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Original Article

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Effectiveness and Safety of Co-Amoxiclav in Dental Infections: A Multicenter, Real-World Study

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Abstract

Objective*:** To assess the clinical effectiveness and safety of Co-Amoxiclav in the real-world treatment of dental infections. ***Design*:** Multicenter, retrospective, real world evidence study. ***Subjects: 4,436 adults diagnosed with dental infections ***Methods:*** This study included patients aged ≥ 18 years with a confirmed diagnosis of dental infections, who were treated with co-amoxiclav and had complete treatment documentation, including both baseline and follow-up visits. Data were extracted from medical records. The primary endpoints were the therapeutic efficacy and safety of co-amoxiclav. Statistical analysis included descriptive statistics and the paired t-test. ***Results***: The mean age of participants was 40.23 ± 12.20 years, while the most common diagnoses was undifferentiated dental infections (52%). Co-amoxiclav 625 mg twice daily for 5–7 days was the most common regimen (40.98%), with 95.55% reporting complete symptom resolution at 7 ± 2 days. Significant reductions were observed in C-reactive protein, white blood cell count, and Visual Analog Scale pain scores ($p < 0.0001$), with minimal treatment-related adverse events (0.16%). ***Conclusion***: Co-amoxiclav exhibited robust clinical effectiveness and a favourable safety profile in treating dental infections, with most patients achieving complete symptom resolution and a low incidence of adverse events.

Keywords: ***Amoxicillin/ clavulanic acid, antimicrobial resistance, dental caries, effectiveness, odontogenic infections, safety.***

Introduction

Odontogenic infections are dental infections originating within the oral cavity, primarily involving the teeth and their supporting structures. These infections commonly result from pulpal involvement secondary to advanced dental caries, periodontal disease, or pericoronal inflammation [1,2]. Common manifestations include dental caries, periodontal diseases such as gingivitis and periodontitis, periapical abscesses (infection around the tooth root) and pericoronitis (inflammation surrounding a partially erupted tooth) [3]. Dental abscesses often develop following untreated caries, trauma, or unsuccessful endodontic treatment. Bacterial toxins released in periapical tissues induce acute inflammation [4]. The predominant oral pathogens in healthy individuals encompass Streptococcus, Staphylococcus, Klebsiella and Fusobacterium, which contribute to various dental infections [5,6].

Dental caries (prevalence 13%-76%) and periodontal diseases (23%-99%) are among the most common oral health conditions worldwide, with notably higher rates in slum populations [7]. In India, dental caries remains a major public health concern, affecting approximately 54.16% of the population [8]. The incidence of dental infections is influenced by factors including geographic location, socioeconomic status, oral hygiene practices, healthcare accessibility, and the overall health profile of the population. These infections continue to pose a significant public health challenge, impacting individuals across all age groups [9,10]. While many dental infections are mild and localized, some can lead to severe, life-threatening complications requiring hospitalization [8]. Locally, they may cause abscesses, tooth loss, and pain; systemically, they are linked to cardiovascular, respiratory, and other chronic diseases. Transient bacteraemia from dental infections can also trigger serious conditions like brain abscess, cavernous sinus thrombosis, and Ludwig's angina [11].

Dental antibiotic prescriptions account for approximately 10% of global antibiotic use [12]. The selection of an appropriate antibiotic depends on factors including the type and severity of infection, the patient's medical history, and any known drug allergies [13]. Antibiotic therapy should be reserved for cases with clear clinical indications and prescribed only by qualified professionals. Inappropriate or excessive use contributes to antimicrobial resistance and adverse outcomes [14]. Judicious prescribing-selecting the appropriate agent, dose, and duration is essential, particularly in the presence of systemic infection. The rising prevalence of resistance is strongly linked to the misuse of broad-spectrum antibiotics [15].

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Amoxicillin/clavulanic acid (co-amoxiclav) was approved by the U.S. Food and Drug Administration in 1984 for the treatment of various bacterial infections, including dental infections. Amoxicillin is a broad-spectrum penicillin antibiotic, while clavulanic acid functions as a beta-lactamase inhibitor, thereby restoring amoxicillin's efficacy against resistant bacteria. In dental infections, co-amoxiclav exerts its therapeutic effect primarily through inhibition of bacterial cell wall synthesis and overcoming beta-lactamase–mediated resistance [16].

Despite the widespread use of antibiotics in dental practice, real-world evidence regarding their clinical effectiveness and safety in the Indian adult population remains limited. Amid rising concerns about antimicrobial resistance, this multicentre retrospective real-world observational study evaluates the clinical effectiveness and safety of co-amoxiclav in the treatment of dental infections. The analysis of data from multiple clinical sites across India affords critical insights into the real-world utilization of co-amoxiclav within a heterogeneous patient population.

Methods

Study design and population

This single-arm, multicentre, retrospective real-world study utilized medical records from 4,436 patients diagnosed with dental infections who presented to outpatient departments and received co-amoxiclav therapy. Eligible participants were adults aged 18 years or older, of any gender, who attended outpatient hospital departments; had a confirmed diagnosis of dental infection; and were prescribed co-amoxiclav either as primary treatment or adjunct therapy. Additionally, included patients had documented clinical diagnoses and treatment outcomes following co-amoxiclav administration, with complete medical records covering both therapy initiation and follow-up visits. Exclusion criteria comprised patients under 18 years of age, those not prescribed co-amoxiclav as primary or adjunct therapy, and individuals with incomplete medical documentation.

Data collection

Study investigators and site personnel identified eligible patients through a thorough review of existing medical records at each participating centre, applying predefined selection criteria. Individual prescriptions and laboratory reports were screened, and relevant data was systematically recorded in a standardized reporting system. Each patient record was assigned a unique identification number, starting from 001 for each investigator site. The baseline visit was defined as the initiation of co-amoxiclav therapy, with data collection occurring at baseline (Day 0) and during a follow-up visit.

The primary endpoints included therapeutic effectiveness and safety outcomes. At baseline, comprehensive demographic data-including age, gender, height, weight, and medical diagnosis-were collected for all participants. The therapeutic response was assessed and stratified as cured, improved, or worsened. Safety was monitored through documentation of any adverse events occurring during the treatment period. Follow-up assessments were conducted approximately 7 ± 2 days after treatment initiation. Both physical examinations and laboratory investigations were performed at baseline and follow-up to evaluate clinical progression and treatment efficacy. The key parameters included C-reactive protein (CRP), white blood cell (WBC) count, and pain severity assessed using the Visual Analogue Scale (VAS), all recorded at both baseline and follow-up visits.

Statistical Analyses

Statistical analysis was performed using descriptive statistics to summarize sample characteristics, including means, standard deviations, and frequencies for categorical variables. This approach facilitated the understanding of symptom distribution, treatment responses, and demographic patterns within the sample, enabling nuanced interpretation of the study findings. The paired t-test was employed to evaluate changes in key clinical parameters between baseline and follow-up. All analyses were conducted using SPSS software, with statistical significance defined at a 95% confidence interval (CI).

Ethical Considerations

The study protocol was reviewed and approved by a registered Institutional Ethics Committee (IEC) before commencement. This research complied with the Ethical Guidelines for Biomedical Research on Human Participants as established by the Indian Council of Medical Research (ICMR). Informed consent was waived due to the retrospective nature of the study, which utilized anonymized patient data extracted from medical records of individuals previously treated with co-amoxiclav. Patient confidentiality was maintained rigorously throughout the study.

Results

Baseline characteristics

Patient demographics are outlined in Table I. The study enrolled 4,436 participants, with a mean age of 40.23 ± 12.20 years, reflecting a broad age distribution. The study population was predominantly male, comprising 3,052 individuals (69%), while females accounted for 1,384 participants (31%).

The most commonly observed dental infection was undifferentiated dental infections, comprising 52% of the study population, followed by dental abscess (25%), dental caries (6%), pericoronitis (5%), gingivitis (4%), pulpitis (4%), periodontitis (3%) and periodontal abscess (1%) (Figure I). Additionally, 40.98% of participants were prescribed co-amoxiclav 625 mg to be taken twice daily for a duration of 5 to 7 days (Table II).

Treatment Response

An important aspect of the study was assessing the therapeutic response (effectiveness) to Co-amoxiclav in patients with dental infections (Table III). Majority of patients showed complete resolution of symptoms (95.55%). An additional 4.37% of patients experienced symptomatic improvement, though not complete resolution. Only a small percentage reported worsening of symptoms, suggesting that Co-amoxiclav was generally effective in managing dental infections during the observed follow-up period.

The mean C-reactive protein (CRP) level demonstrated a significant reduction, decreasing from 18.49 at baseline to 9.12 at the first follow-up visit, indicating a marked decrease in inflammation ($p < 0.0001$). Similarly, the mean white blood cell (WBC) count showed a substantial decline from 10,396 to 8,083, suggesting improvement in immune response and resolution of infection or inflammation ($p < 0.0001$). Pain scores on the Visual Analogue Scale (VAS) also declined markedly from 4.83 to 2.03, indicating symptomatic relief following treatment (Table IV).

The temperature decreased significantly from 100.99 ºF (indicative of fever) to 97.77 ºF, suggesting a resolution of fever or infection (Table V). Additionally, the mean pulse rate decreased from 83.67 beats per minute to 75.78, reflecting improved cardiovascular status. Overall, the data demonstrate significant improvements across key physical parameters, supporting a positive response to treatment.

Adverse events

The occurrence of treatment-related adverse events was minimal, affecting just 0.16% (7 cases) of participants. The vast majority of participants (99.84%) did not experiences any adverse events. All reported cases of adverse events were appropriately managed with treatment (Table VI).

Table I: Demographic characteristics of the study population (n = 4,436).

Parameter	**Mean**	**SD**
Age	40.23	12.20
Gender	**N**	**%**
Male	3052	69
Female	1384	31
	Mean	**SD**
Height (cm)	158.42	11.49
Weight (kg)	59.47	8.66
Diagnosis	**n**	**%**
Undifferentiated dental infections	2289	52
Dental abscess	1096	25
Dental caries	282	6
Pericoronitis	224	5
Gingivitis	189	4
Pulpitis	174	4
Periodontitis	139	3
Periodontal abscess	43	1
Dental infection (Total cases)	**4,436**	**100**

Table II: Descriptive statistics of Co-amoxiclav dosage patterns in dental infection management (n=4,436).

Duration	**n**	**%**
Dosage 200/125 mg thrice daily		
5-7 days	19	0.43
Dosage 400/57 mg thrice daily		
5-7 days	5	0.11
Dosage 500/125 mg twice daily		
5-7 days	1818	40.98
8-14 days	750	16.91
Dosage 500/125 mg thrice daily		
5-7 days	878	19.79
8-14 days	770	17.36
Dosage 875/125 mg twice daily		
5-7 days	70	1.58
8-14 days	21	0.47
Dosage 875/125 mg thrice daily		
5-7 days	63	1.42
8-14 days	42	0.95

Table III: Clinical response in dental infection patients after co-amoxiclav treatment (n = 4,436).

Treatment response	**n**	**%**
Cure	4239	95.55
Improvement	194	4.37
Worsening	3	0.08
Total response	**4436**	**100**

Table IV: Changes in key parameters from baseline to follow-up interval (n = 4,436).

Parameter	**Baseline**		**Follow-up visit**		**Statistical analysis**
	Mean	**SD**	**Mean**	**SD**	**t-test (p-value)**
CRP (mg/L)	18.49	14.12	9.12	6.02	< 0.0001*
WBC (per µL)	10396	3817	8083	2381	< 0.0001*
Pain on VAS	4.83	1.51	2.03	1.86	< 0.0001*

Table V: Changes in physical parameters from baseline to follow-up intervals (n = 4,436).

Parameters	**Baseline (Mean ± SD)**	**Follow-up (Mean ± SD)**
Temperature (ºF)	100.99 ± 2.03	97.77 ± 1.79
Pulse rate (bpm)	83.67 ± 10.57	75.78 ± 8.17

Table VI: Incidence of adverse events among the study population at follow-up visit (n = 4,436).

Adverse events	**n**	**%**
Yes	7	0.16
No	4429	99.84
Total	**4436**	**100**

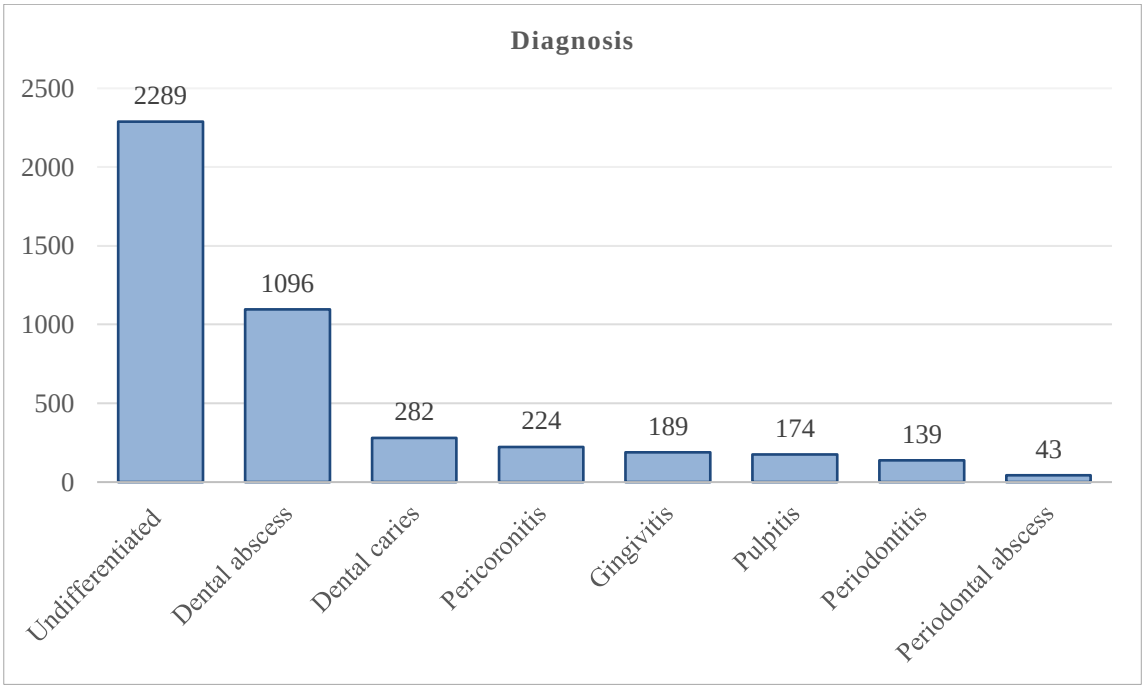


Figure 1: A Subpopulation Analysis of dental infections in the Study Population (n = 4,436).

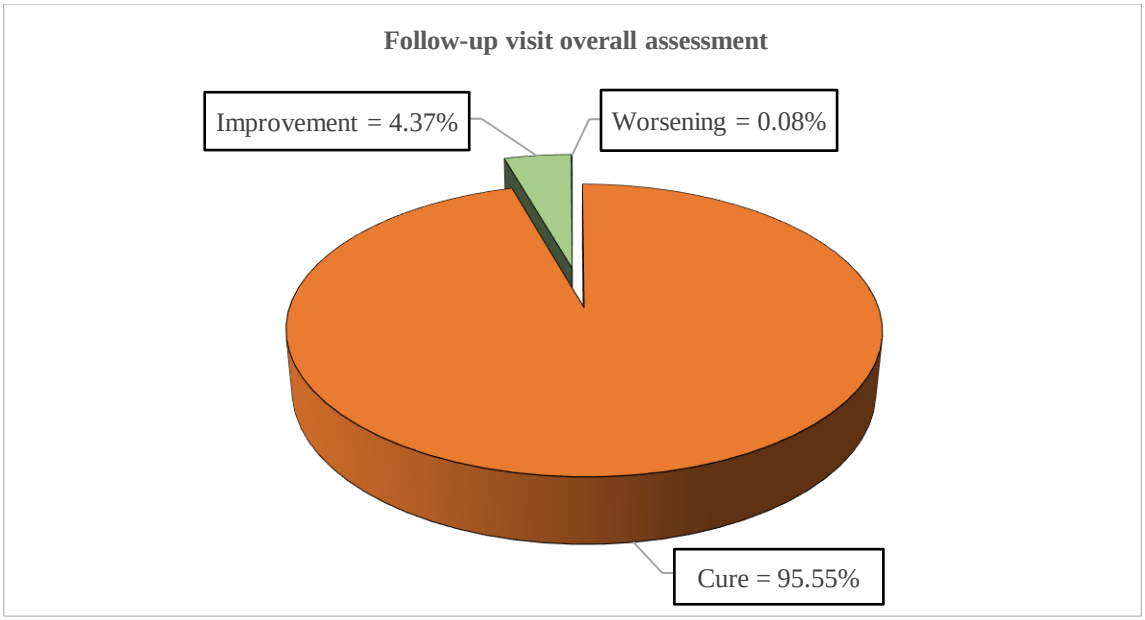
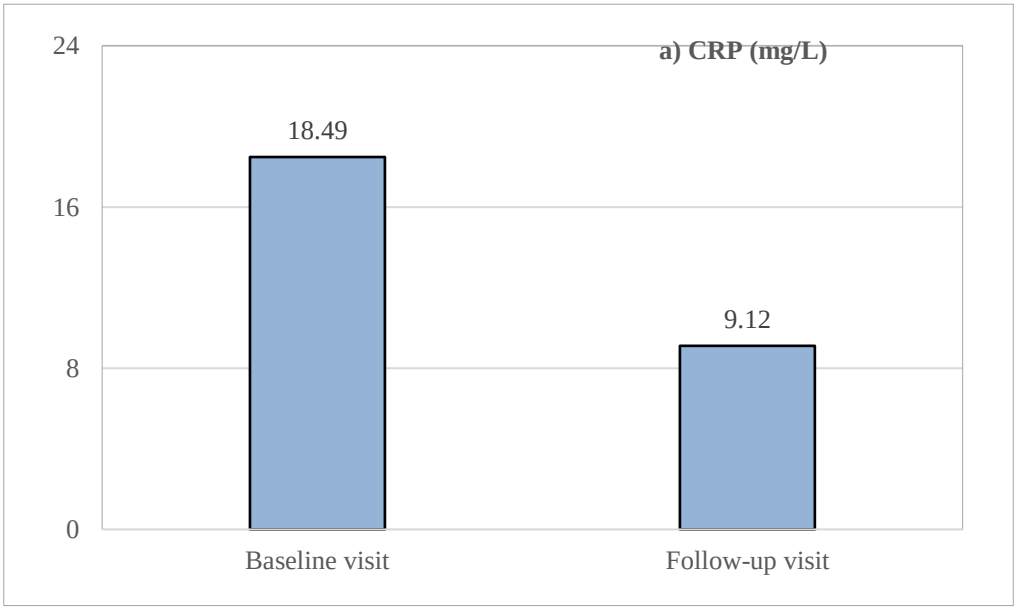
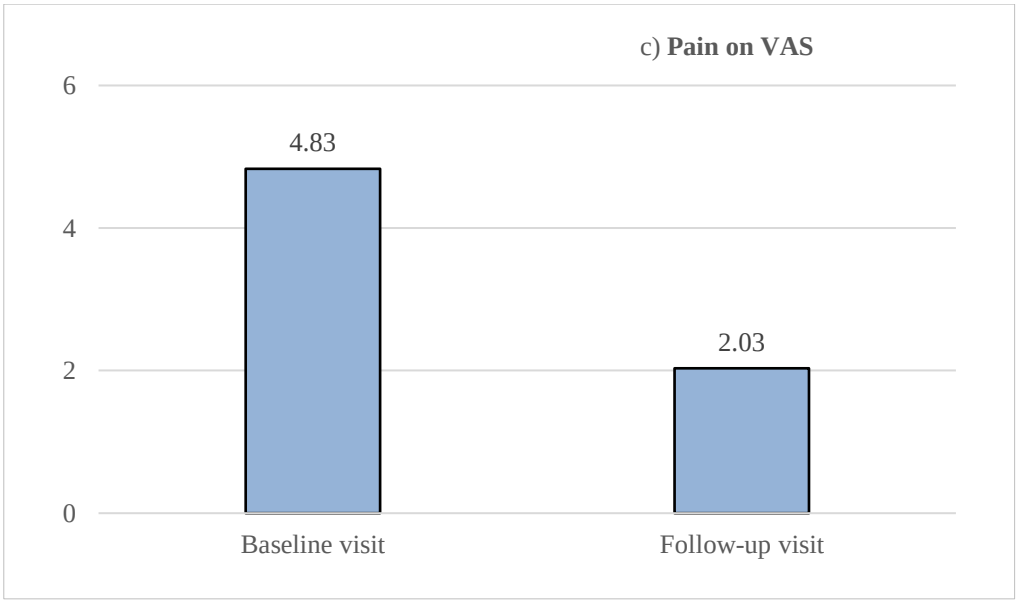
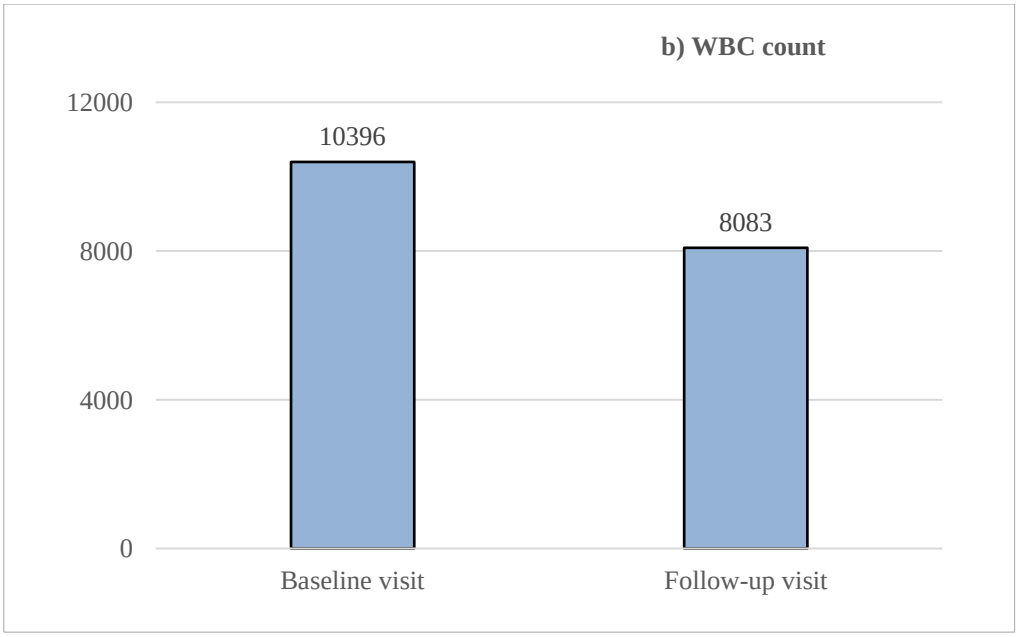


Figure II: Follow-up visit overall assessment (n = 4,436).







(a) CRP (C-reactive protein), (b) WBC count (White Blood Cell count), (c) Pain on VAS (Visual Analogue Scale), (n = 4,436).

Figure III: Changes in key parameters from baseline to follow-up interval

Discussion

This study evaluated the clinical effectiveness and safety of co-amoxiclav in the treatment of dental infections among adult patients. The findings demonstrated high clinical effectiveness, with the majority of participants reporting symptomatic improvement following therapy. A significant reduction in pain intensity was observed, further corroborating the therapeutic benefit of co-amoxiclav. These outcomes were statistically significant ($p < 0.0001$), underscoring the effectiveness of the treatment. Co-amoxiclav was well tolerated in most cases, with few adverse effects reported. Notably, a substantial proportion of patients achieved infection resolution within seven days of starting therapy. These results are consistent with existing literature and prior studies that have documented the efficacy of amoxicillin-clavulanate combinations in managing dental infections.

Multiple clinical studies have demonstrated the efficacy and safety of co-amoxiclav in managing dental infections. In a Phase IV trial by Tancawan et al., co-amoxiclav (875/125 mg BID) was shown to be non-inferior to clindamycin (150 mg QID), with a 7.7% treatment difference within the 10% non-inferiority margin, and higher clinical success by Day 5 [17]. Adriaenssen et al., in a multicenter trial across 106 dental practices, reported clinical success in 96% of patients treated with co-amoxiclav, compared to 91% with azithromycin, for acute periapical abscesses [18]. In the present study, co-amoxiclav achieved a 95.55% complete resolution rate. Similarly, Sulejmanagic et al. found that co-amoxiclav significantly outperformed amoxicillin alone in reducing postoperative pain and swelling, reinforcing its clinical superiority. Collectively, these findings support co-amoxiclav as a preferred antibiotic for odontogenic infections [19] A study by Frank Halling et al. reported that, after amoxicillin, amoxicillin/clavulanic acid is the second most commonly prescribed antibiotic by dentists [20]. Beyond its dental applications, co-amoxiclav has demonstrated effectiveness in treating a range of other infections, including acute otitis media, sinusitis, pneumonia, urinary tract infections, and skin and soft tissue infections [21].

In a separate study, Ingo Sobottka et al. assessed the antimicrobial susceptibility of 87 bacterial isolates from 37 patients with odontogenic abscesses. All isolates were sensitive to amoxicillin–clavulanic acid, while 98% showed susceptibility to moxifloxacin and levofloxacin. Susceptibility to doxycycline, clindamycin, and penicillin was observed in 76%, 75%, and 69% of isolates, respectively [22]. Given its consistently high susceptibility rates across diverse pathogens and proven clinical efficacy, co-amoxiclav emerges as a strong antibiotic choice for the treatment of dental infections, particularly in cases where resistance to other agents is a concern.

While most patients in the present study achieved clinical cure or improvement, a small subset experienced symptom worsening, suggesting possible resistance to co-amoxiclav. Resistance to β-lactams-primarily due to β-lactamase production and altered penicillin-binding proteins-continues to pose clinical challenges. Although clavulanic acid enhances amoxicillin's activity, its effectiveness is strain-dependent [16]. Such outcomes underscore the impact of inappropriate or excessive antibiotic use, which can promote resistant organisms by disrupting normal flora and contributing to persistent or recurrent infections. Antibiotic selection should consider both intrinsic and acquired resistance. High-dose amoxicillin-clavulanic acid (875/125 mg TID or 2000/125 mg BID) remains the preferred regimen for caries-associated odontogenic infections, including pulpitis, abscesses, and select periodontal infections. However, its use should be balanced against the potential risk of hepatotoxicity [23].

In the present study, alongside symptomatic improvement, a significant reduction in C-reactive protein (CRP) levels and white blood cell (WBC) counts was observed following co-amoxiclav administration. This decline is clinically significant, as elevated CRP levels and WBC counts have been consistently associated with dental infections in previous studies [24,25]. In the current study, most participants tolerated co-amoxiclav well, with only a few adverse events reported. However, the literature documents a range of typically mild to moderate side effects, most commonly gastrointestinal disturbances such as nausea, vomiting, abdominal discomfort, anaphylaxis reaction and diarrhoea [18,19,26].

The strengths of this study include its large sample size of 4,436 participants, which enhances both the statistical power and the generalizability of the findings across diverse populations and clinical settings. Although dental infections are highly prevalent among adults, data on this population—particularly within the Indian context—remain limited, with much of the existing literature outdated by several decades. By assessing both the effectiveness and safety of Co-Amoxiclav, the study provides a balanced evaluation relevant to real-world dental practice. The use of existing clinical data ensures a cost- and time-efficient approach. Importantly, the study addresses a significant evidence gap in the Indian context, offering updated insights into dental infection management amid the growing concerns of antimicrobial resistance.

However, the retrospective design of the study imposes certain limitations. These include the lack of detailed adverse event reporting, absence of microbiological data, and insufficient information on the specific treatment regimens followed by patients. Additionally, the study evaluated only a single treatment arm, which restricts the ability to comprehensively assess the effectiveness and safety of co-amoxiclav relative to other antibiotics commonly used in India.

In conclusion, this study highlights the notable effectiveness and safety of co-amoxiclav in the management of dental infections, with most patients experiencing clinical cure and a low incidence of adverse events. These findings support the real-world effectiveness of co-amoxiclav, despite the growing challenge of antimicrobial resistance. However, to assess long-term outcomes, prospective studies are needed. Future research should include comparative analyses with other commonly used antibiotics to further clarify the relative efficacy and safety of co-amoxiclav.

Declarations

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Conflict of interest declaration

Authors AP, DP, and AS are full-time employees of the Medical Affairs Department, Alkem Laboratories Ltd., Mumbai, India.

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Ethical Clearance: Reviewed and approved by a registered Institutional Ethics Committee (IEC).

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