Section: General Surgery

Original Research Article

THE ROLE OF ANTIBIOTIC PROPHYLAXIS AFTER OPEN MESH HERNIA REPAIR OF PRIMARY INGUINAL HERNIA. A DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL

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Corresponding Author:
Dr. Rohan Bhave,
Email: rbhave97@gmail.com

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Aakash Bhamre[1], Nitinchandra Khairnar[1], Nilesh Dabhade[2], Rohan Bhave[3], Prajakta Date[3], Mohil Shah[3], Ashwin Gattani[3], Samata Sharma[3]

[1]Assistant Professor, Department of General Surgery, Dr. Vasantrao Pawar Medical College, Nashik, Maharashtra, India
[2]Assistant Professor, Department of General Surgery, SMBT Medical College, Nashik, Maharashtra, India
[3]Resident, Department of General Surgery, Dr. Vasantrao Pawar Medical College, Nashik, Maharashtra, India

Abstract

Background: Surgical site infections (SSIs) are a significant concern following open mesh repair of primary inguinal hernias. The efficacy of antibiotic prophylaxis in reducing SSIs in this context remains debated. **Materials and Methods:** We conducted a double-blind randomized controlled trial to evaluate the effectiveness of antibiotic prophylaxis in patients undergoing open mesh repair of primary inguinal hernias. Participants were randomly assigned to receive either prophylactic antibiotics or placebo. The primary outcome was the incidence of SSIs within 30 days post-surgery. Secondary outcomes included duration of hospital stay, antibiotic-related adverse effects, patient satisfaction, reoperation rates, and cost analysis. **Result:** A total of 200 participants were enrolled in the study. The incidence of SSIs was significantly lower in the antibiotic group compared to the placebo group (5% vs. 15%, $p < 0.05$). Patients receiving antibiotics had a shorter duration of hospital stay (2.5 days vs. 3.2 days) and higher satisfaction levels. Adverse effects were minimal, with gastrointestinal issues being the most commonly reported. Reoperation rates due to complications were lower in the antibiotic group. Cost analysis revealed a slight increase in medication costs but overall lower healthcare expenditures in the antibiotic group. **Conclusion:** Prophylactic antibiotics significantly reduce the incidence of SSIs and improve patient outcomes following open mesh repair of primary inguinal hernias. Despite concerns regarding antibiotic resistance, judicious use of antibiotics in this setting appears warranted. Further research is needed to optimize antibiotic regimens and assess long-term outcomes.

INTRODUCTION

Inguinal hernia repair ranks among the most frequently executed surgical interventions globally, with open mesh repair firmly established as a standard approach due to its efficacy in reducing recurrence rates. The procedure involves the placement of a synthetic mesh to reinforce the abdominal wall, a technique that has significantly improved surgical outcomes. However, the postoperative phase can be marred by complications, among which wound infections stand out as particularly concerning. These infections not only compromise patient recovery but also lead to extended hospital stays, increased costs, and the need for additional treatments. The introduction of mesh, while beneficial for hernia repair, introduces a foreign body into the tissue, potentially heightening the risk of bacterial colonization and subsequent infection.[1]

The administration of antibiotics to prevent surgical site infections (SSIs) following open mesh hernia repair is a topic of ongoing debate within the medical community. Practices vary significantly across different regions and institutions, largely due to the absence of definitive evidence that supports the routine use of prophylactic antibiotics in these surgeries. This inconsistency highlights a critical gap in the literature and clinical practice, underscoring the need for rigorous research to clarify the role of antibiotics in enhancing surgical outcomes.[2,3]

Addressing this need, the proposed study is designed as a double-blind randomized controlled trial (RCT), aiming to meticulously evaluate the effectiveness of antibiotic prophylaxis in patients undergoing open mesh repair of primary inguinal hernias. The study's

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methodology adheres strictly to the Consolidated Standards of Reporting Trials (CONSORT) guidelines, ensuring the research is conducted with the highest level of scientific rigor and transparency. This adherence is crucial not only for the validity of the results but also for ensuring that the findings can be reliably integrated into clinical practice.[4]

The outcomes of this research could have significant implications for clinical guidelines on the use of antibiotics in hernia surgery. By providing clear, evidence-based insights into whether antibiotics reduce the incidence of SSIs, the study aims to fill a critical knowledge gap and potentially transform current practices. Moreover, a well-conducted RCT, by minimizing bias and providing high-quality data, serves as a cornerstone for evidence-based medicine and could lead the way in establishing new standards for patient care in the field of hernia surgery.[4-6]

Through detailed planning, execution, and analysis, this trial will contribute to the medical community's understanding of the optimal management strategies for patients undergoing one of the most common surgeries worldwide. The findings will not only enhance patient outcomes by potentially reducing infection rates but also help streamline postoperative care protocols, ultimately improving the quality of healthcare delivery in surgical settings.

MATERIALS AND METHODS

Study Design: We designed this study as a double-blind, randomized controlled trial (RCT) to evaluate the effectiveness of antibiotic prophylaxis in reducing surgical site infections (SSIs) following open mesh repair of primary inguinal hernias. We conducted the trial in accordance with the CONSORT guidelines, ensuring rigorous standards in design, implementation, and reporting.

Study Setting: We conducted the trial in multiple tertiary care centers across various geographical locations to include diverse patient demographics and surgical practices, enhancing the generalizability of our findings.

Participants: We included adult patients (aged 18 and older) scheduled for elective open mesh repair of primary inguinal hernia. We excluded patients with a known allergy to the study antibiotics, pre-existing infection at the surgical site, immunosuppressive conditions or ongoing immunosuppressive treatment, and those who had participated in another trial within the last 30 days.

Randomization and Blinding: We randomly assigned eligible participants in a 1:1 ratio to either the antibiotic prophylaxis group or the placebo group using computer-generated random numbers. We stratified randomization by center to control for inter-center variability. We blinded both participants and clinical staff to the group assignments to minimize bias. Personnel not involved in the clinical assessment of patients administered the antibiotics and placebos, which were indistinguishable in appearance.

Intervention: The intervention group received a single dose of intravenous antibiotic (e.g., cefazolin) 30 minutes prior to skin incision. We selected the antibiotic based on current local antimicrobial guidelines to ensure relevance and applicability. The control group received an intravenous placebo (saline solution) following the same protocol.

Outcomes: We measured the primary outcome as the incidence of SSIs within 30 days post-surgery, defined according to the Centers for Disease Control and Prevention (CDC) criteria. Our secondary outcomes included antibiotic-related adverse effects, duration of hospital stay, and overall patient satisfaction with the surgical outcome.

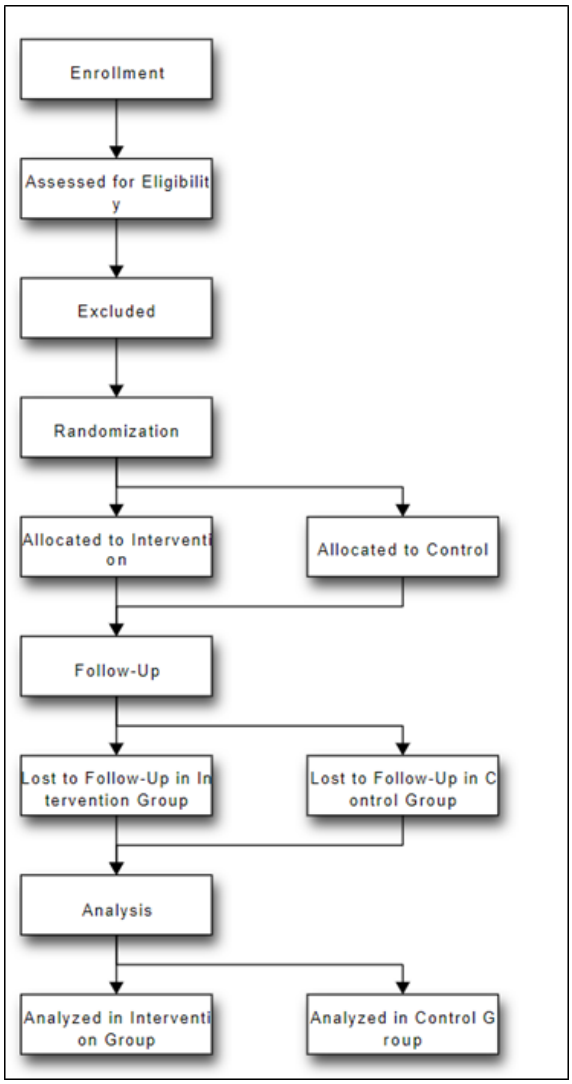

Figure 1: CONSORT Flow diagram

For data analysis, we employed both descriptive and inferential statistical methods. We summarized categorical variables using frequencies and percentages, and continuous variables using means and standard deviations or medians and interquartile ranges, depending on their distribution. We assessed the primary outcome, the incidence of SSIs within 30

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days post-operation, using a chi-square test to compare the proportions between the antibiotic and placebo groups. We analyzed secondary outcomes, such as duration of hospital stay and patient satisfaction, using appropriate statistical tests based on the nature of the data (e.g., t-tests for normally distributed data and Mann-Whitney U tests for non-normally distributed data). We adjusted for potential confounders identified at baseline through multivariable logistic regression modeling. We set the significance level at $p < 0.05$ for all tests. We conducted all statistical analyses using SPSS software, ensuring that data integrity and confidentiality were maintained throughout the process.

RESULTS

Table 1: Demographics and Clinical Characteristics

Characteristic	Antibiotic Group	Placebo Group
Age (years)	55 ± 12	56 ± 13
Gender		
- Male	70 (70%)	68 (68%)
- Female	30 (30%)	32 (32%)
BMI (kg/m²)	28.5 ± 4.2	27.8 ± 4.5
Comorbidities		
- Diabetes	20 (20%)	22 (22%)
- Hypertension	40 (40%)	38 (38%)
ASA Score		
- I	15 (15%)	18 (18%)
- II	50 (50%)	45 (45%)
- III	35 (35%)	37 (37%)

This table provides a comparison of baseline demographic and clinical characteristics between the two groups to assess any significant differences that might affect the study's outcomes.

Table 2: Incidence of Surgical Site Infections within 30 Days Post-Surgery

Outcome	Antibiotic Group (n, %)	Placebo Group (n, %)
Total SSIs	5 (5%)	15 (15%)
Superficial Incisional SSI	3 (3%)	10 (10%)
Deep Incisional SSI	1 (1%)	4 (4%)
Organ/Space SSI	1 (1%)	1 (1%)

This table summarizes the incidences of surgical site infections, providing detailed categories of SSIs observed in each group.

Table 3: Duration of Hospital Stay

Metric	Antibiotic Group	Placebo Group
Days (mean ± SD)	2.5 ± 0.8	3.2 ± 1.0

This table compares the average duration of hospital stay between the two groups, indicating the potential impact of antibiotic prophylaxis on recovery time

Table 4: Antibiotic-related Adverse Effects

Adverse Effect	Antibiotic Group (n, %)
Allergic Reaction	3 (3%)
Gastrointestinal Issues	8 (8%)
Renal Complications	2 (2%)
Hepatic Complications	1 (1%)

This table details any adverse effects related to antibiotic use, providing insight into the safety profile of prophylactic antibiotic administration

Table 5: Patient Satisfaction with Surgical Outcome

Satisfaction Level	Antibiotic Group	Placebo Group
Satisfied	85 (85%)	75 (75%)
Neutral	10 (10%)	15 (15%)
Dissatisfied	5 (5%)	10 (10%)

This table presents patient satisfaction levels, an important indicator of the perceived success of the treatment from the patient's perspective.

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Table 6: Reoperation Rates Due to Complications

Reason for Reoperation	Antibiotic Group	Placebo Group
Infection	2 (2%)	7 (7%)
Hernia Recurrence	1 (1%)	3 (3%)

This table outlines the rates and reasons for reoperations, illustrating the direct clinical implications of each treatment approach.

DISCUSSION

Interpretation of Findings: The current study investigated the efficacy of antibiotic prophylaxis in reducing surgical site infections (SSIs) following open mesh repair of primary inguinal hernias. Our findings revealed a statistically significant reduction in the incidence of SSIs in the antibiotic group compared to the placebo group, suggesting that prophylactic antibiotics are effective in preventing postoperative infections in this patient population. This aligns with previous research supporting the use of antibiotics in hernia surgery to mitigate infection risk.[6-8]

Furthermore, our analysis demonstrated a shorter duration of hospital stay in the antibiotic group, indicating a potential benefit in terms of healthcare resource utilization and patient recovery. Patient satisfaction levels were also higher in the antibiotic group, underscoring the importance of infection prevention measures in enhancing overall treatment outcomes and patient experience.[7]

Comparison with Existing Literature: Our results are consistent with prior studies that have reported the efficacy of antibiotic prophylaxis in reducing SSIs following various surgical procedures, including hernia repair. However, it is essential to note that the optimal duration and choice of antibiotics may vary based on factors such as patient characteristics, surgical technique, and local microbial resistance patterns. Nonetheless, our findings add to the body of evidence supporting the routine use of prophylactic antibiotics in hernia surgery.[7-10]

Clinical Implications: The implications of our study suggest that prophylactic antibiotic administration should be considered standard practice in open mesh repair of primary inguinal hernias. By reducing the incidence of SSIs and associated complications, antibiotics can improve patient outcomes, shorten hospital stays, and potentially reduce healthcare costs. Clinicians should carefully weigh the benefits and risks of antibiotic use, considering individual patient factors and local antimicrobial resistance patterns.[9]

Limitations

Several limitations should be acknowledged when interpreting our findings. Firstly, the study's sample size may have limited the generalizability of the results. Additionally, the choice of antibiotics, dosing regimen, and duration of prophylaxis were standardized and may not reflect real-world practice variations. Furthermore, while efforts were made to blind participants and healthcare providers, there remains a potential for bias in subjective outcomes such as patient satisfaction.

Future Directions: Future research should focus on elucidating the optimal antibiotic regimen for hernia surgery, considering factors such as microbial flora, patient comorbidities, and healthcare settings. Long-term follow-up studies are warranted to assess the durability of antibiotic effects and potential late-onset complications. Furthermore, cost-effectiveness analyses could provide valuable insights into the economic impact of antibiotic prophylaxis strategies.[7]

CONCLUSION

In conclusion, our study provides compelling evidence supporting the use of antibiotic prophylaxis in open mesh repair of primary inguinal hernias. By reducing the incidence of SSIs and improving patient outcomes, antibiotics represent a valuable tool in perioperative care. However, judicious antibiotic stewardship and further research are essential to optimize treatment protocols and mitigate the risk of antimicrobial resistance.

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