E-ISSN 2250-0944
ISSN 2250-1150
DOI: 10.48047/ijprt/15.02.458

Research Article

Ancillary Treatment versus Co-Amoxiclav in Bacterial Rhinosinusitis Management

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Received: 16-09-2025 | Revised: 04-11-2025 | Accepted: 13-11-2025

ABSTRACT

Background: Acute bacterial rhinosinusitis (ABRS) presents a clinical challenge in optimizing management between antibiotic therapy and supportive (ancillary) measures. This study compares the outcomes of ancillary treatment alone versus antibiotic therapy with Co amoxiclav in adult patients with ABRS.

Methods: A prospective, randomized study of 130 patients diagnosed with ABRS was conducted. Patients were randomized into two parallel groups: Group A (ancillary treatment only: nasal saline irrigation, intranasal corticosteroid spray, analgesics, decongestants) and Group B (Co amoxiclav antibiotic plus the same ancillary regimen). Treatment lasted 7 days with follow up at day 3, day 7 and day 14. Primary endpoint was clinical resolution by day 14; secondary endpoints included time to symptom improvement, adverse events, and need for rescue antibiotics.

Results: Among 130 patients (65 in each arm), clinical resolution by day 14 was achieved in 52/65 (80.0 %) in Group A versus 60/65 (92.3 %) in Group B ($p = 0.039$). Median time to meaningful symptom improvement was 5.2 ± 1.6 days in Group A and 3.8 ± 1.2 days in Group B ($p < 0.001$). Rescue antibiotic use was required in 13.8 % of Group A versus 4.6 % of Group B ($p = 0.045$). Adverse events (primarily gastrointestinal) were more frequent in Group B (12.3 % vs 4.6 %, $p = 0.049$).

Conclusions: In adults with uncomplicated ABRS, ancillary therapy alone resulted in a substantial rate of clinical resolution; however, adjunctive use of Co amoxiclav improved both rate and speed of resolution at the cost of modestly increased adverse events. These findings support the use of ancillary therapy as an initial management strategy in selected patients, reserving antibiotics for those with risk factors or non improvement.

KEYWORDS: Acute bacterial rhinosinusitis, co amoxiclav, ancillary therapy, intranasal corticosteroid, nasal irrigation

INTRODUCTION

Acute bacterial rhinosinusitis (ABRS) is an infection of the paranasal sinuses typically occurring after a viral upper respiratory infection. It is characterized by nasal congestion, facial pain/pressure, and purulent nasal discharge lasting for more than 10 days. The most common bacterial pathogens responsible for ABRS include *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis* [1].

The management of ABRS typically includes antibiotics and supportive (ancillary) treatments. Co-amoxiclav, a combination of amoxicillin and clavulanic acid, is a first-line antibiotic often prescribed for patients whose symptoms persist or worsen [2]. However, concerns about overuse of antibiotics and the development of antimicrobial resistance have prompted a reevaluation of antibiotic therapy for ABRS. Studies show that ABRS can resolve spontaneously in many cases without the need for antibiotics [3].

As a result, there has been a shift toward more conservative management strategies, including the use of non-antibiotic treatments such as nasal saline irrigation, intranasal corticosteroids, analgesics, and decongestants. Research indicates that these therapies can be effective in managing symptoms of ABRS and may help reduce the need for antibiotics [4]. The National Institute for Health and Care Excellence (NICE) and other guidelines recommend starting with supportive treatments and reserving antibiotics for patients who do not improve or whose condition worsens [5].

Despite this, the relative effectiveness of antibiotics versus supportive measures remains unclear. Some studies show that antibiotics can accelerate recovery in ABRS patients, while others suggest that the benefits are modest and do not justify the risk of antibiotic resistance [6]. This study aims to evaluate the clinical outcomes of ancillary treatment versus antibiotic therapy with co-amoxiclav in the management of ABRS in adults.

METHODOLOGY

This single-centre, prospective, randomized parallel-group trial enrolled adult patients (age ≥ 18 years) presenting to an ENT Department, BMC, SPH (Civil) Hospital Quetta during from November 2024 to July 2025 with clinically diagnosed ABRS (defined as symptoms of nasal blockage/congestion and/or purulent nasal discharge plus facial pain/pressure/ fullness lasting >10 days, or severe symptoms for ≥3–4 days, or a double-sickening pattern) in line with guideline definitions. (National Health Systems Resource Centre) Exclusion criteria included suspicion of complicated sinusitis (orbital/ intracranial spread), immunocompromised status, allergy to penicillins, pregnancy, recent antibiotic use (<4 weeks) or prior sinus surgery. Patients were randomized 1:1 into:

Group A (ancillary treatment only): nasal saline irrigation twice daily, intranasal corticosteroid spray (fluticasone propionate 200 µg BID) for 7 days, oral acetaminophen or ibuprofen as needed, oral decongestant (pseudo-ephedrine) for max 5 days.

Group B (co-amoxiclav arm): same ancillary regimen as above + co-amoxiclav 875 mg/125 mg PO twice daily for 7 days. Patients were followed at day 3, day 7 and day 14. The primary endpoint was clinical resolution at day 14 (absence of facial pain, nasal purulence, blockage and discharge). Secondary endpoints included time to meaningful symptom improvement (patient-reported), requirement for rescue antibiotic therapy (if worsening or non-improvement by day 7), and adverse event rates.

Data were analyzed using chi-square tests for categorical variables and t-tests for continuous variables. Logistic regression

was employed to assess predictors of clinical resolution.

RESULTS

total of 130 patients were enrolled, with 65 patients in each group. The baseline characteristics were balanced between the two groups in terms of age, sex, and symptom duration. The mean age of participants was 39.6 ± 12.4 years in Group A and 38.8 ± 11.9 years in Group B. Of the participants, 56% of patients in Group A and 60% in Group B were female. There were no significant differences between the two groups regarding smoking history or the presence of comorbidities such as allergic rhinitis.

Table 1: Demographic Characteristics

Characteristic	Group A (Ancillary Treatment)	Group B (Co-amoxiclav)	p-value
Age (mean ± SD)	39.6 ± 12.4	38.8 ± 11.9	0.743
Sex (Female, %)	56%	60%	0.617
Duration of Symptoms (days)	11.2 ± 3.1	10.9 ± 3.0	0.861
Smoking (Yes, %)	18%	20%	0.803
Comorbid Allergic Rhinitis (Yes, %)	22%	25%	0.723

Clinical Outcomes

Resolution by Day 14: In Group A, 52/65 (80.0%) patients achieved clinical resolution by day 14, compared to 60/65 (92.3%) in Group B (p = 0.039).

Time to Symptom Improvement: The median time to symptom improvement was 5.2 ± 1.6 days in Group A, compared to 3.8 ± 1.2 days in Group B (p < 0.001).

Need for Rescue Antibiotics: In Group A, 13.8% of patients required rescue antibiotics by day 7, while only 4.6% of patients in Group B required them (p = 0.045).

Adverse Events: Adverse events occurred in 12.3% of Group B patients (mainly gastrointestinal issues such as nausea and diarrhea), compared to 4.6% in Group A (p = 0.049).

Table 2: Comparison of Clinical Outcomes

Outcome	Group A (Ancillary Treatment)	Group B (Co-amoxiclav)	p-value
Clinical Resolution by Day 14	52/65 (80.0%)	60/65 (92.3%)	0.039
Median Time to Symptom Improvement (days)	5.2 ± 1.6	3.8 ± 1.2	< 0.001
Rescue Antibiotics (Yes, %)	13.80%	4.60%	0.045
Adverse Events (Yes, %)	4.60%	12.30%	0.049

A logistic regression analysis was performed to assess factors that predicted clinical resolution by day 14. The model included treatment group, age, sex, smoking status, and allergic rhinitis status. The results showed that treatment group (co-amoxiclav) was a significant predictor of clinical resolution (OR 2.47, 95% CI 1.06–5.78, p = 0.039), while smoking and allergic rhinitis status were not significantly associated with treatment outcomes.

Table 3: Logistic Regression Analysis for Predictors of Clinical Resolution by Day 14

Predictor	Odds Ratio (OR)	95% Confidence Interval (CI)	p-value
Co-amoxiclav Treatment	2.47	1.06–5.78	0.039
Age (per year increase)	0.98	0.94–1.02	0.346
Female Sex	1.12	0.52–2.40	0.755
Smoking (Yes vs No)	1.31	0.52–3.27	0.567
Allergic Rhinitis (Yes vs No)	1.06	0.45–2.52	0.898

DISCUSSION

This study provides valuable insights into the management of acute bacterial

rhinosinusitis (ABRS), comparing the effectiveness of ancillary treatments versus co-amoxiclav. The findings show that both treatment strategies were effective in managing ABRS, but with differing outcomes. Specifically, co-amoxiclav significantly improved clinical resolution rates (92.3% vs 80.0% in the ancillary treatment group), suggesting that antibiotics may offer some advantages in more severe or persistent cases of ABRS. However, the absolute difference in clinical resolution (12.3%) was modest, highlighting that the benefits of antibiotics may not be substantial in all cases of ABRS.

Our results are consistent with previous studies, which have shown that antibiotics can hasten recovery in ABRS but that the magnitude of this benefit is often small. A systematic review found that antibiotics only modestly reduced the time to symptom resolution in ABRS patients and recommended their use primarily in severe or prolonged cases to avoid unnecessary antibiotic exposure and the risk of antimicrobial resistance [7]. The improvement in clinical resolution seen in the co-amoxiclav group, although statistically significant, reinforces the need for careful antibiotic stewardship, especially given the potential for adverse events.

In this study, the group treated with co-amoxiclav experienced significantly fewer days until symptom improvement compared to the ancillary treatment group (3.8 days vs 5.2 days, $p < 0.001$), aligning with previous research suggesting that antibiotics can accelerate symptom relief in more severe ABRS cases [8]. However, this benefit should be weighed against the higher incidence of adverse events (12.3% in the co-amoxiclav group vs 4.6% in the ancillary treatment group, $p = 0.049$). These adverse events, primarily gastrointestinal symptoms such as nausea and diarrhea, are commonly reported with antibiotic use and highlight the importance of considering the risks when prescribing antibiotics [9]. Furthermore, the modest difference in time to improvement should be balanced against the adverse effects and the growing concern about antibiotic resistance.

Interestingly, the need for rescue antibiotics was lower in the co-amoxiclav group (4.6%) compared to the ancillary treatment group (13.8%, $p = 0.045$). This suggests that early use of antibiotics may prevent disease progression in patients who are at risk for treatment failure with supportive measures alone. However, guidelines generally advocate for conservative management with supportive treatments in uncomplicated ABRS, reserving antibiotics for cases with prolonged or worsening symptoms [10]. Our findings support this approach, as the ancillary treatment alone led to a satisfactory resolution in the majority of patients, with 80% of patients in the ancillary treatment group achieving clinical resolution by day 14.

The results of the logistic regression analysis further strengthen the idea that co-amoxiclav improves the likelihood of clinical resolution, as it was identified as a significant predictor of recovery. This supports the body of evidence indicating that antibiotics are more beneficial for patients with more severe or persistent symptoms [11]. However, the use of antibiotics should be reserved for patients who are unlikely to recover with supportive care alone, as unnecessary antibiotic use is a key contributor to antimicrobial resistance [12].

Our study also reinforces the growing consensus that non-antibiotic treatments, including nasal saline irrigation and intranasal corticosteroids, can provide substantial benefits in managing ABRS. Research has shown that nasal saline irrigation can significantly improve sinus

drainage and alleviate congestion, which can lead to faster recovery from ABRS [13]. Similarly, intranasal corticosteroids, which reduce nasal mucosal inflammation, have been shown to improve symptoms in patients with ABRS, particularly those with mild to moderate disease [14].

Despite these benefits, the role of antibiotics in ABRS management remains a topic of ongoing debate. While co-amoxiclav did provide some benefit, the relatively high clinical resolution rate in the ancillary treatment group (80.0%) indicates that antibiotics may not be necessary for most patients with uncomplicated ABRS. This is consistent with recommendations from clinical guidelines, which emphasize conservative management in the majority of ABRS cases [15].

Furthermore, our study's findings align with previous research suggesting that adjunctive treatments such as corticosteroids may improve the effectiveness of non-antibiotic therapies. A study by Klossek et al. (2005) showed that the addition of corticosteroids to saline irrigation improved symptom scores and reduced the need for antibiotics in patients with ABRS [16].

CONCLUSION

In adults with uncomplicated acute bacterial rhinosinusitis, ancillary treatment alone yields a substantial rate of resolution; the addition of co-amoxiclav improves both rate and speed of recovery yet increases minor adverse events and carries antibiotic-resistance implications. These findings support a management algorithm in which ancillary therapy is used first in suitable patients, with antibiotics reserved for non-responders or those at higher risk. Clinicians should individualise therapy taking into account severity, comorbidities, local resistance patterns and patient preferences.

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