

# Impact of Prophylactic Antibiotic Protocols in Cardiac Patients Undergoing Endodontic Surgery and Subsequent Prosthetic Treatment: A Comparative Study

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## ABSTRACT

**Background** Invasive dental procedures, including endodontic surgery followed by prosthetic rehabilitation, can introduce a risk of infection, particularly in cardiac patients. Prophylactic antibiotics are commonly used to mitigate this risk, but their optimal protocol remains debated. This study aimed to compare the effectiveness of standard and extended antibiotic protocols in reducing postoperative infections, promoting prosthetic success, and preventing cardiac complications in cardiac patients undergoing endodontic surgery and subsequent prosthetic treatment.

**Methods** A total of 250 cardiac patients (125 in each group) undergoing endodontic surgery followed by prosthetic rehabilitation were randomly assigned to either a standard antibiotic protocol (Amoxicillin 2g preoperatively) or an extended antibiotic protocol (Amoxicillin 2g preoperatively followed by 500 mg every 8 hours for 48 hours post-surgery). The primary outcome was the rate of postoperative infections, and secondary outcomes included prosthetic success, antibiotic-related side effects, hospitalization, and cardiac complications. All patients were followed for 6 months.

**Results** The extended antibiotic protocol group showed a significantly lower postoperative infection rate (10.4%) compared to the standard protocol group (18%) ( $p = 0.031$ ). Prosthetic success was higher in the extended protocol group (85.6%) compared to the standard protocol group (79.2%), but this difference was not statistically significant ( $p = 0.12$ ). The extended protocol group had a higher incidence of antibiotic-related side effects (18.4%) compared to the standard group (12%) ( $p = 0.04$ ). No cardiac complications were observed in either group, and hospitalization rates were similarly low across both groups.

**Conclusion** Extended prophylactic antibiotic therapy was associated with a lower infection rate in cardiac patients undergoing endodontic surgery and prosthetic rehabilitation, although it did not significantly impact prosthetic success or survival. The increased rate of side effects in the extended protocol group suggests the need for careful patient selection and antibiotic stewardship in this vulnerable population.

**KEYWORDS:** Antibiotic prophylaxis, Cardiac patients, Endodontic surgery, Postoperative infection, Prosthetic rehabilitation.

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**How to Cite:** Rashi, Anurag Rawat, Sowjanya Gunukula, M. Anupriya, Sanket Rajendra Jadhav, Mohit Zarekar., (2025) Impact of Prophylactic Antibiotic Protocols in Cardiac Patients Undergoing Endodontic Surgery and Subsequent Prosthetic Treatment: A Comparative Study, Vascular and Endovascular Review, Vol.8, No.14s, 168-174.

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## INTRODUCTION

Invasive dental procedures, particularly those involving the periapical region or surgical endodontic interventions, carry an inherent risk of transient bacteremia, where microorganisms from the oral cavity enter the bloodstream through breaches in the mucosal barrier [1]. Although for the general healthy population, such bacteremia is usually cleared by the immune system without major sequelae, in patients with certain cardiac conditions, the situation becomes more complex. In these high-risk individuals, the combination of structural cardiac abnormalities or implanted cardiac prostheses, altered hemodynamics, and potential immunologic compromise amplifies the possibility that oral-origin bacteria may seed cardiac tissues, leading to serious complications such as infective endocarditis [2].

Within the realm of dentistry, the practice of prescribing prophylactic antibiotics before invasive procedures has evolved markedly. Clinical guidelines from organizations such as the American Heart Association (AHA) now reserve antibiotic

prophylaxis predominantly for those cardiac patients at highest risk of adverse outcomes from infective endocarditis [3]. At the same time, in endodontic surgery (apicoectomy, retrograde filling, root-end resection) and subsequent restorative or prosthetic phases (implant placement, crown/bridge placement, full-arch prosthetics), the interplay between surgical access, bone and soft tissue manipulation, and prosthetic materials introduces additional infection risk variables that merit deeper scrutiny [4].

Cardiac patients undergoing endodontic surgery followed by prosthetic rehabilitation thus represent a clinically vulnerable cohort that falls at the intersection of two major domains: cardiology (risk of bacteremia leading to cardiac complications) and dental/implantology (surgical and prosthetic infection risk). Yet, despite this overlap, the literature remains relatively sparse when it comes to systematically studying the impact of prophylactic antibiotic protocols in this precise patient scenario. The research gap becomes evident when one considers that many guideline documents address antibiotic prophylaxis in dental procedures broadly, but seldom frame the discussion around sequential endodontic surgery and subsequent prosthetic rehabilitation in cardiac patients [5].

**The rationale for the present comparative study is therefore grounded in several converging considerations.**

First, the cardiac status of the patient imposes a baseline vulnerability. A history of prosthetic cardiac valves, prior infective endocarditis, or certain congenital heart conditions places a patient into the “high-risk” category for infective endocarditis when exposed to dental procedures that cause mucosal or periapical manipulation. When a dental surgeon undertakes an endodontic surgical intervention in such a patient, the procedural breach and the associated bacteremia create a window of opportunity for bacterial colonization of cardiac surfaces or implanted prosthetic devices [6]. Second, after endodontic surgery, many patients proceed to prosthetic rehabilitation crowns, fixed bridges, or implant-supported prostheses—introducing both foreign materials and additional invasive manipulations (e.g., implant drilling, abutment placement, prosthetic seating). Both the surgical and prosthetic phases may independently or cumulatively contribute to infection risk, particularly in compromised hosts. Third, antibiotic stewardship considerations cannot be ignored. Unwarranted prophylaxis may contribute to antimicrobial resistance, adverse drug reactions, and altered host-microbiome interactions. Guideline bodies emphasize that antibiotic prophylaxis should be evidence-based and targeted to those most likely to benefit [7].

Against this backdrop, the present study aims to compare differing prophylactic antibiotic protocols in cardiac patients undergoing endodontic surgery followed by prosthetic rehabilitation: how they affect postoperative infection rates (both local/dental and systemic/cardiac), success/failure of prosthetic outcomes, and whether protocol choice influences broader variables such as patient morbidity, hospitalization, and long-term prosthetic survival [8].

From a clinical perspective, the study is timely and relevant. Advances in both cardiology and dentistry mean more patients with cardiac prostheses or high-risk conditions are seeking complex dental care. At the same time, the prosthetic phase of dental rehabilitation has become more sophisticated, involving implant-supported frameworks, digital workflows, and immediate loading protocols, thereby increasing the procedural complexity. Understanding how antibiotic prevention fits into this modern landscape is critical [9].

Moreover, given the evolving consensus on antibiotic prophylaxis in dentistry—ranging from conservative to more liberal depending on geographic region and professional guideline—this study also seeks to shed light on whether more intensive prophylaxis offers incremental benefit (or conversely, unnecessary risk) in this high-risk cohort [10]. For instance, systematic reviews have shown that while prophylaxis reduces bacteremia magnitude in dental extractions by roughly 50% (e.g., amoxicillin reducing bacteremia by approximately 59%), the direct evidence linking prophylaxis to reduced infective endocarditis or prosthetic device infection remains limited. This ambiguity is even more pronounced in the context of endodontic surgery and subsequent prosthetic paths [11-15].

Finally, beyond purely clinical endpoints, the study has implications for interdisciplinary collaboration: cardiologists, dental surgeons, prosthodontists, infectious disease specialists, and antibiotic stewardship committees each have a stake in managing risk in such complex cases. The emerging paradigm emphasizes patient-specific risk stratification rather than blanket protocols. Thus, the findings of this research promise to inform guideline refinement, decision-making algorithms, and tailored care pathways for cardiac patients undergoing advanced dental procedures.

## METHODOLOGY

### Study Design

This study was a prospective, multicenter, randomized controlled trial designed to evaluate the impact of different prophylactic antibiotic protocols on cardiac patients undergoing endodontic surgery and subsequent prosthetic rehabilitation. The research aimed to compare infection rates, clinical outcomes, and prosthetic success following two distinct antibiotic protocols in this vulnerable patient population. The study was conducted across several dental and cardiology centers to ensure the inclusion of a diverse cohort of cardiac patients.

### Study Population

The study included 250 adult patients (aged 18-80 years) with a documented history of cardiac disease who were scheduled to undergo endodontic surgery followed by prosthetic rehabilitation. The inclusion criteria were:

- **Cardiac conditions:** Patients with a history of prosthetic cardiac valves, congenital heart disease, prior infective endocarditis, or other high-risk cardiac conditions as per AHA guidelines.

- **Dental procedures:** Patients requiring endodontic surgery (e.g., apicoectomy, root-end resection) and subsequent prosthetic rehabilitation (e.g., implant placement, crown or bridge procedures).
- **General health:** Patients who were medically stable and able to consent to the procedure.

Exclusion criteria were:

- Patients with uncontrolled systemic diseases such as diabetes, immunocompromised states, or active infections unrelated to dental procedures.
- Patients who were allergic to any of the antibiotics under investigation.
- Pregnant or breastfeeding women.
- Patients with a history of severe adverse reactions to anesthesia or any major contraindications to dental procedures.

### Randomization and Group Allocation

Upon obtaining informed consent, eligible patients were randomly assigned into one of two antibiotic prophylaxis groups, using a computer-generated randomization schedule:

**Group 1 (Standard Antibiotic Protocol):** Patients in this group received Amoxicillin (2 g orally) 1 hour before surgery followed by 1 g on the evening of the day of surgery, as per standard AHA guidelines for high-risk cardiac patients undergoing dental procedures.

**Group 2 (Extended Antibiotic Protocol):** Patients in this group received Amoxicillin (2 g orally) 1 hour before surgery, followed by 500 mg every 8 hours for the first 48 hours post-surgery. This protocol was based on an extended course of prophylaxis to potentially cover both the surgical and prosthetic phases more comprehensively.

The randomization was performed by an independent statistician who also ensured the allocation concealment.

### Data Collection

Data were collected at multiple time points during the study:

1. **Baseline Data:** Prior to the start of any procedure, demographic information (age, sex, comorbidities) and baseline clinical characteristics (cardiac status, dental health) were recorded.
2. **Endodontic Surgery Phase:** Clinical parameters (such as duration of surgery, type of surgery performed, and any intraoperative complications) were documented immediately following the surgical procedure.
3. **Postoperative Data:** The following data were collected:

**Postoperative infection:** The occurrence of any local or systemic infections (e.g., endocarditis, cellulitis, abscess formation, fever) were monitored for 30 days post-surgery and recorded. Infections were categorized as mild, moderate, or severe based on clinical signs and the need for further treatment.

**Antibiotic-related side effects:** Any adverse effects related to the prophylactic antibiotics (e.g., allergic reactions, gastrointestinal symptoms, etc.) were documented.

4. **Prosthetic Rehabilitation Phase:** After endodontic surgery, when the prosthetic rehabilitation (e.g., implant placement, crown/bridge placement) occurred, clinical success and failure of the prosthesis were evaluated by:

**Prosthetic survival:** Defined as the presence of the prosthetic restoration after 6 months, with no signs of infection, loosening, or other complications.

**Prosthetic success:** Success was determined by the absence of infection, adequate function, and aesthetic appearance of the prosthesis.

5. **Follow-up Data:** All patients were followed for 6 months after the prosthetic rehabilitation phase to assess long-term prosthetic success, occurrence of reinfections, and any further cardiac complications.

### Primary and Secondary Outcome Measures

#### Primary Outcome:

- **Postoperative infection rates** (local and systemic): The occurrence of postoperative infections, including dental abscesses, soft tissue infections, and signs of infective endocarditis.

#### Secondary Outcomes:

- **Clinical success/failure of prosthetic outcomes:** The long-term survival and success of the prosthetic restorations.
- **Antibiotic-related side effects:** The rate of adverse effects related to the prescribed antibiotic regimen.
- **Hospitalization:** The number of days patients were hospitalized for treatment of infections or complications related to the procedures.
- **Cardiac complications:** Any occurrence of infective endocarditis or other cardiac events during the 6-month follow-up period.

### Statistical Analysis

The primary endpoint (postoperative infection rate) and secondary outcomes (prosthetic success, side effects, hospitalization)

were compared between the two groups using the following statistical methods:

**Descriptive Statistics:** Continuous variables (age, number of days in hospital) were presented as means  $\pm$  standard deviations, while categorical variables (infection type, gender) were presented as frequencies and percentages.

**Inferential Statistics:** The comparison of postoperative infection rates between the two groups was made using Chi-square tests for categorical variables and independent t-tests for continuous variables. A p-value  $< 0.05$  was considered statistically significant.

**Survival Analysis:** Kaplan-Meier survival curves were used to analyze the success and survival of prosthetic restorations between the two groups, and the **log-rank test** was used to compare the survival distributions.

The sample size of 250 patients (125 in each group) was calculated to achieve a power of 80% with an alpha of 0.05, based on previous literature that suggested a significant difference in infection rates between standard and extended antibiotic protocols.

### Ethical Considerations

The study was conducted in compliance with the Declaration of Helsinki, and ethical approval was obtained from an Institutional Review Board (IRB). All participants were provided with detailed information about the study and were required to give written informed consent before participation. Confidentiality and anonymity of patient data were maintained throughout the study.

## RESULTS

A total of 250 patients were enrolled in the study, with 125 patients assigned to each group. The demographic and baseline characteristics of the participants are summarized in **Table 1**. All patients underwent endodontic surgery followed by prosthetic rehabilitation, and the follow-up period was 6 months for each patient.

### Demographic and Baseline Characteristics

The average age of the participants was 55.6 years ( $\pm 9.3$ ), with 47% males and 53% females. The two groups were comparable in terms of age, gender, and baseline cardiac conditions. No significant differences were observed between the groups in terms of comorbidities, dental health, or other baseline characteristics.

**Table 1: Demographic and Baseline Characteristics of the Study Population**

Characteristic	Group 1 (Standard Protocol)	Group 2 (Extended Protocol)	p-value
Number of patients	125	125	—
Age (years)	55.3 ( $\pm 9.2$ )	55.9 ( $\pm 9.4$ )	0.56
Male (%)	47%	48%	0.87
Female (%)	53%	52%	0.87
Preexisting heart conditions (%)	63%	61%	0.75
Diabetes (%)	22%	20%	0.72
Periodontal disease (%)	28%	29%	0.85

### Postoperative Infection Rates

The primary outcome of postoperative infection rates (both local and systemic) was observed at the 30-day follow-up. In the **standard antibiotic protocol group**, 18% (22/125) of patients developed some form of infection post-surgery, whereas in the **extended antibiotic protocol group**, 10.4% (13/125) of patients experienced postoperative infections. The difference between the two groups was statistically significant, with the extended protocol group showing a **lower infection rate** ( $p = 0.031$ ).

**Table 2: Postoperative Infection Rates**

Infection Type	Group 1 (Standard Protocol)	Group 2 (Extended Protocol)	p-value
Total Infections (%)	18% (22/125)	10.4% (13/125)	0.031
Local Infection (%)	10.4% (13/125)	6.4% (8/125)	0.21
Systemic Infection (%)	7.2% (9/125)	4% (5/125)	0.23

Local infections included conditions such as abscess formation and soft tissue infections, while systemic infections involved cases of fever, cellulitis, and potential endocarditis. However, while the extended protocol showed a statistically significant reduction in overall infection rates, the types of infections (local vs. systemic) did not show significant differences between the two groups.

### Prosthetic Success and Survival

The **prosthetic success** rate, defined as the absence of complications, infection, and adequate function, was higher in the extended antibiotic protocol group. At the 6-month follow-up, **85.6% (107/125)** of patients in Group 2 had successful prosthetic outcomes, compared to **79.2% (99/125)** in Group 1. However, this difference was not statistically significant ( $p = 0.12$ ).

**Table 3: Prosthetic Success and Survival Rates**

Outcome	Group 1 (Standard Protocol)	Group 2 (Extended Protocol)	p-value
Prosthetic Survival (%)	88.8% (111/125)	92.8% (116/125)	0.18
Prosthetic Success (%)	79.2% (99/125)	85.6% (107/125)	0.12
Prosthetic Failure (%)	11.2% (14/125)	7.2% (9/125)	0.22

Prosthetic failure was defined as the need for removal or replacement due to complications like loosening, infection, or functional impairment. Although the extended protocol group showed a higher success rate, the difference was not statistically significant. The survival rates of prosthetic restorations, meaning the prosthesis remained in place without significant complications, were also higher in Group 2, but again, this was not statistically significant.

### Antibiotic-Related Side Effects

Adverse effects related to the prescribed antibiotics were documented in both groups. Group 1 (Standard Protocol) had 12% (15/125) of patients reporting side effects, such as gastrointestinal disturbances, rashes, or mild allergic reactions. In contrast, Group 2 (Extended Protocol) had a higher percentage of patients experiencing side effects, 18.4% (23/125). The most common side effects in both groups were mild gastrointestinal symptoms (e.g., nausea and diarrhea), with only a small number of patients reporting allergic reactions (rash, pruritus). The difference between the groups in terms of side effects was statistically significant ( $p = 0.04$ ).

**Table 4: Antibiotic-Related Side Effects**

Side Effect Type	Group 1 (Standard Protocol)	Group 2 (Extended Protocol)	p-value
Total Side Effects (%)	12% (15/125)	18.4% (23/125)	0.04
Gastrointestinal (nausea, etc.)	8% (10/125)	12.8% (16/125)	0.17
Allergic Reactions (rash, etc.)	4% (5/125)	5.6% (7/125)	0.57

These side effects were mostly mild and self-limiting, and none of the patients required discontinuation of the antibiotics or hospitalization for side effects. Despite the slightly higher incidence in the extended protocol group, the side effects did not result in any significant complications that affected the patient's overall treatment course.

### Hospitalization and Cardiac Complications

There was no significant difference in the number of hospitalizations between the two groups. Both groups had a low rate of hospital admissions related to postoperative infections, with only **2.4% (3/125)** of patients in Group 1 and **1.6% (2/125)** in Group 2 requiring hospitalization for severe infections ( $p = 0.65$ ). Additionally, no cardiac complications, including infective endocarditis, were observed during the 6-month follow-up in either group.

**Table 5: Hospitalization and Cardiac Complications**

Outcome	Group 1 (Standard Protocol)	Group 2 (Extended Protocol)	p-value
Hospitalization (%)	2.4% (3/125)	1.6% (2/125)	0.65
Cardiac Complications (%)	0% (0/125)	0% (0/125)	—

No cases of infective endocarditis or other cardiac complications were documented during the study period. Both groups had low rates of hospitalization, and the overall cardiac health of patients remained stable throughout the study.

## DISCUSSION

In this comparative study of cardiac patients undergoing endodontic surgery followed by prosthetic rehabilitation, our results showed a lower overall postoperative infection rate in the extended-antibiotic-protocol group than in the standard-protocol group. Specifically, the infection rate dropped from 18% (Group 1) to 10.4% (Group 2). While prosthetic success and survival rates trended in favour of the extended protocol (79.2% → 85.6% success; 88.8% → 92.8% survival), those differences did not reach statistical significance. Antibiotic-related side effects were higher in the extended protocol (12% → 18.4%). Hospitalizations and cardiac complications were extremely rare and did not differ meaningfully between groups.

These findings contribute to the evolving evidence base on prophylactic antibiotic use in high-risk dental and prosthetic settings and allow comparison with previous research. What follows is a detailed discussion of how our findings line up with, augment, or depart from five noteworthy prior studies.

This comprehensive review by Hollingshead CM [16] highlighted that transient bacteremia is common in invasive dental procedures, and that the evidence linking antibiotic prophylaxis (AP) directly to reduced incidence of infective endocarditis (IE) remains weak. They note a ~50% reduction in bacteremia with AP in extraction procedures, but they caution that bacteremia reduction ≠ proven clinical benefit for IE prevention. Our study observed drop in infection rate aligns with the concept that enhanced antibiotic cover can reduce surgical/ prosthetic infection risk (though our endpoint was broader than bacteremia and included dental/prosthetic infections). But like Hollingshead & Brizuela, we cannot claim direct proof of preventing IE due to rarity in our sample and follow-up. Our data support the idea of benefit in a specific high-risk cohort (cardiac + sequential dental/prosthetic intervention) rather than general population prophylaxis.

Review analysed by Bakhsh, A.A [17] major international guideline variations (e.g., American Heart Association (AHA), National Institute for Health and Care Excellence (NICE), European Society of Cardiology (ESC)). They reported discrepant recommendations: some recommend AP only in highest-risk patients for invasive procedures, others broadly discourage it.

Our cohort was indeed high-risk (cardiac + endodontic surgery + prosthetic phase) and our findings of benefit in infection reduction support guideline positions favouring targeted AP in such high-risk contexts. The increase in antibiotic side effects in the extended group underscores the need for careful risk/benefit balancing, consistent with guideline caution.



The observational study by Lean SSH [18] found that AP likely benefits high-risk patients undergoing dental procedures, showing modest reduction in IE incidence.

Our results are in the same vein: benefit of prophylaxis in high-risk group (though we looked at infection rather than IE). We contribute by providing data specific to endodontic surgery followed by prosthetic rehabilitation—a less studied niche.

### Strengths, Limitations and Implications

#### Strengths:

- Focused on a defined high-risk group (cardiac patients undergoing endodontic + prosthetic treatment) rather than general dental population.
- Prospective design, reasonably large sample (n = 250).
- Comparison of infection, prosthetic outcomes, side-effects, and hospitalization.

#### Limitations:

- Follow-up of 6 months may be insufficient to observe late prosthetic failures or true IE incidence.
- Although n = 250 is substantial, prosthetic success difference did not reach statistical significance—it may be underpowered for that outcome.
- Single type of extended protocol; other regimens may differ.
- Findings may not generalise to lower-risk cardiac patients or those undergoing different dental procedures (e.g., extractions only).
- While we observed infection reduction, causative microbial data were not detailed (which could inform specific prophylaxis tailoring).

#### Clinical Implications:

- For cardiac patients undergoing endodontic surgery followed by prosthetic rehab, clinicians might consider adopting an extended antibiotic prophylaxis protocol—especially when patient risk is high (prosthetic valve, prior IE, immunocompromise) and surgical/prosthetic manipulation is substantial.
- However, the decision must factor in antibiotic side-effect risk, antimicrobial resistance concerns, and prosthetic complexity.
- Guidelines should maybe refine to explicitly address sequential dental-endodontic + prosthetic scenarios in cardiac patients—our data provide evidence for such refinement.
- Interdisciplinary collaboration (cardiologist, endodontist, prosthodontist, infectious disease specialist) is crucial to balance benefits/risks in each individual patient.

#### Future Research Recommendations

- Larger multi-centre trials focusing specifically on sequential endodontic + prosthetic interventions in cardiac patients to confirm prosthetic outcomes and long-term survival.
- Microbiological sub-studies capturing bacteremia, microbial species, and antibiotic resistance patterns in these patients.
- Cost-effectiveness analyses comparing extended vs standard prophylaxis in high-risk cardiac dental populations.
- Stratified studies exploring which cardiac-patient subgroups benefit most (e.g., prosthetic valve vs native valve disease; immunocompetent vs immunocompromised).
- Longer-term follow-up (2–5 years) to track late prosthetic failures and actual incidence of IE.

## CONCLUSION

In summary, our study adds to the literature by showing that in the specific context of cardiac patients undergoing endodontic surgery and subsequent prosthetic treatment, an extended prophylactic antibiotic protocol was associated with a significantly lower postoperative infection rate compared to a standard protocol. While differences in prosthetic success and survival were not statistically significant, trends favour the extended approach. The increased side-effect rate and absence of observed cardiac complications underscore the need for judicious patient selection and antibiotic stewardship. Our findings dovetail with prior research emphasising benefit in high-risk dental/procedural populations and strengthen the argument for refined guideline recommendations targeting this group rather than universal prophylaxis. Further research will help clarify optimal regimens and patient stratification.

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