

**ORIGINAL RESEARCH**

# A Prospective Randomized Trial evaluating the efficacy of antibiotic prophylaxis in reducing surgical site infections in patients undergoing Elective Abdominal Surgery in our Institute in Tribal Area

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**ABSTRACT:**

**Introduction:** Surgical site infections (SSIs) are a common complication of abdominal surgery, and the optimal regimen and duration of antibiotic prophylaxis remain unclear. This study aimed to evaluate the efficacy of antibiotic prophylaxis in reducing SSIs in patients undergoing elective abdominal surgery.

**Methods:** A prospective randomized trial was conducted in 98 adult patients undergoing elective abdominal surgery. Patients were randomized into the cefazolin prophylaxis group or the no prophylaxis group. Patients were followed up for at least 30 days postoperatively to monitor for the development of SSIs.

**Results:** The incidence of SSIs was significantly lower in the antibiotic prophylaxis group (6.3%) compared to the no prophylaxis group (24.0%) ( $p=0.02$ ). There were no significant differences in the rates of other postoperative complications between the two groups.

**Conclusion:** This study provides evidence that a single preoperative dose of intravenous cefazolin is effective in reducing the incidence of SSIs in adult patients undergoing elective abdominal surgery. Further studies are needed to determine the optimal regimen and duration of prophylaxis in patients undergoing abdominal surgery.

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**Introduction:**

Surgical site infections (SSIs) are a common complication of abdominal surgery, leading to increased morbidity and mortality rates. Antibiotic prophylaxis is commonly used to reduce the risk of SSIs, but the optimal regimen and duration of prophylaxis remain unclear. This study was carried out at Zydus Medical College, Dahod to evaluate the efficacy of antibiotic prophylaxis in reducing SSIs in patients undergoing elective abdominal surgery.

**Review of Literature:** Surgical site infections (SSIs) continue to be a major concern in patients undergoing

abdominal surgery. Despite numerous studies evaluating the efficacy of antibiotic prophylaxis in reducing SSIs, there is still a lack of consensus in the medical community regarding the optimal approach. While some studies have demonstrated that prophylaxis with first-generation cephalosporins, like cefazolin, can be effective in reducing SSIs, others have failed to find significant differences between prophylaxis and no prophylaxis. Furthermore, the ideal duration of prophylaxis remains unclear, with some studies suggesting that a single preoperative dose is sufficient, while others recommend continued prophylaxis postoperatively. Future research is necessary to

determine the most effective and appropriate use of antibiotic prophylaxis in reducing SSIs in patients undergoing abdominal surgery. Additionally, it is important to consider the potential risks and benefits of antibiotic prophylaxis, including the potential for the development of antibiotic-resistant bacteria. Ultimately, the decision to use antibiotic prophylaxis should be individualized based on the patient's specific risk factors and the surgeon's clinical judgment.

**Methods:** A prospective randomized trial was conducted in 98 adult patients (age  $\geq 18$  years) undergoing elective abdominal surgery at a single center between January 1, 2021 and November 3, 2022.

#### **Inclusion criteria:**

- Only patients who were scheduled for elective abdominal surgery should be included in the study.
- Patients aged 18 years and above should be included.
- Patients who have provided informed consent to participate in the study were included.

#### **Exclusion criteria:**

- Patients with known allergy to cefazolin were excluded from the study.
- Patients who had received antibiotics within the previous two weeks were excluded.
- Patients with pre-existing infections or open wounds were excluded.
- Pregnant or lactating women were excluded.

#### **Sample size calculation:**

- A power analysis was conducted to determine the appropriate sample size for the study.
- The sample size was large enough to ensure that the results were statistically significant.

#### **Randomization:**

- Patients were randomized into the two groups (cefazolin prophylaxis or no prophylaxis) using a computer-generated randomization sequence.
- Allocation concealment was ensured to prevent selection bias.

#### **Blinding:**

- The study was double-blind, meaning that neither the patients nor the investigators knew which group each patient belongs to.
- Blinding was ensured by using identical-appearing placebos for the no prophylaxis group.

#### **Prophylaxis administration:**

- The cefazolin prophylaxis was administered in

accordance with the hospital's standard operating procedure for prophylactic antibiotic use.

- The prophylaxis was administered within 60 minutes prior to incision.

#### **Follow-up:**

- Patients were followed up for at least 30 days postoperatively to monitor for the development of SSIs.
- The patients were monitored for signs of infection such as fever, redness, pain, and discharge from the surgical site.
- Follow-up was done by investigators who are blinded to the patient's group allocation.

**Microbiological Analysis:** Intraoperative cultures were obtained from all patients and analyzed for bacterial growth. The most commonly isolated organisms were *Escherichia coli* (31%), *Klebsiella pneumoniae* (15%), and *Staphylococcus aureus* (13%). The majority of isolates (81%) were susceptible to cefazolin.

#### **Results:**

Of the 98 patients included in the study, 48 received antibiotic prophylaxis and 50 received no prophylaxis. The overall incidence of SSIs was 15.3% (15/98). The incidence of SSIs was significantly lower in the antibiotic prophylaxis group (6.3%, 3/48) compared to the no prophylaxis group (24.0%, 12/50) ( $p=0.02$ , relative risk reduction=74.0%, number needed to treat=6). There were no significant differences in the rates of other postoperative complications between the two groups.

Table 2: Incidence of SSIs

<b>Outcome</b>	<b>Antibiotic Prophylaxis Group</b>	<b>No Prophylaxis Group</b>	<b>p-value</b>
Incidence of SSIs (%)	6.3 (3/48)	24.0 (12/50)	0.02

#### **Conclusion:**

This study provides evidence that a single preoperative dose of intravenous cefazolin is effective in reducing the incidence of SSIs in adult patients undergoing elective abdominal surgery. This finding supports the use of antibiotic prophylaxis in this population. The most commonly isolated organisms in this study were *Escherichia coli*, *Klebsiella pneumoniae*, and *Staphylococcus aureus*, with the majority of isolates being susceptible to cefazolin. Further studies are needed to determine the optimal regimen and duration of prophylaxis in patients undergoing abdominal surgery. The study included 98 patients, aged 18 years or older, who were randomly assigned to receive either

prophylactic antibiotics or a placebo before surgery. Patients with a history of antibiotic use within two weeks of surgery, allergy to the study drugs, or existing infections were excluded from the study<sup>2</sup>.

The study found that prophylactic antibiotics significantly reduced the incidence of SSIs in patients undergoing colorectal surgery, with only 5% of patients who received antibiotics developing an SSI compared to 25% of patients who received a placebo<sup>1</sup>. The study also found that the most common microorganisms found in SSIs were *Escherichia coli* and *Bacteroides fragilis*<sup>3</sup>.

This study provides strong evidence for the use of antibiotic prophylaxis in reducing the incidence of SSIs in elective colorectal surgery. The findings of this study have been supported by subsequent studies and have been incorporated into guidelines for preventing SSIs in surgical patients<sup>4,5</sup>.

Other studies have also identified additional risk factors associated with SSIs, such as smoking, obesity, and longer surgery duration<sup>6,7</sup>. Healthcare facilities can use these risk factors to identify patients who may benefit from additional infection prevention measures.<sup>8,9</sup>

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