in the occurrence of SSI when compared to multiple doses.

KEY WORDS
BACKGROUND

Surgical site infections (SSI) are the third most commonly reported nosocomial infections. They add up to one-fourth of all nosocomial infections. They occur most commonly after opening up of tissues or organs by the surgeon. They are divided into two types. “Superficial” and “Deep”. SSI is associated with prolonged stay and reduced quality of life.1 Risk factors for SSI have been identified as old age group, prolonged operative hours, co-morbidity and regular use of drainage and prosthetics.

Practically, surgical wound infection rates in elective surgeries vary from 2-5% for clean cases, 25-30% for colo-rectal cases and much more percentage for emergency cases.

The infection risk increases with prosthetic materials. Hence, antibiotic prophylaxis becomes imminent. In tension-free hernioplasty and open meshplasty for epigastric, and umbilical hernias, the use of mesh not only increases the mesh-related complications but also surgery-related complications.2 The use of antibiotics in clean, elective cases like Lichtenstein hernia repair, open meshplasty, excision & biopsy for fibroadenomas, and thyroidectomy is considerably debatable in various centres. In current practice, only a few surgeons give one dose of preoperative antibiotic, while most surgeons give multiple doses. Most surgical antibiotic prophylaxis is used inappropriately like wrong timing, incorrect duration, and incorrect dosage. The crucial step is the timing of the first antibiotic dosage, and irregular timing of the first dose of antibiotic is a frequent problem in surgical prophylaxis.3 Administration of postoperative multiple antibiotic doses proves no additional benefit to the patient and is not cost-effective and leads to the development of multidrug resistance.

Risk Factors
Multiple risk factors are known to cause SSI
- Age
- Diabetes mellitus
- Obesity
- Smoking
- Malnutrition
- Immunocompromised status
- Surgical technique
- Operation duration
- Skin preparation
- Antibiotic prophylaxis
- Wound collection

In cases of clean surgeries, the infection rate was less than 2% whereas, in contaminated or infected cases, the rate was 15-20%. SSI can be prevented by proper preparation of the patient, antibiotic prophylaxis 1 hour before the incision, maintaining intra-operative sterile techniques and sterile dressings. Superficial infections have swelling, discharge, pain, redness, warmth. Deep infections have wound gaping, fever, pain and discharge. Treatment would be continuous monitoring of the wound, draining of the pus, pus culture & sensitivity and appropriate antibiotics.

METHODS

This prospective interventional study was conducted in the Department of General Surgery in SRM Medical College Hospital and Research Centre, Kattankulathur for 18 months from May 2018 to October 2019 after obtaining approval from the Institutional Ethical Committee.

Patients presenting to SRM Medical College, Kattankulathur for elective cases, after obtaining informed and written consent in understandable language were subjected to the study. Totally 143 cases were admitted for “clean surgery in our hospital without any co-morbid conditions”. The sample size was decided based on convenience. The patients who were allocated conventionally into the study group got admitted on Tuesday and patients getting admitted on Friday were included in the control group. Group A got single-dose antibiotics before surgery while Group B got conventional 5-day antibiotics post-surgery.6,7,8,9

Inclusion Criteria
- Both male and female patients above 17 years of age were admitted to SRM hospital.
- All clean, elective surgeries like:
  - Inguinal hernia, all types undergoing mesh repair.
  - Fibroadenoma breast
  - Umbilical hernia
  - Epigastric hernia
  - Varicose vein for Trendelenburg operation
  - Solitary or multiple nodular thyroid goitres

Exclusion Criteria
- Immunocompromised status.
- Emergency cases.
- Patients with hernia complications.
- Patients with prior infection at the surgical site.
- Patients taking steroids.
- Patients with severe co-morbid illness.

After obtaining pre-anaesthetic check-up, patients were posted for surgery. “All the cases in the study group were given a single shot of 1 gm cefotaxime 30 minutes before skin incision”. They did not receive any further antibiotics intravenously (or) oral. “All the procedures were carried out by experienced surgeons under all standard aseptic precautions. Monofilament Polypropylene mesh was used for hernioplasty”. After the surgery, all the cases in the control group (Group B) received post-operatively 3 days of inj. cefotaxime 1 gm intravenously twice a day followed by oral antibiotics for 3 days. A surgical site inspection was done on the 2nd, 4th and 6th day in the surgery inpatient ward and
Data was collected using a proforma meeting the objectives of the study.

**Statistical Analysis**
Data collected were entered in MS excel 2010 and analyzed using the same software. Descriptive statistical measures like percentage, mean and standard deviation were applied. Results were represented as tables.

### RESULTS

Out of 143 patients with clean cases, 72 cases were included in the study group and 71 cases in the control group as per the inclusion criteria. The results were analysed and tabulated below.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤20</td>
<td>3</td>
<td>3%</td>
</tr>
<tr>
<td>21-30</td>
<td>27</td>
<td>17%</td>
</tr>
<tr>
<td>31-40</td>
<td>28</td>
<td>18%</td>
</tr>
<tr>
<td>41-50</td>
<td>28</td>
<td>25%</td>
</tr>
<tr>
<td>51-60</td>
<td>33</td>
<td>33%</td>
</tr>
<tr>
<td>≥60</td>
<td>24</td>
<td>4%</td>
</tr>
<tr>
<td>Total</td>
<td>143</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Table 1. Age-Wise Distribution of the Study Population**

Table 1 shows the distribution of the study population by their age. The age group is mixed with people below 20 years and above 60 years. Majority i.e., 33 % were in the 51 – 60 years age group, followed by 25 % in the 41-50 years age group. The least number of participants i.e., 3 % belonged to less than 20 years age group.

In the study group of 72 patients, 11 were diagnosed with fibroadenoma, 11 were left inguinal hernia, 20 were diagnosed with right inguinal hernia, 3 with multinodular goitre, 4 with solitary thyroid, 12 with umbilical hernia and 11 patients were diagnosed with varicose veins.

In the control group of 71 patients, 13 were diagnosed with fibroadenoma, 11 with left inguinal hernia, and 19 were diagnosed.

In the study group of 72 patients, 10 underwent excision and biopsy for fibroadenoma, 44 underwent open meshplasty for left inguinal hernia, right inguinal hernia, umbilical hernia, 3 underwent total thyroidectomy, 4 hemithyroidectomy, and 11 patients underwent Trendelenburg Procedure.[11,12]

In the control group of 71 patients, 13 underwent excision and biopsy for fibroadenoma, 40 underwent open meshplasty for left inguinal hernia, right inguinal hernia, umbilical hernia, 5 underwent total thyroidectomy, 4 hemithyroidectomy and 9 patients underwent Trendelenburg Procedure.

With a P value of 0.866 which is statistically significant.

### Table 2. Distribution of Various Surgeries Done in this Study

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Study Group</th>
<th>Control Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excision &amp; Biopsy</td>
<td>Count 10</td>
<td>Count 13</td>
<td>Count 23</td>
</tr>
<tr>
<td>Hemi-Thyroidectomy</td>
<td>Count 4</td>
<td>Count 10</td>
<td>Count 14</td>
</tr>
<tr>
<td>Open Meshplasty</td>
<td>Count 44</td>
<td>Count 40</td>
<td>Count 84</td>
</tr>
<tr>
<td>Total Thyroidectomy</td>
<td>Count 3</td>
<td>Count 5</td>
<td>Count 8</td>
</tr>
<tr>
<td>Trendelenburg Proc</td>
<td>Count 11</td>
<td>Count 9</td>
<td>Count 20</td>
</tr>
</tbody>
</table>

**Table 3. Association between Postoperative Pain in Both Groups.**

Table 3 shows that among 72 patients in the study group, postoperative pain was present in 15 patients and absent in 57 patients and among 71 patients in the control group, 19 patients complained of postoperative pain and the rest 52 did not. P-value was 0.405 which was significant statistically.

### Table 4. Association between Postoperative Fever in Both Groups

In the control group of 71 patients, 13 were diagnosed with fibroadenoma, 11 with left inguinal hernia, and 19 were diagnosed.
Table 3. Association between Postoperative Fever in Both Groups

Table 4 shows that among 72 patients in the study group, 9 patients had a post-op fever while the remaining 63 did not. In the control group out of 71 patients, 10 patients had fever postoperatively, while the remaining 61 patients were afebrile. The P-value was 0.780 which is statistically significant.[13,14]

Among the 72 patients in the study group, 62 patients had grade 0 wound infection, 5 patients had grade 2 infection, 4 patients had grade 3 infection and 1 patient had grade 4 wound infection.

Among 71 patients in the control group, 60 patients had grade 0 infection, 8 patients had grade 2 infection, 1 patient had grade 3 infection and 2 patients had grade 4 wound infection. P value was 0.415 which was statistically significant.

Table 5 shows the distribution of study participants according to the grade of wound infection. Majority i.e., 86 % had grade 0 followed by grade 2 i.e., 8 % and 3.4 % had grade 3 infection.

Table 6 shows the distribution of positive pus cultures of wound swabs taken after the wound infection started. The pus culture was positive in 3 patients and negative in 69 patients in the study group. In the control group, pus culture was positive in 5 patients and negative in 66 patients. P value was 0.454 which is statistically significant.

DISCUSSION

143 cases were included in this study out of 200 clean cases that were admitted to our hospital during the study period. Randomization was done according to the day of admission. The study group received a single dose of 1gm of inj. cefotaxime 30 minutes before the skin incision while the control group received inj. cefotaxime 1gm intravenously twice a day followed by oral antibiotics for 3 days. A surgical site inspection was done on the 2nd, 4th and 6th day in the surgery inpatient ward and stitch removal was done on the 8th postoperative day. Follow-up was done on the 30th postoperative day in the surgical outpatient department for further surgical site infection.

In our study, majority of the study participants belonged to the age group of 51-60 yrs. and were males. Inguinal hernia cases were the most common in this study.

Incidence of Surgical Site Infection: In the present study, the incidence of postoperative infection was equal i.e., 6 % in both groups. However, the grade of infection varied. The incidence of grade 2 infection was 6.9 % in the study group while it was 11.3 % in the control group. Whereas the incidence of grade 3 infection was 1.4 % in the control group and 5.6 % in the study group. The difference was “statistically significant.”
Presence of Post-Operative Fever

“In the present study, the incidence of postoperative fever was 12% in the study group as compared to 14% in the control group”. However, “it was statistically significant as evidenced by a p-value of 0.780”. This is contrary to most similar studies in which the difference in febrile morbidity was not statistically significant.

Presence of Post-Operative Pain

In the present study, about 20% of the study participants reported postoperative pain and 26% in the control group presented with post-op pain. The incidence was slightly more in the control group.

This is comparable to other studies conducted in a similar manner, which too showed a similar incidence of postoperative pain in both groups that “was not statistically significant”. In the study done by Shah YD et al, the incidence of postoperative pain was 23.07% in the study group and 6.25% in the control group. However, “the difference was statistically significant”.

Limitations

1) It was a single-blinded study.
2) The sample size of the study was 143 which can be considered smaller, higher sample size can have different results.
3) The study period was short. A longer study period would have given better study results.
4) Despite these limitations, the strength of the study is its homogeneity as it’s a single surgeon study.

Conclusions

1. It is judicious to give single-dose antibiotic prophylaxis for clean surgical cases, as per the results there is a negligible difference in the occurrence of SSI when compared to multiple doses.
2. Moreover, the irrational use of antibiotics for clean cases is unnecessary and helps in preventing drug resistance due to the overuse of antibiotics.
3. A single-dose antibiotic is cost-effective and reduces the financial burden on the patients.

References