INTRODUCTION

Bacteria that enter the body through surgical incisions cause surgical site infections. Each year, they put the lives of millions of people in danger and help spread antibiotic resistance. An infection that develops at the site of a surgical procedure is known as a surgical site infection. Infections at the site of surgery can occasionally just affect the skin. Other, more serious surgery site infections might affect tissues under the skin, organs, or implanted materials. In 1992, the phrase "surgical site infection" (SSI) was used to replace the earlier phrase "surgical wound infection".

Infections that damage either the incision or deep tissue at the surgical site and happen within 30 days of a surgical procedure (or within a year if an implant is left in place after the treatment) are known as SSIs. The pathogens that cause disease vary on the type of operation; the Staphylococcus aureus, Coagulase-negative staphylococci, Enterococcus species, and E. coli are the most often isolated organisms. The risk of SSI is influenced by a variety of patient-related and procedure-related factors; therefore, prophylaxis calls for a "bundle" strategy that pays systematic attention to a number of risk factors in order to lower the likelihood of bacterial contamination and strengthen the patient's defenses. Good patient preparation, aseptic technique, and attention to surgical technique are all stressed in the Centers for Disease Control and Prevention's guidelines for the prevention of surgical site infections (SSIs). Antimicrobial prophylaxis is also indicated in some cases.

According to the CDC's healthcare-associated infection (HAI) prevalence survey, inpatient surgeries were thought to be the cause of 110,800 surgical site infections (SSIs) in 2015. 11% of surgical patients in low- and middle-income nations get an infection. A 5% decrease in the SSI standardized infection ratio (SIR) associated to all NHSN operational procedure categories taken together compared to the prior year was recorded in 2020, according to the HAI data results for 2020 released in the NHSN's HAI Progress Report. SIR associated with the NHSN surgical procedure categories of the Surgical Care Improvement Project.
SSIs continue to be a major source of morbidity, prolonged hospitalization, and death despite improvements in infection control procedures, including better operating room ventilation, sterilizing processes, barriers, surgical technique, and accessibility to antibiotic prophylaxis. According to reports, SSI accounts for 20% of all HAIs, is linked to a 2- to 11-fold increase in the likelihood of mortality, and is directly responsible for 75% of SSI-associated deaths. SSI is the most expensive HAI type, with an estimated yearly cost of $3.3 billion. It increases hospital costs by more than $20,000 each admission and lengthens hospital stays by 9.7 days. The use of antibiotics to stop infections at the surgical site is known as surgical antibiotic prophylaxis. Even while infection may not be clinically obvious, it must be separated from the proactive use of antibiotics to treat early illness, such as a perforated appendix. Hospital practices now utilize antibiotics for surgical prophylaxis between 30 and 50 percent of the time. But 30 to 90 percent of this prophylactic is misguided. Most frequently, an antibiotic is administered at the incorrect time or for an excessively lengthy period of time. Both duration of prophylaxis and which particular surgical techniques should receive prophylaxis are still up for debate. To guarantee appropriate tissue concentrations at the moment of the surgical incision, prophylactic antibiotics are typically administered intravenously as a bolus on induction of anesthesia. Given that most beta-lactams have extremely short half-lives, the time of dose is particularly crucial. The infusion of Vancomycin must begin earlier so that it can end an hour before induction because it must be given over an extended period of time. Less frequently than intravenous antibiotics, intramuscular antibiotics are administered. They are frequently administered during pre-medication in order to reach peak tissue levels at the most crucial moment—the time of the surgical site. In order to ensure optimal tissue concentrations during surgery, oral or rectal antibiotics must be administered beforehand. To further reduce the rate of wound infection, a search for other methods of administering prophylactic antibiotics was initiated. The intra-incisional infiltration with prophylactic antibiotics is one such technique. As a result of the antibiotic being absorbed from the incision site, this technique ensures a significant level of antibiotics there at the incision site and has been demonstrated to offer systemic coverage. This is mainly because the antibiotic adheres to the tissues near the incision and is thus present in high concentrations when the incision is most contaminated.

Justification
Since the presence of microorganisms in the incision at the time of closure constitutes the most essential factor in the pathogenesis of wound sepsis, the timing, route, and duration of antibiotic prophylaxis in surgical procedure presume great significance in that they ought to ensure that as greater a concentration as possible reaches the wound before contamination. Antibiotics should be administered locally, intravenously, and responsibly in this era of cost control and rising drug resistance. So, this study helps to compare both intravenous and intra incisional site antibiotic site administration among patients posted for elective surgeries.

Aim of the study was to compare the efficacy of pre-operative antibiotic infiltration along the incision site and prophylactic parenteral antibiotic therapy in reducing surgical site infection primary objectives were determination of the incidence of surgical site infections among patients treated with prophylactic parenteral antibiotic therapy and pre-operative antibiotic infiltration along the incision and comparison of the efficacy of pre-operative antibiotic infiltration along the incision site and prophylactic parenteral antibiotic therapy in reducing surgical site infection.

**MATERIALS AND METHODS**

This is a single blinded randomized controlled study conducted in Department of General Surgery, Government Royapettah Hospital and Government Kilpauk Medical College during the period of two years (October 2020 – October 2022). A total of 120 people were selected by simple random sampling method. Our study population included patients aged 18 – 60 years irrespective of gender undergone elective surgery for various indications. Inclusion criteria were age 18 – 60 years, both genders, duration of surgery less than two hours, clean and clean-contaminated surgical procedure, open and laparoscopic surgeries and willingness to give consent for participation in this study. Exclusion criteria were patients with comorbid conditions like Diabetes Mellitus, Hypertension, Vascular Diseases, Auto immune diseases and skin infections, patients with altered immune status such as immune compromised, history of prolonged steroid therapy and hypersensitivity reactions, patients less than 18 years, patients who underwent emergency procedures and participants not willing to give consent.

120 patients were divided into three groups at random using simple randomization. Lots were coded with the letters A (40), B (40), and C (30) and serially numbered from 1 to 120. The interviewees were given a range of options to choose from without being informed of their group affiliation. Depending on their choice, they were assigned to either the A, B, or C group. For group A, prophylaxis by preoperative intra incisional infiltration of the antibiotic was done. One gram of Cefotaxime diluted in 10 ml of distilled water was infiltrated along the incision site and the subcutaneous tissue in the proposed line of incision. For Group B, a single dose of 1 gram of Cefotaxime was administered intravenously 20 minutes before the surgical incision at the time of induction of

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anesthesia. For group C, prophylaxis by both systemic and intra-incisional infiltration of the antibiotic was given (1 gram of Cefotaxime was administered intravenously and 1 gram of Cefotaxime diluted in 10 ml of distilled water was infiltrated along the site of proposed incision 20 minutes before incision).

The observer was blinded in the study. Operational definition for Surgical site infections (SSI) according to CDC, is an infection at the surgical site is one that develops in the area of the body where the surgery was performed. Infections at the surgical site can occasionally be limited to the skin's surface. Other, more serious surgical site infections can affect organs, implanted materials, tissues under the skin, or both.[2]

Data was collected among participants by interview method using a semi structured questionnaire. One day prior to the surgery, test dose of antibiotic was given intra-dermally to exclude hypersensitivity reactions. Part was shaved in the morning of the surgery before the patient had bath with soap and water. In operation theatre, after induction of anesthesia, the parts were prepared with povidone iodine scrub (Beta scrub) followed by methylated spirit. The antibiotic was infiltrated along the incisional site 20 min before the surgery. Standardization of incision was done for all the cases (Appendectomy-7.5 cm, Herniorrhaphy-7.5 cm, Subtotal Thyroidectomy-10 cm, Cholecystectomy-10 cm). The dose of antibiotic used for infiltration was 1 gram of Cefotaxime dissolved in 10 ml of distilled water and it was infiltrated uniformly 1 cm circumferentially around all the margins of the planned incision with a disposable syringe and 16 G needle in subcutaneous tissue plane. Operation site was covered by occlusive dressings for 48 hours, when first inspection of the suture site was carried out. The suture site was left open thereafter to inspect daily except in patients who developed infection. Cases where surgical site infection was suspected, occlusive dressing was resorted to daily with povidone iodine. Wound complications were documented as per Centers for Disease Control and Prevention (CDC) guidelines. Patients developing any discharge from the surgical wound were investigated by pus swabs for culture and appropriate antibiotics were administered as per culture sensitivity report. Sutures were removed on 10th post op day and patients were discharged by 14th post op day.

Three variables were used to measure outcome. Those were, one dependent variable, surgical site infections and two independent variables, age as a continuous variable expressed in numbers and gender as a categorical variable (male/female). Null hypothesis was assumed as there is no difference in the efficacy between pre-operative antibiotic infiltration along the incision site and prophylactic parenteral antibiotic therapy in reducing surgical site infection.

Statistical Analysis
Data was entered in Microsoft excel 2019 and analyzed by SPSS (Statistical Package of Social Sciences) version 21. The variables were analyzed by using descriptive and inferential statistics. The data of continuous variables obeying normal distribution and non-normal distribution were represented by “mean ± standard deviation (x ± s)” and “median (lower quartile, upper quartile) (M (P25-P75))”, respectively. Continuous variables that obey normal distribution were tested by t-test, and continuous variables that do not obey normal distribution are tested by nonparametric rank sum test (Wilcoxon.). The categorical variables were expressed by percentage and the chi-squared test was used for comparison between groups. All the statistics were tested by a two-sided test, with a p-value less than 0.05 considered to be statistically significant. All confidence intervals (CI) were set to 95%.

The study protocol was presented to the Institutional ethics board for the permit of the study and was cleared. Informed oral consent was obtained from their patients before the start of the study.

RESULTS
This study was conducted among 120 patients posted for various surgeries randomized into three groups. The mean age of participants was 41.275 with Standard deviation of 16.69 ranging from 18 – 76 years among Group A participants. The mean age of participants was 42.575 with Standard deviation of 16.855 ranging from 18 – 75 years among Group B participants. The mean age of participants was 47.2 with Standard deviation of 17.082 ranging from 18 - 76 years among Group C participants. Among three groups, there was no significant difference among age group. The proportion of more than thirty years were higher in all groups.85% of the participants were males and 15% of them were females in Group A, with a male: female ratio of 5:1. 80% of the participants were males and 12% of them were females in Group B and the male: female ratio was 5:1. In group C, 85% of the participants were males and 15% of them were females with a male: female ratio of 5:1. Among three groups, there was no significant difference among gender. The proportion of male gender were higher in all groups.

![Figure 1: Diagram showing comparison of age differences between the 3 groups](image-url)
In group A, 37.5% of them had cholecystitis and appendicitis. 22.5% of them were diagnosed with hernia and 2.5% of them had thyroid disorders. In group B, 37.5% of them had cholecystitis and appendicitis. 22.5% of them were diagnosed with hernia. In group C, 37.5% of them had cholecystitis and appendicitis. 22.5% of them were diagnosed with hernia. 43% of the wound were clean wounds and 58% of them were clean contaminated wounds. 45% of the wound were clean wounds and 55% of them were clean contaminated wounds in Group B as well as in group C. 15% of the participants had surgical site infections in Group A, 12% in Group B and 5% in Group C.

Probability value was considered significant when it was <0.05.

When prevalence of SSI was compared among the three groups, there was no significant difference. The proportion of surgical site infections were higher Group A compared with other groups. The Group C had lower proportion of SSI [Table 4].

Figure 2: Gender distribution in the groups

Figure 3: Comparison of SSI prevalence among the groups

Table 1: Age distribution of participants in the groups

<table>
<thead>
<tr>
<th>Group</th>
<th>10-30 years</th>
<th>&gt;30 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>35%</td>
<td>65%</td>
</tr>
<tr>
<td>Group B</td>
<td>30%</td>
<td>70%</td>
</tr>
<tr>
<td>Group C</td>
<td>22.5%</td>
<td>77.5%</td>
</tr>
</tbody>
</table>

Table 2: Age difference comparison among participants

<table>
<thead>
<tr>
<th>Age group</th>
<th>Group A (%)</th>
<th>Group B (%)</th>
<th>Group C (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-30 years</td>
<td>14(40%)</td>
<td>12(34.3%)</td>
<td>9(25.7%)</td>
<td>0.465</td>
</tr>
<tr>
<td>&gt;30 years</td>
<td>26(30.6%)</td>
<td>28(32.9%)</td>
<td>31(36.5%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Gender distribution among the participants

<table>
<thead>
<tr>
<th>Gender</th>
<th>Group A (%)</th>
<th>Group B (%)</th>
<th>Group C (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>34(34%)</td>
<td>32(32%)</td>
<td>34(34%)</td>
<td>0.787</td>
</tr>
<tr>
<td>Female</td>
<td>6(30%)</td>
<td>8(40%)</td>
<td>6(30%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 4: P values of descriptive variables by Pearson’s Chi-Square test

<table>
<thead>
<tr>
<th>Variable</th>
<th>P values of descriptive variables by Pearson’s Chi-Square test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosis</td>
<td>0.913 Not significant</td>
</tr>
<tr>
<td>Type of wound</td>
<td>0.967 Not significant</td>
</tr>
<tr>
<td>Duration of hospital stay</td>
<td>0.646 Not significant</td>
</tr>
</tbody>
</table>

Table 5: Difference in prevalence of SSI among the groups

<table>
<thead>
<tr>
<th>SSI</th>
<th>Group A</th>
<th>Group B</th>
<th>Group C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>15%</td>
<td>12.5%</td>
<td>5%</td>
</tr>
<tr>
<td>No</td>
<td>85%</td>
<td>87.5%</td>
<td>95%</td>
</tr>
</tbody>
</table>

Table 6: Comparison of SSI occurrence among the groups

<table>
<thead>
<tr>
<th>SSI</th>
<th>Group A (%)</th>
<th>Group B (%)</th>
<th>Group C (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>6(46.2%)</td>
<td>5(38.5%)</td>
<td>2(15.4%)</td>
<td>0.326</td>
</tr>
<tr>
<td>No</td>
<td>34(31.8%)</td>
<td>35(32.7%)</td>
<td>38(35.5%)</td>
<td></td>
</tr>
</tbody>
</table>
DISCUSSION

This study was conducted among 120 patients posted for various surgeries randomized into three groups. The Patil A et al.\(^\text{[11]}\) included a total of 33 (55%) male participants and 27 (45%) female patients. 9 (30%) men and 21 (70%) women made up Group A (intravenous). Twelve (40%) females and 18 (60%) males made up Group B (intracisional). Our study included 80% of males and 12% of females in Group B. 85% of males and 15% of females in Group A. The male and female ratio was 5:1. Our study showed that 15% of the participants had surgical site infections in Group A (intravenous antibiotics). 12% of the participants had surgical site infections in Group B (intra incisional) and 5% of the participants had surgical site infections in Group C (intra incisional and intravenous antibiotics). During the follow-up period, one patient in Group A (3.3%) and 4 individuals in Group B (13.3%) displayed symptoms of a postoperative surgical site infection, extending their hospital stays (p >0.05) in Patil A et al.\(^\text{[11]}\) research. Dogra et al (12) found that the overall incidence of SSI was 10% in Group A (intra incisional), 18% in Group B (intravenous antibiotics), and 2.5% in Group C (intra incisional and intravenous antibiotics). There was a lower proportion of SSI in Group C comparable with our results. Intracisional and systemic antibiotics had lower proportion of SSI as same as our results. Infection rates at the surgical site were higher in Group A (intravenous) than in (Intracisional) Group B (25% vs. 8.33%) by Anand et al.\(^\text{[13]}\) research. Our study reported that among three groups, there was no significant difference among surgical site infections. The proportion of surgical site infections were higher Group A compared with other groups. The Group C had lower proportion of SSI. Patil A et al.\(^\text{[11]}\) reported that a lower incidence of SSI was observed in people who received intra incisional antibiotics, despite the difference not being statistically significant compared with intravenous antibiotics which was similar to our study results. Wang et al.\(^\text{[14]}\) stated that for patients with abdominal infections, intraoperative incision irrigation with high-volume NS is linked to a decreased rate of SSI. Soleymani et al.\(^\text{[15]}\) in a study found that intra incisional was found to effective against oral antibiotics. The results were similar across the studies that the use of intra incisional alone or in combination of intravenous antibiotics had reduction of SSI but there was no statistical significance. Moesgaard et al.\(^\text{[16]}\) in an animal model described that intra incisional antibiotics as an addition to systemic administration do not decrease wound infection rates in contaminated abdominal surgery which was contrast to our study results. Therefore, the null hypothesis rejected. There was a difference in the efficacy between pre-operative antibiotic infiltration along the incision site and prophylactic parenteral antibiotic therapy in reducing surgical site infection. But the surgical site infections might vary due to host factors and immunological factors.

CONCLUSION

This study was conducted among 120 patients posted for various surgeries randomized into three groups (intravenous, intra incisional and both). This study demonstrates that SSI infection rates have decreased in all classes of wounds following preoperative intravenous with an intra-incisional injection of a broad spectrum antibiotic (Cefotaxime). The intra-incisional approach theoretically achieves a larger concentration at the incision site, making it a better method of preventive antibiotic administration. But a bigger randomized control experiment where characteristics like the antibiotic’s levels in the blood and around the incisional site at different times and its affinity for fatty tissue are also evaluated can better prove this fact.

Limitations

The sample size was smaller (n = 40) which was difficult to generalize the results. The host factors can be assessed for the significance of SSI. The antibiotic concentration measurement might be helpful to assess the level of SSI prevented due to that particular antibiotic. The antibiotic resistance can be a confounding factor and can increase the risk of infection.

REFERENCES

10. Kumar DJA. A study comparing preoperative intra incisional antibiotic infiltration and prophylactic intravenous antibiotic administration for reducing surgical site infection. European