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Evaluating Prophylactic Antibiotic Use in Clean Surgical Cases: A Comparative Study on Postoperative Outcomes and Infection Rates

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Abstract

Introduction

While clean surgeries have a low infection risk, postoperative infections can still cause complications. This study evaluates the impact of prophylactic antibiotics on infection rates and wound healing in such surgeries.

Materials and Methods

A total of 100 patients at Krishna Hospital were divided into two groups: Group A received a single dose of antibiotics, and Group B received none. Infections and wound healing were monitored on days 2, 5, 10, and 30. Statistical analysis compared infection rates and recovery between groups.

Results

Group A had a significantly lower infection rate (6% vs. 26%) and faster healing. These results suggest prophylactic antibiotics reduce complications in clean surgeries.

Conclusion

Prophylactic antibiotics in clean surgeries reduce infections and enhance healing, supporting their selective use to optimize patient outcomes and uphold antibiotic stewardship.

Keywords

Clean surgery, prophylactic antibiotics, surgical site infection, wound healing, postoperative complications, antibiotic stewardship, infection prevention

I. Introduction

Clean surgical cases, characterized by procedures performed in sterile environments without opening the gastrointestinal, respiratory, or genitourinary tracts, typically carry a low risk of infection. Defined as procedures where no inflammation or contamination is present, clean surgeries represent a unique category in surgical practice due to their minimal association with postoperative infections [1]. The goal of such operations is to maintain sterile conditions rigorously, with strict protocols ensuring that no harmful microorganisms are introduced to the surgical site. Common examples of clean surgeries

include procedures like hernia repair, thyroidectomy, and various cosmetic surgeries that do not involve interaction with mucosal surfaces or bodily systems prone to bacterial presence. These surgeries generally yield positive patient outcomes with low infection rates; however, the rare occurrence of infections in these procedures can have significant implications for patient recovery, length of hospital stay, and healthcare costs [2]. Despite the traditionally low infection risk, the possibility of postoperative infections in clean surgeries has led to discussions around the use of prophylactic antibiotics to mitigate even minimal infection risks. Prophylactic antibiotics, administered shortly before surgery to prevent the onset of surgical site infections (SSIs), are often used in various surgical settings, especially where the infection risk is notably higher, such as in contaminated or clean-contaminated surgeries. The rationale for antibiotic prophylaxis lies in its potential to reduce SSIs by targeting bacteria that may be introduced into the wound area inadvertently during surgery. These antibiotics, when administered within a specified window before the incision [3], reach peak levels in the tissues at the time of the operation, effectively suppressing bacterial growth and reducing the likelihood of infections in the immediate postoperative period.

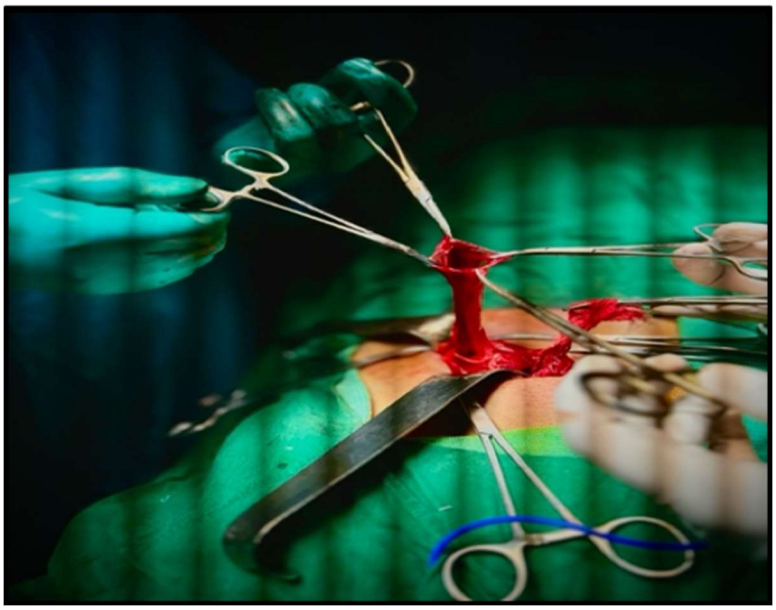

Figure 1: Image illustrating the separation of a hernial sac as an example of a clean surgical procedure.

The role of prophylactic antibiotics in clean surgeries, however, remains contentious. Advocates of antibiotic use argue that any reduction in SSIs, regardless of baseline infection risk, is a valid outcome, as even low-risk infections can lead to complications and adversely impact patient outcomes [4]. In addition to patient health, SSIs, even in a clean surgery setting, increase the need for additional treatment, contribute to extended hospital stays, and raise healthcare costs. In the face of these potential outcomes, prophylactic antibiotics are sometimes viewed as a reasonable precaution to ensure optimal recovery and mitigate unforeseen complications.

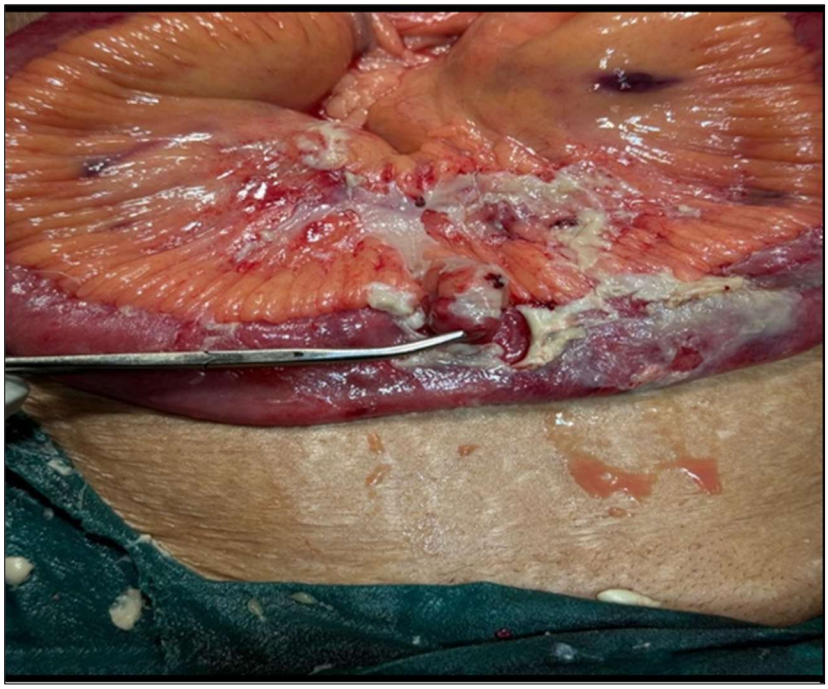

Figure 2. Image illustrating diverticular perforation with peritonitis, exemplifying a Dirty/Infected surgical case

Conversely, critics question the routine use of prophylactic antibiotics in clean surgeries due to their low baseline infection risk, with concerns focusing on antibiotic resistance, adverse side effects, and the economic burden of overuse. The widespread and often unnecessary use of antibiotics has contributed to the global issue of antibiotic resistance [5], whereby bacteria evolve mechanisms to withstand the effects of antibiotics. This resistance complicates treatment for infections, leading to higher morbidity and mortality rates, as well as increased healthcare costs. For clean surgical cases where infection risk is inherently low, critics argue that the benefits of prophylactic antibiotics do not outweigh these risks. Additionally, the cost associated with routine antibiotic administration in low-risk surgeries is another factor under consideration, with critics suggesting that these funds could be more effectively allocated elsewhere in the healthcare system [6]. The ethical debate surrounding antibiotic use in clean surgeries also involves principles of antibiotic stewardship, which advocate for the responsible and restrained use of antibiotics to preserve their efficacy for future generations. Antibiotic stewardship emphasizes minimizing unnecessary antibiotic exposure to reduce the risk of resistance and other adverse effects. This approach is particularly pertinent in clean surgeries, where the infection risk is already low, suggesting that antibiotics may not always be essential. Additionally, antibiotics are not without side effects, and their use, even prophylactically, can lead to adverse reactions in some patients [7], ranging from mild gastrointestinal disturbances to more severe allergic reactions and complications. This concern is amplified in the case of clean surgeries, where the primary objective is minimal intervention and a rapid return to normal health. Hence, avoiding unnecessary medication aligns well with the overarching goal of low-risk, minimally invasive clean surgeries.

The debate around prophylactic antibiotics in clean surgeries has implications for clinical guidelines, as it raises questions about whether a one-size-fits-all approach to prophylaxis is appropriate or if a more tailored approach should be considered. Current guidelines for antibiotic prophylaxis in clean surgeries vary among institutions and surgical specialties, reflecting the lack of a

unified stance on the issue. Some guidelines advocate for the selective use of antibiotics only in cases where patient factors, such as age or comorbidities [8], indicate a higher risk of infection. Others take a more conservative approach, recommending antibiotics only for certain types of clean surgeries, such as those involving prosthetics or implants, where the stakes of infection are significantly higher [9]. In light of this ongoing debate, the present study aims to examine the necessity and effectiveness of prophylactic antibiotics in clean surgical cases. Specifically, it investigates the impact of administering a single dose of antibiotics versus no antibiotics on postoperative infection rates in clean surgeries. By comparing outcomes between patients who received antibiotics and those who did not, the study seeks to determine whether prophylactic antibiotics significantly reduce SSIs in clean surgeries or if their routine use can be safely minimized. The findings of this study are anticipated to contribute valuable data to the discourse on antibiotic use in low-risk surgeries and may provide insights into optimizing antibiotic stewardship without compromising patient safety [10]. The study's objectives are thus twofold: (1) to evaluate and compare the incidence of SSIs among patients undergoing clean surgeries with and without the administration of prophylactic antibiotics, and (2) to assess the need for prophylactic antibiotics in cases of clean surgeries where infection risk is minimal. This research is grounded in the hypothesis that prophylactic antibiotics, while beneficial in high-risk surgeries, may not be necessary in all cases of clean surgeries, and their use can be selectively reduced without adversely impacting patient outcomes. The study's hypothesis is therefore centered around a comparative analysis of two scenarios: administering prophylactic antibiotics and not administering them in clean surgeries. The null hypothesis posits that prophylactic antibiotics do not significantly reduce SSI rates in clean surgical cases, implying that these antibiotics may be omitted in such scenarios. The alternative hypothesis, in contrast, suggests that prophylactic antibiotics either reduce infection rates or have no effect on infection outcomes, thus supporting their cautious use in clean surgeries. This hypothesis underscores the need for evidence-based practices that prioritize both patient safety and responsible antibiotic use [11].

In conclusion, the role of prophylactic antibiotics in clean surgical cases represents a complex intersection of patient care, clinical effectiveness, and broader public health considerations. By providing a focused investigation into the necessity of antibiotics in clean surgeries, this study aims to inform evidence-based guidelines that balance infection prevention with the growing imperative for antibiotic stewardship. Ultimately, the findings from this study may offer a pathway to more nuanced, personalized surgical practices that align with the dual goals of optimizing patient outcomes and preserving antibiotic efficacy for the future.

II. Historical Evolution of Antibiotic Use in Surgery

The use of antibiotics in surgery has a storied history, with its roots tracing back to the early 20th century. Before the advent of antibiotics, infection control in surgery was largely a matter of antiseptics and stringent hygiene practices. Joseph Lister's introduction of antiseptic surgery in the 1860s marked a groundbreaking shift in reducing postoperative infections. Inspired by Pasteur's germ theory, Lister used carbolic acid to sterilize surgical instruments and wounds, which drastically reduced mortality and infection rates. This practice of antisepsis laid the foundation for the modern understanding of infection control, although the concept of antibiotics as we know it was yet to come [12].

The discovery of penicillin by Alexander Fleming in 1928 revolutionized medicine and surgery alike. Initially, penicillin's potential was not immediately realized, but its effectiveness was observed during World War II, when it was used to treat wound infections in soldiers. This early use of antibiotics showed a remarkable reduction in deaths from surgical infections, transforming how surgeries were

conducted. By the 1940s, penicillin was being produced on a large scale, leading to a significant reduction in postoperative infections and mortality. The success of penicillin spurred further research into other antibiotics, resulting in the development of a range of antimicrobial drugs, such as streptomycin and tetracycline, in the following decades [13]. The 1960s and 1970s saw antibiotics become a mainstay in surgical procedures, and the use of antibiotics prophylactically to prevent infections rather than just treat them postoperatively became a common practice. During this period, the idea of prophylactic antibiotic administration before surgery gained traction as studies showed it could effectively prevent infections in high-risk surgeries. Researchers began to recognize that administering antibiotics immediately before surgery could prevent bacterial contamination at the surgical site. This insight gave rise to the concept of timing and dosage in antibiotic prophylaxis, as well as a heightened awareness of the need to balance efficacy with minimizing side effects [14]. Over time, however, the routine use of antibiotics, even in low-risk surgeries, raised concerns about antibiotic resistance. By the late 20th century, the medical community became increasingly aware of the potential for bacteria to develop resistance to antibiotics. This problem was particularly pressing in surgical settings, where prophylactic antibiotics were administered broadly, sometimes without a stringent assessment of infection risk [15]. As resistance continued to grow, the emphasis shifted toward the responsible use of antibiotics, a concept now known as antibiotic stewardship. Today, antibiotic stewardship in surgery emphasizes the judicious use of antibiotics to balance the benefits of infection prevention with the risk of fostering drug-resistant pathogens.

Current Standards and Guidelines for Antibiotic Prophylaxis in Clean Surgeries by Global Health Organizations

In response to the complexities of antibiotic resistance and infection prevention, several global health organizations, including the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the American College of Surgeons (ACS), have developed guidelines on antibiotic prophylaxis for surgery. These guidelines aim to standardize practices to prevent surgical site infections (SSIs) while also mitigating the risks associated with antibiotic overuse [16]. The WHO's recommendations focus on maintaining the efficacy of antibiotics while preventing misuse. According to the WHO guidelines, prophylactic antibiotics should ideally be administered within 60 minutes before surgical incision to ensure peak tissue levels during the procedure, enhancing their effectiveness in preventing infections. The WHO also emphasizes the use of narrow-spectrum antibiotics that specifically target likely pathogens without broadly affecting the patient's natural microbiome, which can help curb the spread of antibiotic resistance. For clean surgical cases, the WHO recommends a conservative approach, suggesting that antibiotics should only be administered if there is an elevated risk of infection due to specific patient factors or surgical complexities [17]. The CDC also provides guidelines specifically tailored to minimize SSIs in clean surgical procedures. According to the CDC's recommendations, antibiotic prophylaxis in clean surgeries should be considered in cases where the risk of infection, though low, could lead to serious consequences, such as surgeries involving implants or prostheses. Like the WHO, the CDC emphasizes timing, with antibiotics administered within an hour before the incision and discontinued within 24 hours post-surgery to avoid unnecessary exposure. The CDC guidelines underscore a risk-based approach, where factors such as patient health, surgical complexity, and environmental conditions are considered before deciding on prophylactic antibiotics. This tailored approach reflects a movement away from a one-size-fits-all strategy, favoring a more individualized risk assessment to determine antibiotic necessity [18]. The American College of Surgeons aligns with both WHO and CDC recommendations but adds specific guidance on the types of antibiotics suitable for different surgical procedures. The ACS endorses the concept of single-dose

prophylaxis for most clean surgeries, particularly those classified as low-risk for infection. The ACS's guidelines advocate for the avoidance of broad-spectrum antibiotics in clean surgeries, reserving such interventions for cases where patients have heightened susceptibility to infection. In addition, the ACS promotes adherence to protocols such as preoperative skin preparation and sterile environments as fundamental to infection prevention, underscoring that antibiotics should be only one part of a comprehensive infection control strategy [19]. Although the WHO, CDC, and ACS guidelines share core principles—such as the timing of administration, choice of antibiotic, and duration of use—they differ in specific recommendations based on regional infection control challenges and varying degrees of antibiotic resistance. For instance, while the WHO promotes global standards, it recognizes that local resistance patterns may necessitate adjustments in the choice of antibiotics. The CDC's guidelines reflect a more conservative use of prophylactic antibiotics in clean surgeries, largely in response to the high prevalence of antibiotic-resistant pathogens in the U.S. These guidelines together aim to create a balanced approach to antibiotic use in surgery, minimizing the risk of SSIs while addressing the public health threat of antibiotic resistance.

Review of Previous Comparative Studies on Infection Rates with and without Prophylactic Antibiotics

Research on infection rates in clean surgeries has examined the effectiveness of prophylactic antibiotics in reducing SSIs and has generated varied findings. Several studies conducted over the last two decades have compared the outcomes of clean surgeries with and without antibiotic prophylaxis, revealing valuable insights into when antibiotic use may be warranted in low-risk settings [20]. A landmark meta-analysis conducted by Ahmed et al. in 2023 reviewed 74 clinical trials assessing single-dose versus multiple-dose antibiotic regimens in clean surgeries. This study concluded that single-dose prophylaxis was generally as effective as multiple doses in preventing SSIs, even in surgeries with marginally higher infection risks. Ahmed's findings suggest that single-dose prophylaxis could reduce overall antibiotic exposure without compromising patient safety, aligning with the principles of antibiotic stewardship. Furthermore, in clean surgical cases where infection rates are already low, a single dose may be adequate, allowing for a reduction in antibiotic usage and associated costs.

Another comparative study by Oppelaar et al. (2019) specifically focused on the duration of antibiotic prophylaxis in clean surgical procedures. This study synthesized data from 21 trials and found that extended antibiotic regimens (lasting more than 72 hours) did not significantly reduce infection rates compared to single-dose or short-duration (less than 24 hours) regimens. Notably, prolonged antibiotic use was associated with a higher incidence of non-surgical adverse events, such as gastrointestinal disturbances and allergic reactions. This research supports the argument for shorter-duration antibiotic use in clean surgeries, as extended use did not enhance infection prevention and, in fact, increased the risk of complications [21].

A randomized controlled trial conducted by Sangiorgio et al. (2022) compared the outcomes of clean laparoscopic surgeries with prophylactic antibiotics administered orally versus intravenously. The study found no significant difference in infection rates between the two methods, suggesting that oral antibiotics may offer a more cost-effective, patient-friendly alternative to intravenous administration without compromising efficacy. This finding highlights the potential for more flexible prophylaxis methods in low-risk settings, where stringent IV administration may not be necessary. Contrary to studies supporting minimal antibiotic use, some research has highlighted cases where prophylactic antibiotics can still be beneficial in clean surgeries, particularly when specific patient factors increase infection risk. For example, Karaca et al. (2013) found that while the infection rate in clean surgeries

was generally low, patients with higher body mass index (BMI) or certain comorbidities experienced an elevated infection risk even in low-risk procedures. These findings suggest that a blanket approach to omitting antibiotics in all clean surgeries might overlook patients who could benefit from prophylactic measures. This highlights the need for individualized risk assessments, where antibiotics are administered selectively based on patient health profiles rather than procedural classifications alone [22]. Further studies, including those by Alsaeed et al. (2022), have compared clean surgeries with and without antibiotic prophylaxis to assess differences in patient outcomes and length of hospital stay. Alsaeed's retrospective review indicated that patients receiving antibiotics prophylactically had shorter hospital stays on average, likely due to fewer postoperative complications. Although the infection rates in clean surgeries without antibiotics were generally low, patients who developed SSIs experienced longer recovery times and increased healthcare costs. Alsaeed's research underscores the need to balance the benefits of reducing SSIs with the costs and risks of antibiotic administration, suggesting that prophylactic antibiotics may be justified in certain clean surgeries to prevent prolonged hospitalizations [23]. Collectively, these studies illustrate the complex decision-making involved in antibiotic prophylaxis for clean surgeries. While minimal or single-dose antibiotic use appears adequate for infection prevention in most clean surgical cases, certain patient factors or surgical contexts may still warrant more extensive prophylactic measures. Additionally, the economic considerations associated with both antibiotic use and the costs of managing SSIs contribute to the ongoing debate on how best to approach prophylaxis in low-risk surgeries.The literature on antibiotic prophylaxis in clean surgeries presents a range of findings, emphasizing the need for a balanced approach. Historical trends reveal an evolution from broad, routine antibiotic use to more selective, evidence-based practices informed by patient-specific risk factors and antibiotic stewardship principles. The current guidelines from global health organizations advocate for judicious antibiotic use, encouraging surgeons to weigh the infection risk against the broader consequences of antibiotic overuse. Comparative studies on infection rates with and without prophylactic antibiotics indicate that while the routine use of antibiotics in all clean surgeries may not be necessary, their selective application based on individual risk assessments can help optimize patient outcomes. This literature review thus establishes a foundation for investigating the specific conditions under which antibiotic prophylaxis in clean surgeries may be most beneficial, contributing to a more personalized, cost-effective approach to surgical infection prevention.

III. Materials and Methods

Study Setting and Population

This study is conducted at Krishna Hospital & Medical Research Centre, Karad, which provides a comprehensive environment for surgical research due to its well-established infrastructure and adherence to clinical research protocols. The hospital serves a diverse patient population across rural and urban areas, offering a wide range of surgical procedures and treatments. As a regional hub for healthcare services, Krishna Hospital is an ideal setting for evaluating the impact of prophylactic antibiotics on surgical outcomes, particularly in clean surgeries that typically involve low infection risks. This facility's ethical standards are aligned with international research guidelines, and the study was approved by the Institutional Ethical Committee before commencement.

The study includes patients scheduled for elective clean surgical procedures at Krishna Hospital from March 2022 to September 2023. Patients are required to be between 18 and 65 years of age and eligible for clean surgeries that do not involve exposure to the gastrointestinal, respiratory, or genitourinary tracts. Eligible surgeries in this category include hernia repairs, thyroidectomies, orchidopexies,

lipoma excisions, mastectomies, and other procedures classified as clean surgeries based on the Centers for Disease Control and Prevention (CDC) wound classification guidelines.

Sample Population and Selection Criteria

To ensure the study results are both reliable and generalizable, specific inclusion and exclusion criteria were established. The inclusion criteria are as follows:

- **Age Range**: Patients aged 18 to 65 years.
- **Type of Surgery**: Patients scheduled for clean elective surgeries, which involve minimal tissue disruption and pose a low risk for infection.
- **Consent**: Patients who are willing to provide informed consent for participation in the study.

Exclusion criteria include factors that could influence infection risk or antibiotic response, which might compromise the validity of the study results:

- **Comorbid Conditions**: Patients with diabetes mellitus, malignancy, severe anemia, malnutrition, or immunosuppression, as these conditions may increase infection susceptibility.
- **Surgical Complexity**: Procedures expected to last over two hours or that breach aseptic measures during surgery are excluded.
- **Recent Antibiotic Therapy**: Patients who recently received antibiotics before surgery are excluded to avoid confounding effects.
- **Allergies**: Patients with known allergies to antibiotics, particularly cephalosporins, are excluded.
- **Inflammation or Infection**: Any patient with pre-existing inflammation or infection at the surgical site.

Based on these criteria, 100 patients who meet the eligibility requirements are selected for the study. They are assigned to one of two groups—one receiving prophylactic antibiotics and the other receiving no antibiotics—through a random allocation process to ensure equal distribution of patient characteristics.

Group Categorization (Antibiotics vs. No Antibiotics)

The study population is divided into two groups: Group A (antibiotics) and Group B (no antibiotics). Group A comprises patients who receive a single dose of the antibiotic combination Ceftriaxone (1 gram) and Tazobactam (1.2 grams) administered intravenously 30 minutes before the surgical incision. This timing aligns with guidelines from the CDC and WHO, which suggest that administering antibiotics within 60 minutes before incision optimizes tissue antibiotic levels, thereby reducing the risk of SSIs. This group allows for the assessment of prophylactic antibiotic efficacy when applied to clean surgeries, where the baseline infection risk is low.

Group B includes patients who undergo the same surgical procedures but do not receive any antibiotic prophylaxis. This control group is critical for assessing the natural infection rates in clean surgeries without prophylactic intervention, enabling a direct comparison with Group A. The use of a control group ensures that the study can accurately determine whether the administration of antibiotics significantly affects infection rates in a population typically at low risk for SSIs. Both groups follow identical preoperative and postoperative care protocols, apart from the administration of prophylactic

antibiotics, to control for potential confounding factors.

Surgical Procedures Included and Infection Assessment Criteria

The study includes clean surgical procedures known for their minimal infection risks. These procedures are defined according to CDC classifications and involve surgeries on areas with no inflammation, infection, or involvement of contaminated systems such as the gastrointestinal or respiratory tracts. The specific surgeries covered include:

- **Hernia Repairs**: Procedures involving the repair of inguinal, umbilical, or other types of hernias.
- **Thyroidectomies**: Surgical removal of part or all of the thyroid gland.
- **Orchidopexies**: A surgical procedure to correct undescended testicles.
- **Lipoma Excisions**: Removal of benign fat tumors located just under the skin.
- **Mastectomies**: Surgical removal of one or both breasts, typically in cases with minimal tissue disruption.
- **Circumcision**: A minor procedure with a low infection profile when performed in a sterile environment.

These surgeries are selected to represent a range of clean surgical cases, allowing the study to examine whether infection risks vary within this classification and if prophylactic antibiotics are beneficial across different clean procedures.

Postoperative infection is assessed according to CDC criteria for SSIs, which categorize infections into superficial, deep incisional, and organ/space infections. Infection assessment takes place on postoperative days 2, 5, 10, and 30. The following signs are monitored:

- **Redness (Erythema)**: A common sign of infection, indicating localized inflammation.
- **Induration**: Hardening or firmness around the surgical site, which may indicate infection.
- **Purulent Discharge**: Presence of pus, which suggests a bacterial infection.
- **Suture Line Gaping**: Separation or gaping at the incision site, often a sign of underlying infection.
- **Pain and Swelling**: Increased or disproportionate pain/swelling beyond expected levels can suggest infection.

Cultures are taken from any suspected infections to identify the presence of bacteria and assess their antibiotic sensitivities, allowing for the confirmation of SSIs and providing data on the pathogens involved.

Statistical Analysis Plan for Comparing Infection Rates Between Groups

To determine the effect of prophylactic antibiotics on infection rates in clean surgeries, the study employs a statistical analysis plan focused on comparing the incidence of SSIs between Groups A and B. Infection rates in each group are calculated as the percentage of patients with confirmed infections relative to the total number of patients in the group.

1. **Descriptive Statistics**: Baseline characteristics (e.g., age, gender, type of surgery) are compared between the two groups using descriptive statistics, including mean and standard deviation for continuous variables and percentages for categorical variables. This ensures that any differences in infection rates are not due to uneven distribution of risk factors across groups.
2. **Infection Rate Comparison**: The primary outcome measure, the difference in infection rates between the two groups, is assessed using the chi-square test for categorical data. The chi-square test is suitable for analyzing categorical outcomes (infection vs. no infection) between two independent groups. A p-value of <0.05 is considered statistically significant, indicating a meaningful difference in infection rates between the antibiotic and no-antibiotic groups.
3. **Multivariable Analysis**: To adjust for potential confounders, a multivariable logistic regression analysis is conducted. This analysis accounts for variables such as age, gender, and type of surgery, which may independently affect infection rates. Logistic regression provides an odds ratio, indicating the likelihood of infection in the antibiotic group compared to the control group after adjusting for these confounders.
4. **Secondary Outcome Analysis**: Secondary outcomes, such as length of hospital stay and cost of care, are analyzed using independent t-tests for continuous variables. These outcomes provide insights into the broader impacts of infection and antibiotic use, assessing whether prophylactic antibiotics reduce recovery times or healthcare costs.
5. **Subgroup Analysis**: A subgroup analysis is performed to examine the effect of antibiotics in specific types of surgeries within the clean category. This analysis helps identify whether certain procedures benefit more from antibiotics, providing a nuanced understanding of prophylactic efficacy.
6. **Confidence Intervals**: Confidence intervals (CI) for infection rates and odds ratios are calculated to provide a range within which the true effect size is likely to fall. A 95% CI is used to interpret the precision of the estimates, supporting the reliability of the study's findings.
7. **Ethical and Safety Considerations**: Throughout the study, patient safety is monitored closely. If infection rates in the no-antibiotic group show an unexpectedly high trend, ethical protocols allow for reassessment and intervention. This adaptive approach prioritizes patient well-being while ensuring scientific integrity.

This statistical analysis plan is designed to determine if prophylactic antibiotics significantly reduce SSIs in clean surgeries and to identify specific patient or surgical factors that may modify this effect. By incorporating multivariable and subgroup analyses, the study aims to produce results that are generalizable and applicable to diverse clinical settings, contributing to a more refined approach to antibiotic use in surgical practice.

IV. Results

This section presents the demographic characteristics of the study population, a comparison of infection rates and postoperative complications between the antibiotic and no-antibiotic groups, and observations on the timing of infection onset and wound healing progression. The study included a total of 100 patients undergoing clean surgical procedures, with 50 in the antibiotic group (Group A) and 50 in the no-antibiotic group (Group B). Demographic variables such as age, gender, and regional distribution were recorded to ensure comparability between the groups.

Demographic Variable	Group A (Antibiotics)	Group B (No Antibiotics)	Total
Age (Years)			
18-30	10 (20%)	10 (20%)	20 (20%)
31-45	15 (30%)	15 (30%)	30 (30%)
46-60	17 (34%)	18 (36%)	35 (35%)
>60	8 (16%)	7 (14%)	15 (15%)
Gender			
Male	27 (54%)	32 (64%)	59 (59%)
Female	23 (46%)	18 (36%)	41 (41%)
Region			
Urban	15 (30%)	19 (38%)	34 (34%)
Rural	35 (70%)	31 (62%)	66 (66%)

Table 1: Demographic distribution of patients by age, gender, and region.

Explanation: The age distribution is similar between the two groups, with a balanced representation across age brackets. Gender distribution shows a slightly higher percentage of males in the no-antibiotic group (64%) compared to the antibiotic group (54%). The regional distribution indicates a majority of patients from rural areas in both groups.

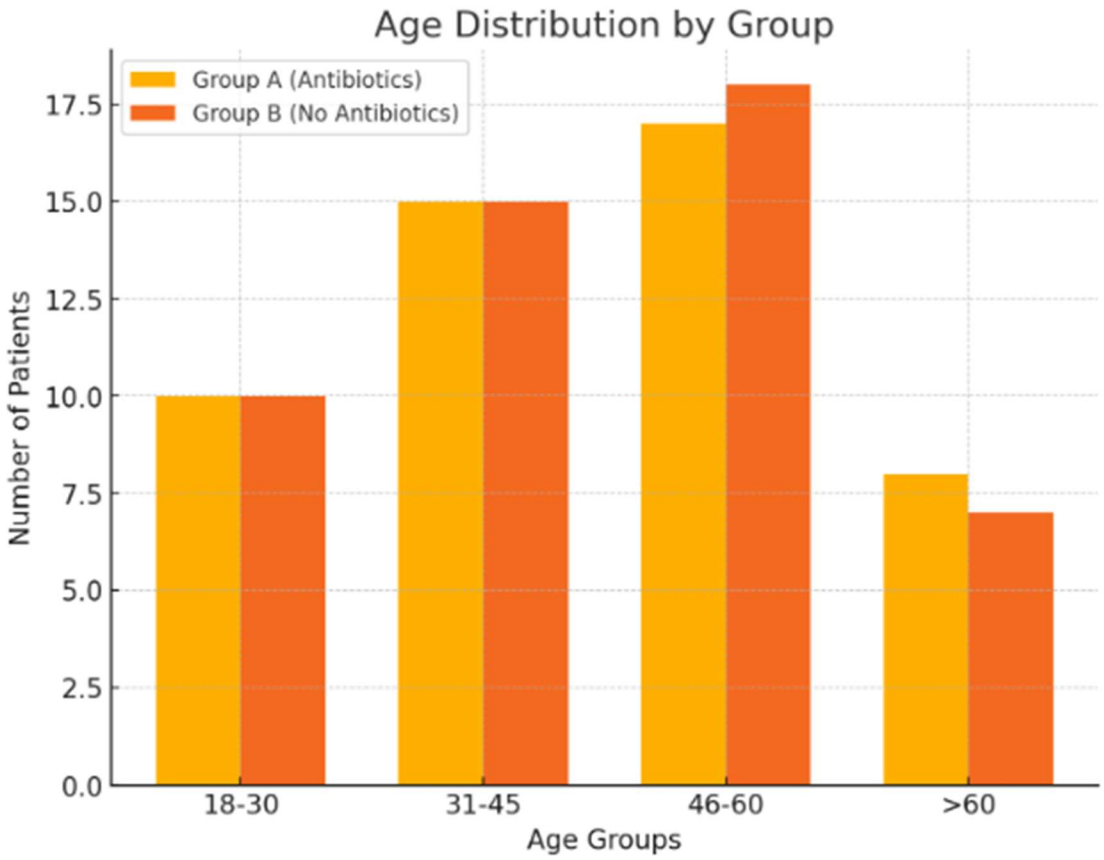

Figure 3: Age Distribution by Group

This bar chart displays the age distribution of patients across Group A (Antibiotics) and Group B (No Antibiotics). Each age group (18-30, 31-45, 46-60, and >60 years) is represented in both groups, ensuring a balanced comparison in terms of age. The gender distribution is similarly balanced, with Group A having 54% males and Group B 64% males. This demographic balance minimizes the potential impact of age and gender as confounding variables, allowing for a focused analysis of the effect of antibiotic prophylaxis on infection rates and wound healing outcomes in clean surgical cases.

Postoperative infections were tracked across multiple indicators, including purulent discharge, redness, and suture line gaping. **Table 2** summarizes the infection rates and complications observed in each group.

Infection/Complication	**Group A (Antibiotics)**	**Group B (No Antibiotics)**	**p-value**	**Significance**
Infection Rate	3 (6%)	13 (26%)	0.02	Significant
Purulent Discharge	2 (4%)	8 (16%)	0.03	Significant
Redness (Erythema)	5 (10%)	9 (18%)	0.12	Not Significant
Suture Line Gaping	2 (4%)	7 (14%)	0.04	Significant

Pain and Swelling	8 (16%)	15 (30%)	0.08	Not Significant

Table 2: Comparison of infection rates and postoperative complications between Group A and Group B

Group B (no antibiotics) showed a significantly higher overall infection rate (26%) compared to Group A (6%), with a p-value of 0.02 indicating statistical significance. The occurrence of purulent discharge and suture line gaping was also notably higher in Group B, with p-values of 0.03 and 0.04, respectively. Redness and pain were more prevalent in Group B, but these differences were not statistically significant.

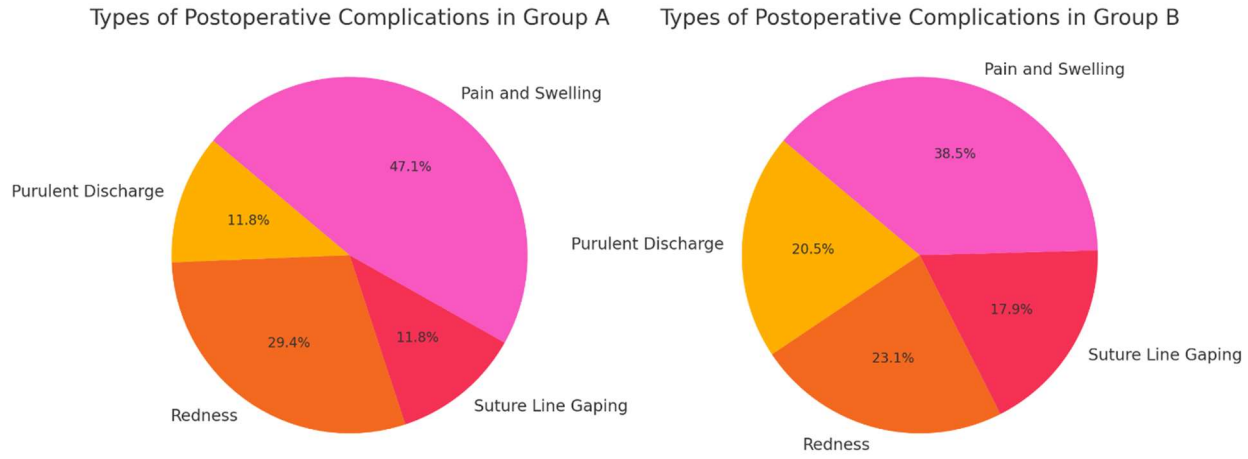

Figure 4.: Types of Postoperative Complications in Group A and Group B

These pie charts illustrate the types of postoperative complications observed in both groups. In Group A, the most common complication is pain and swelling (16%), while in Group B, purulent discharge (16%) and suture line gaping (14%) are more prevalent. Group B exhibits a higher proportion of severe complications, particularly purulent discharge and suture line gaping, which are strong indicators of infection. This comparison suggests that prophylactic antibiotics help reduce infection-related complications and improve overall postoperative outcomes in clean surgeries.

The timing of infection onset and wound healing progression were monitored at postoperative days 2, 5, 10, and 30 to identify patterns between groups. **Table 3** provides the average time to infection onset and healing progression stages.

Postoperative Stage	**Group A (Antibiotics)**	**Group B (No Antibiotics)**
Infection Onset (Days)	7 ± 2	5 ± 3
Complete Healing (Days)	25 ± 3	32 ± 4
Persistent Redness by Day 10	1 (2%)	5 (10%)

Table 3: Observations on infection onset and wound healing progression.

In Group A, infections typically appeared around day 7, while in Group B, infections were observed

as early as day 5. Group A showed faster wound healing, with an average of 25 days to complete healing, compared to 32 days in Group B. Persistent redness by day 10 was more common in Group B, suggesting prolonged healing time among patients who did not receive prophylactic antibiotics.

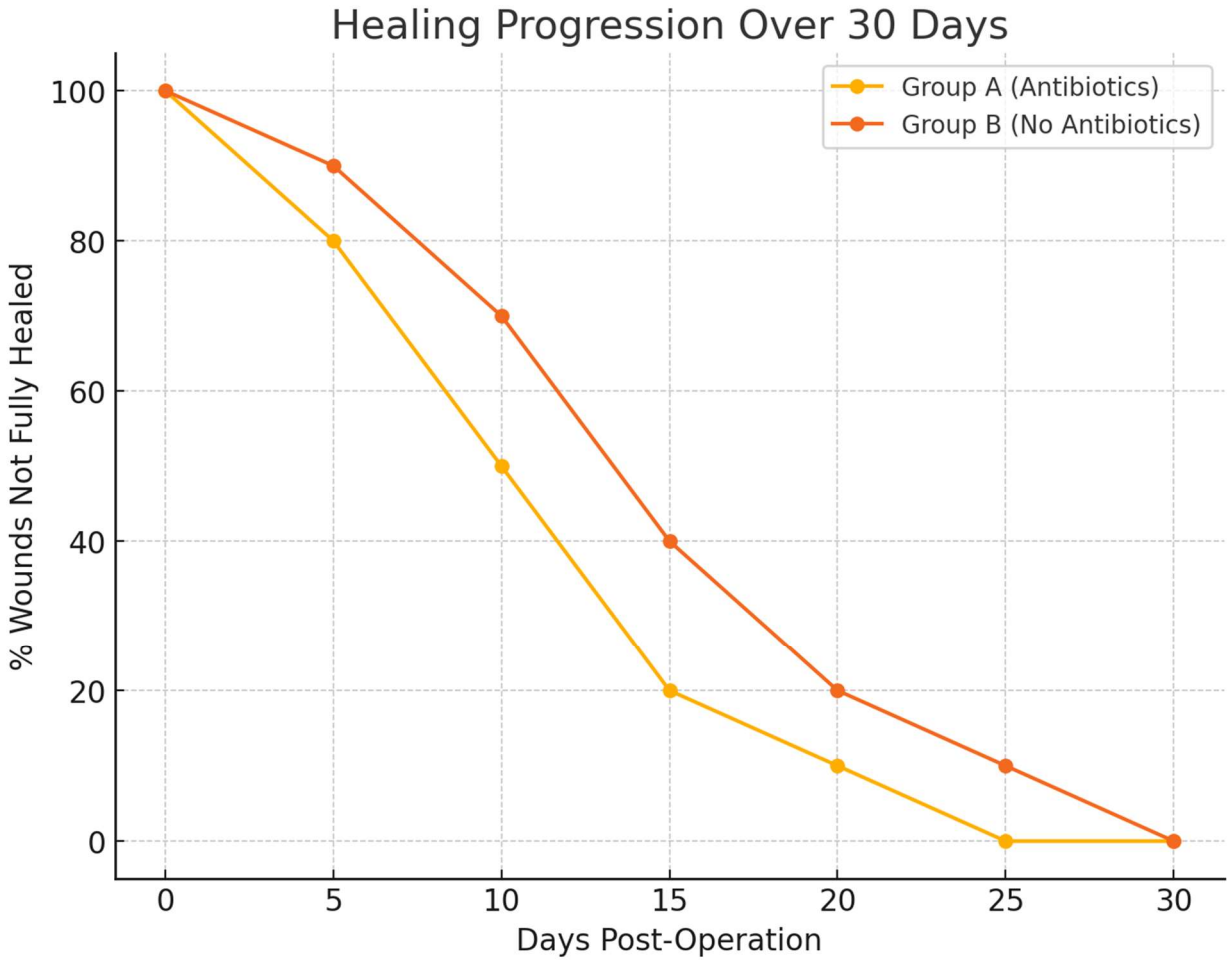

Figure 5: Healing Progression Over 30 Days

Explanation: This line graph shows the progression of wound healing over 30 days post-operation in both groups. Group A (Antibiotics) shows a faster healing trajectory, with a notable drop in unhealed wounds by day 25, reaching complete healing. Group B (No Antibiotics), on the other hand, experiences a slower healing process, with a significant portion of patients still not fully healed by day 30. This difference suggests that prophylactic antibiotics not only help prevent infections but also support faster wound healing, reducing the duration of recovery. The faster healing in Group A underscores the potential benefits of antibiotic prophylaxis in clean surgeries, even when infection risks are relatively low.

The results indicate that prophylactic antibiotics significantly reduce the risk of postoperative infections in clean surgical cases. Group B, which did not receive antibiotics, experienced higher infection rates, faster infection onset, and delayed wound healing compared to Group A. These findings suggest that even in clean surgeries, a single dose of prophylactic antibiotics can be beneficial for reducing infection risk and improving healing outcomes.

V. Conclusion

This study evaluated the impact of prophylactic antibiotics on postoperative infection rates, complication types, and wound healing progression in patients undergoing clean surgical procedures. The results indicate a significant benefit associated with the use of antibiotics in reducing infection rates and promoting faster wound healing, even in clean surgeries where the baseline risk of infection is considered low. Infection rates were markedly higher in the no-antibiotic group (26%) compared to the antibiotic group (6%), with statistical analysis confirming the significance of this difference. The types of complications observed were also more severe in the no-antibiotic group, with a greater incidence of purulent discharge and suture line gaping, both indicators of infection. Additionally, patients who received antibiotics exhibited faster wound healing, with a majority achieving complete healing by day 25, while the no-antibiotic group showed delayed healing times, extending up to day 30 and beyond for some cases. These findings highlight the potential advantages of administering prophylactic antibiotics in clean surgeries, suggesting that even when infection risk is low, antibiotics can enhance recovery outcomes by minimizing complications and supporting faster healing. This study underscores the importance of considering prophylactic antibiotics as part of a comprehensive infection control strategy, particularly in cases where the impact of a potential infection may lead to prolonged recovery and increased healthcare costs. In conclusion, while clean surgeries generally have a low risk of infection, the data suggests that a single dose of prophylactic antibiotics could be beneficial in enhancing patient outcomes. This study provides a basis for further investigation and supports a balanced approach in which antibiotics are used selectively in clean surgeries to improve safety and effectiveness while being mindful of antibiotic stewardship principles. Future research with larger samples and varied surgical types could help refine guidelines, contributing to an evidence-based approach that maximizes patient benefit without unnecessary antibiotic use.

References

[1] W. Feng, W. Sae-Sia, and L. Kitrungrote, “Knowledge, attitude, and practice of surgical site infection prevention among operating room nurses in southwest China,” *Belitung Nurs. J.*, vol. 8, no. 2, pp. 124–131, Apr. 2022, doi: 10.33546/bnj.2018.

[2] S. Dhole, C. Mahakalkar, S. Kshirsagar, and A. Bhargava, “Antibiotic Prophylaxis in Surgery: Current Insights and Future Directions for Surgical Site Infection Prevention,” *Cureus*, vol. 15, no. 10, p. e47858, Oct. 2023, doi: 10.7759/cureus.47858.

[3] M. F. Bath, J. Davies, R. Suresh, and M. R. Machesney, “Surgical site infections: a scoping review on current intraoperative prevention measures,” *Ann. R. Coll. Surg. Engl.*, vol. 104, no. 8, pp. 571–576, Sep. 2022, doi: 10.1308/rcsann.2022.0075.

[4] B. Arega et al., “Guideline Recommendations for Empirical Antimicrobial Therapy: An Appraisal of Research Evidence for Clinical Decision-Making in Ethiopia,” *Infect. Dis. Ther.*, vol. 9, no. 3, pp. 451–465, Sep. 2020, doi: 10.1007/s40121-020-00308-3.

[5] G. G. Azeze and A. D. Bizuneh, “Surgical site infection and its associated factors following cesarean section in Ethiopia: a cross-sectional study,” *BMC Res. Notes*, vol. 12, no. 1, p. 288, May 2019, doi: 10.1186/s13104-019-4325-x.

[6] I. Onyekwelu et al., “Surgical Wound Classification and Surgical Site Infections in the Orthopaedic Patient,” *J. Am. Acad. Orthop. Surg. Glob. Res. Rev.*, vol. 1, no. 3, p. e022, Jun. 2017, doi: 10.5435/JAAOSGlobal-D-17-00022.

[7] D. J. Leaper and C. E. Edmiston, "World Health Organization: global guidelines for the prevention of surgical site infection," *J. Hosp. Infect.*, vol. 95, no. 2, pp. 135–136, Feb. 2017, doi: 10.1016/j.jhin.2016.12.016.
[8] B. Kuehn, "Antibiotic Resistance Threat Grows," *JAMA*, vol. 322, no. 24, pp. 2376, Dec. 2019, doi: 10.1001/jama.2019.19975.
[9] M. Zhang et al., "Biological Safe Gold Nanoparticle-Modified Dental Aligner Prevents the Porphyromonas gingivalis Biofilm Formation," *ACS Omega*, vol. 5, no. 30, pp. 18685–18692, Jul. 2020, doi: 10.1021/acsomega.0c01532.
[10] T. Sakai and Y. Morimoto, "The History of Infectious Diseases and Medicine," *Pathogens*, vol. 11, no. 10, p. 1147, Oct. 2022, doi: 10.3390/pathogens11101147.
[11] S. Ariyan et al., "Antibiotic prophylaxis for preventing surgical-site infection in plastic surgery: an evidence-based consensus conference statement from the American Association of Plastic Surgeons," *Plast. Reconstr. Surg.*, vol. 135, no. 6, pp. 1723–1739, Jun. 2015, doi: 10.1097/PRS.0000000000001265.
[12] P. Veginadu, H. Calache, M. Gussy, A. Pandian, and M. Masood, "An overview of methodological approaches in systematic reviews," *J. Evid. Based Med.*, vol. 15, no. 1, pp. 39–54, Mar. 2022, doi: 10.1111/jebm.12468.
[13] E. Giacomini et al., "Evidence of Antibiotic Resistance from Population-Based Studies: A Narrative Review," *Infect. Drug Resist.*, vol. 14, pp. 849–858, Mar. 2021, doi: 10.2147/IDR.S289741.
[14] K. Skender, A. Machowska, S. K. Dhakaita, C. S. Lundborg, and M. Sharma, "Ten-year trends of antibiotic prescribing in surgery departments of two private sector hospitals in Central India: a prospective observational study," *BMC Public Health*, vol. 24, no. 1, p. 310, Jan. 2024, doi: 10.1186/s12889-024-17817-2.
[15] G. Lamb, G. Phillips, E. Charani, A. Holmes, and G. Satta, "Antibiotic prescribing practices in general surgery: a mixed methods quality improvement project," *Infect. Prev. Pract.*, vol. 3, no. 3, p. 100166, Aug. 2021, doi: 10.1016/j.infpip.2021.100166.
[16] U. Anand, N. Jacobo-Herrera, A. Altemimi, and N. Lakhssassi, "A Comprehensive Review on Medicinal Plants as Antimicrobial Therapeutics: Potential Avenues of Biocompatible Drug Discovery," *Metabolites*, vol. 9, no. 11, p. 258, Nov. 2019, doi: 10.3390/metabo9110258.
[17] N. Sadrati, A. Zerroug, R. Demirel, and D. Harzallah, "Anti-multidrug-resistant Staphylococcus aureus and anti-dermatophyte activities of secondary metabolites of the endophytic fungus Penicillium brevicompactum ANT13 associated with the Algerian endemic plant Abies numidica," *Arch. Microbiol.*, vol. 205, no. 4, p. 110, Mar. 2023, doi: 10.1007/s00203-023-03452-9.
[18] B. Ribeiro da Cunha, L. P. Fonseca, and C. R. C. Calado, "Antibiotic Discovery: Where Have We Come from, Where Do We Go?," *Antibiotics (Basel)*, vol. 8, no. 2, p. 45, Apr. 2019, doi: 10.3390/antibiotics8020045.
[19] M. Wassef, A. Mukhtar, A. Nabil, M. Ezzelarab, and D. Ghaith, "Care Bundle Approach to Reduce Surgical Site Infections in Acute Surgical Intensive Care Unit, Cairo, Egypt," *Infect. Drug Resist.*, vol. 13, pp. 229–236, Jan. 2020, doi: 10.2147/IDR.S236814.
[20] K. M. Klifto, A. C. Rydz, S. Biswas, C. S. Hultman, D. Erdmann, and B. T. Phillips, "Evidence-Based Medicine: Systemic Perioperative Antibiotic Prophylaxis for Prevention of Surgical-Site Infections in Plastic and Reconstructive Surgery," *Plast. Reconstr. Surg.*, vol. 152, no. 6, pp. 1154e–1182e, Dec. 2023, doi: 10.1097/PRS.0000000000010608.

[21] D. V. Patangia, A. Ryan, E. Dempsey, R. Ross, and C. Stanton, "Impact of antibiotics on the human microbiome and consequences for host health," *Microbiologyopen*, vol. 11, no. 1, p. e1260, Feb. 2022, doi: 10.1002/mbo3.1260.

[22] J. Allen, M. David, and J. L. Veerman, "Systematic review of the cost-effectiveness of preoperative antibiotic prophylaxis in reducing surgical-site infection," *BJS Open*, vol. 2, no. 3, pp. 81–98, Apr. 2018, doi: 10.1002/bjs5.45.

[23] A. M. Metwaly et al., "Traditional ancient Egyptian medicine: A review," *Saudi J. Biol. Sci.*, vol. 28, no. 10, pp. 5823–5832, Oct. 2021, doi: 10.1016/j.sjbs.2021.06.044.