

Effectiveness of Co-amoxiclav in Managing Upper Respiratory Tract Infections: A Multicenter Retrospective Real-world Study

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INTRODUCTION

URTIs: A Significant Health Burden [1-3]

- Global incidence: 17.2 billion cases (2019), ~43% of the global disease burden.
- India:
 - □ 2.8% prevalence in children <5 years (NFHS-5, 2019–2021).
 - ☐ Pneumonia: 15.9% of deaths in children under 5 years (2000–2015).

Challenges in Management [4]:

- Antibiotic resistance: Increasing global concern due to resistant bacterial strains.
- Need for effective, broad-spectrum antibiotics to combat resistant pathogens.

> Co-Amoxiclav as a Potential Solution [4]:

- Combines amoxicillin with clavulanate (beta-lactamase inhibitor) to combat resistant bacteria.
- FDA approval: 1996 (US); EMA approval: 2009 (EU).
- Indications: Effective against URTIs like acute sinusitis, AOM, and RTIs.
- Broad-spectrum activity in pediatric and adult populations.

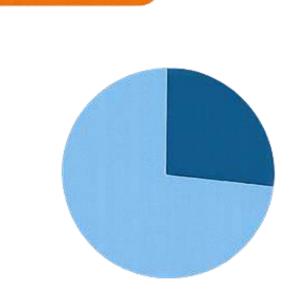
URTIs: A Significant Health Burden



17.2 BILLION CASES (2019)



2.8% PREVALENCE IN CHILDREN <5 YRS (NFHS-5, 2019-2021)



PNEUMONIA: **15.9%**

OF DEATHS IN CHILDREN UNDER S YEARS (2000-2015)

RATIONALE & OBJECTIVE

Healthcare Burden of URTIs:

- Significant impact on healthcare systems, especially in developing nations like India.
- Broad-spectrum antibiotics like Co-amoxiclav are vital for effective management.

> Data Gap:

Limited real-world data on the efficacy and safety of Co-amoxiclav in the Indian adult population.

Study Objective:

- Assess the clinical effectiveness and safety of Co-amoxiclav in managing URTIs.
- Provide real-world evidence across diverse Indian clinical settings to support evidence-based treatment strategies.

METHODOLOGY

- Inclusion: Adults (≥18 yrs) with URTI diagnosis, treated with co-amoxiclav, documented outcomes, and ≥1 follow-up.
- Exclusion: <18 yrs, not prescribed co-amoxiclav, incomplete/unavailable records.

STUDY OVERVIEW

- > Data: Retrospective review of records at baseline (Day 0), follow-up (~Day 7)
- Parameters: Demographics, response (cure, improvement, worsening, mortality), adverse events.
- Endpoints: Clinical response + safety.
- > Analysis: Descriptive stats, Chi-square test.
- Ethics: IEC approved, confidentiality maintained, consent not required.

SCHEDULE

Co-Amoxiclav Therapy



FIRST F/UP VISIT (Day 7±2)

RESULTS

> Participant Demographics:

Total participants (n): 30,258
Mean age: 39 ± 16.3 years
Gender distribution:
• Male: 22,088 (73%)

• Female: 8170 (27%)

➤ Severity of Cases: Mild cases: 74%

> Types of URTIs:

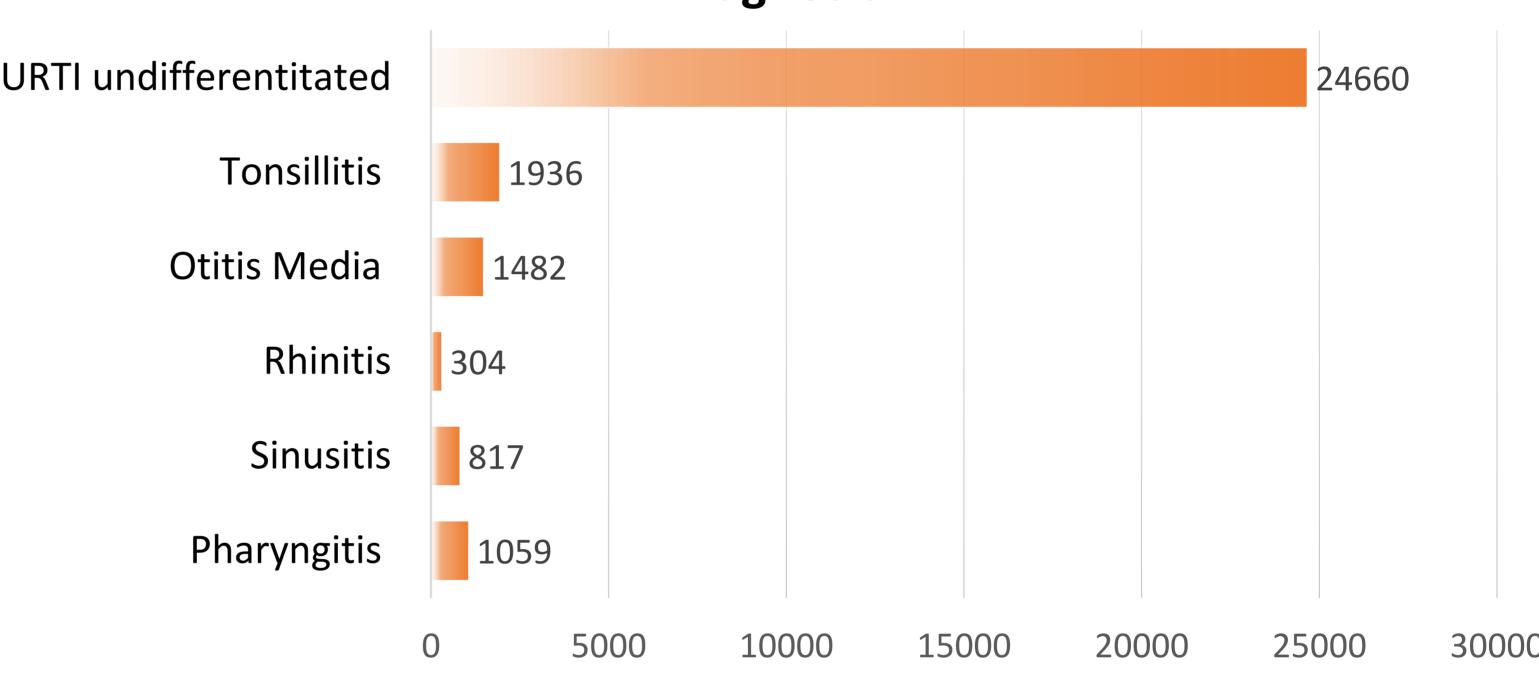
• Undifferentiated URTI: 81.5%

Tonsillitis: 6.4%
Otitis Media: 4.9%
Prescribed Treatment:

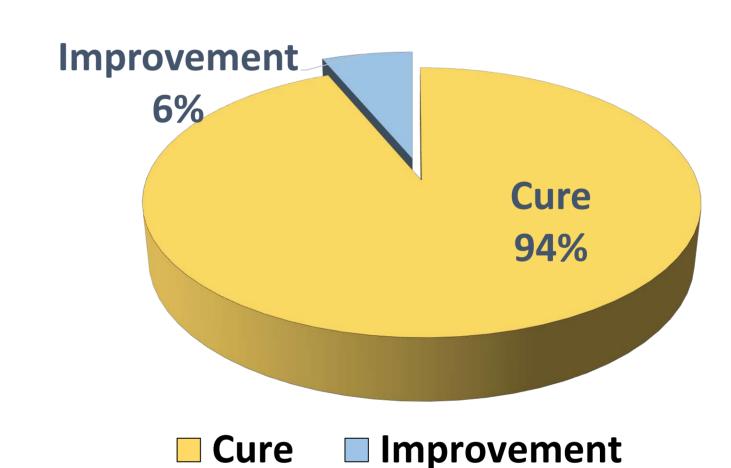
• Co-amoxiclav 625 mg: Prescribed to 80.4% of participants

Typical dosage: Twice daily for 5–7 days

Diagnosis



Clinical outcome



Mean WBC (/cumm) 10,339 8,000 4,000 Visit 1 Visit 2 Mean CRP (g/L) 30 20.11 Visit 1 Visit 2 Visit 1 Visit 1 Visit 1 Vi

CONCLUSION

9.05

Visit 2

Efficacy and Safety:

- Co-amoxiclav is highly effective and safe for URTI treatment.
- Most patients achieved clinical cure with minimal adverse events.

Role in Antimicrobial Resistance:

- Maintains effectiveness despite rising resistance trends.
- Beta-lactamase inhibitors enhance pathogen susceptibility, reinforcing their importance in combination therapies.

> Future Directions:

- Larger studies are needed to validate long-term outcomes.
- Continued research to refine treatment regimens and resistance monitoring.

REFERENCES

- ➤ Jin X, Ren J, Li R, et al. Global burden of upper respiratory infections in 204 countries and territories, from 1990 to 2019. eClinicalMedicine. 2021;37:100986. doi:10.1016/j.eclinm.2021.100986
- National Family Health Survey (NFHS-5), 2019-21. : International Institute for Population Sciences (IIPS); 2021.
- Liu L, Chu Y, Oza S, et al. National, regional, and state-level all-cause and cause-specific under-5 mortality in India in 2000–15: a systematic analysis with implications for the Sustainable Development Goals. Lancet Glob Health. 2019;7(6):e721-e734. doi:10.1016/S2214-109X(19)30080-4
- Evans J, Hanoodi M, Wittler M. Amoxicillin Clavulanate StatPearls NCBI Bookshelf. StatPearls Publ. Published online 2024.