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**Cochrane Clinical Answers****Question:****What are the benefits and harms of antibiotics for adults with acute rhinosinusitis?**

Jane Burch, Agustín Ciapponi

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Answer

Compared with placebo/no treatment for adults (average age 31 to 43 years; 52% to 73% women) showing clinical signs and symptoms of acute rhinosinusitis, antibiotics increases the number of people cured by 7 to 14 days (644 vs 568 per 1000 people, number needed to treat for one additional cure [NNTB] 19; all values on average) and the number with resolution of purulent secretions within 8 to 10 days (744 vs 648 per 1000 people NNTB 10). In addition, fewer people experienced clinical failure (defined in 8 RCTs as an abnormal course of rhinosinusitis leading to commencement or extension of antibiotic therapy) with antibiotics (55 vs 109 per 1000 people). Trials show that most people had full resolution of pain between days four and seven, with no apparent benefit of antibiotics. However, more people experienced an adverse effect with antibiotics than with placebo/no treatment (257 vs 135 per 1000 people; number needed to treat for one additional adverse event 8); this may be due primarily to diarrhea, as this was the only specific adverse effect for which data were available. When reviewers rated the quality of the evidence, it was of high certainty.

Comparisons

1. Antibiotics versus placebo/no treatment

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> OUTCOME 1.1 Cure at 7-14 days

Narrative result

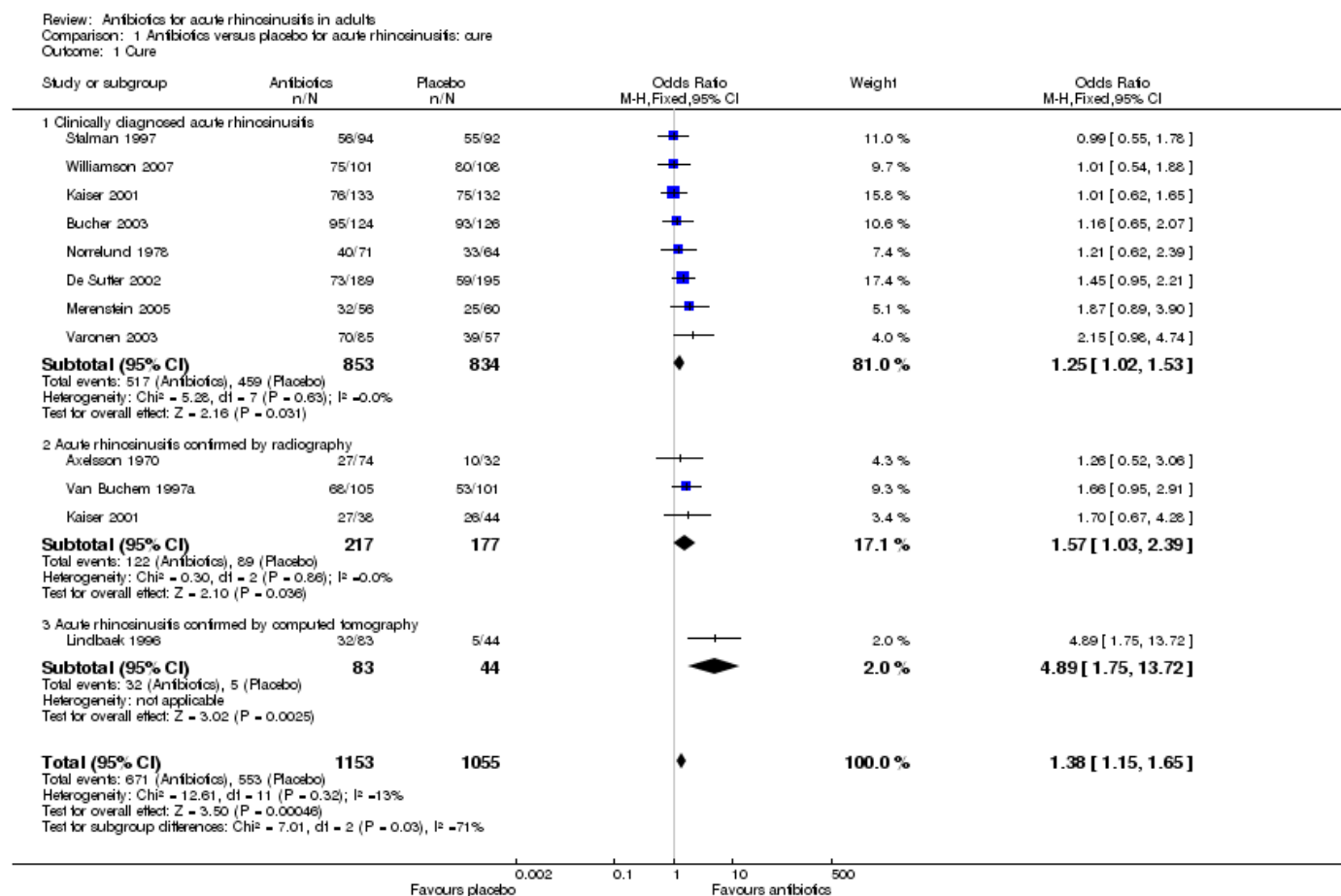
11 RCTs with 2208 participants found that more people were cured with antibiotics than with placebo/no treatment. Definitions of cure varied across trials, but all included resolution or improvement of major symptoms, evaluated by the participant alone. When trials were analyzed by method of rhinosinusitis diagnosis (clinical, radiography, CT) all three analyses showed a benefit of antibiotics.[1]

Quality of the evidence

The reviewers performed a GRADE assessment of the quality of evidence for this outcome at this time point and stated that the evidence was high certainty. [See Summary of findings from Cochrane Review](#)

Relative effect or mean difference

There was a statistically significant difference between groups, in favor of antibiotics (OR 1.38, 95% CI 1.15 to 1.65).

**Figure 1**[Open in figure viewer](#)

Forest plot from Cochrane Review

Absolute effect

644 per 1000 people (95% CI 602 to 684) with antibiotics compared with 568 per 1000 people with placebo/no treatment (calculated using median event rate). The number needed to benefit was 19 (95% CI 10 to 205).

Reference

Lemienre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. *Antibiotics for acute rhinosinusitis in adults*. *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

OUTCOME 1.2 Resolution of purulent secretions at 8-10 days

Narrative result

Three RCTs with 660 participants found that more people had resolution of purulent secretions with antibiotic than with placebo.[2]

Quality of the evidence

The reviewers performed a GRADE assessment of the quality of evidence for this outcome at this time point and stated that the evidence was high certainty. See [Summary of findings from Cochrane Review](#)

Relative effect or mean difference

There was a statistically significant difference between groups, in favor of antibiotics (OR 1.58, 95% CI 1.13 to 2.22).

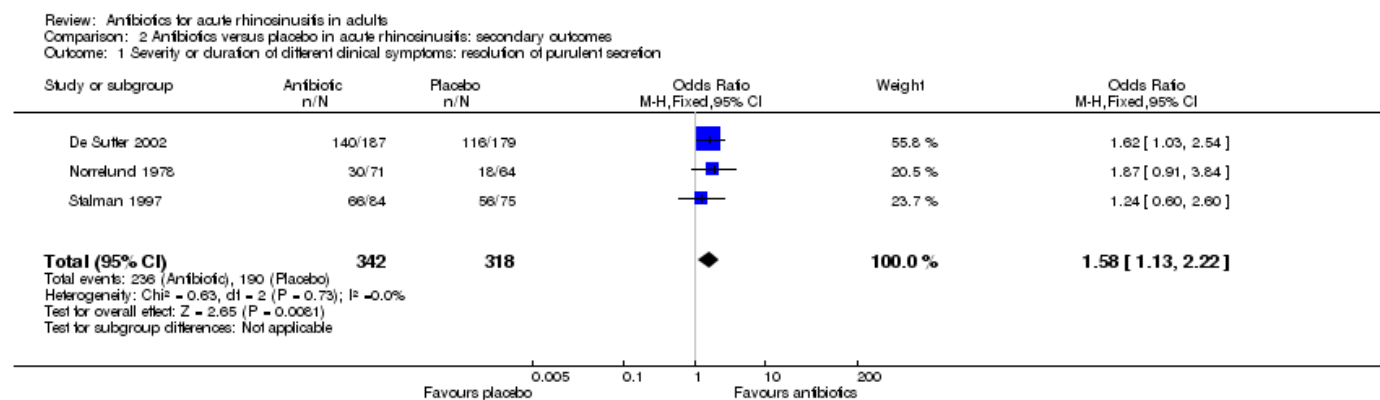


Figure 2

Forest plot from Cochrane Review

[Open in figure viewer](#)

Absolute effect

744 per 1000 people (95% CI 675 to 803) with antibiotic compared with 648 per 1000 people with placebo (calculated using median event rate). The number needed to benefit was 10 (95% CI 6 to 35).

Reference

Lemiengre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. [Antibiotics for acute rhinosinusitis in adults](#). *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

➤ OUTCOME 1.3 Resolution/duration of pain

Narrative result

Five RCTs reported on pain. Three RCTs with 779 participants reported no difference in general pain duration between groups; full resolution of pain for most participants between days 4 and 7. Specific types of pain assessed in some RCTs; facial (1 RCT), on bending forward (1 RCTs), in upper teeth or when chewing (2 RCTs), facial, pressure, or tenderness (2 RCTs), and sinus headache (2 RCTs); none showed a statistically significant difference in pain duration between groups. One RCT with 204 participants reported no difference between groups in symptom scores at one and two weeks for frontal pain, maxillary pain, headache on bending, or tapping pain.[3]

Risk of bias of studies

The reviewers did not perform a GRADE assessment of the quality/certainty of the evidence. Of the five studies, one failed to report adequate allocation concealment and one had unclear numbers of withdrawals, but all used appropriate random sequence generation and blinding of participants/carers/outcome assessors.

Relative effect or mean difference

Results were reported narratively.

Reference

Lemiengre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. [Antibiotics for acute rhinosinusitis in adults](#). *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

> OUTCOME 1.4 Duration of symptoms

Narrative result

Five RCTs with 669 participants reported mean illness duration; most found no statistically significant differences between groups; one trial with 63 participants reported a 6 to 8-day reduction in time to cure with antibiotics.[4]

Risk of bias of studies

The reviewers did not perform a GRADE assessment of the quality/certainty of the evidence. Of the five studies, two failed to report adequate allocation concealment, two did not report on random sequence generation, and one did not report blinding of participants/carers/outcome assessors; all had low numbers of withdrawals.

Relative effect or mean difference

Results were reported narratively. Mean illness durations for individual studies reported. Study 1: 5 days with azithromycin vs 7 days with placebo in people with *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis*, and 6 days in both groups for people without the bacteria. Study 2: Subjective improvement after 3.5 days with antibiotic vs 3.7 days with placebo. Study 3: 6.0 days with antibiotic vs 6.4 days with placebo (P = 0.66). Study 4: 6.0 days with antibiotic vs 6.4 days with placebo (P = 0.66). Study 4: Cured after 9 days with amoxicillin and 11 days with penicillin vs 17 days with placebo in people with a fluid level or total opacification in any sinus on CT. 10 days with penicillin and amoxicillin and 13.5 with placebo for people with only mucosal thickening on CT.

Reference

Lemiengre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. [Antibiotics for acute rhinosinusitis in adults](#). *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

> OUTCOME 1.5 Clinical failure (time frame not reported)

Narrative result

12 RCTs with 2603 participants found that fewer people had clinical failure with antibiotics than with placebo/no treatment. Clinical failure was defined in 8 RCTs as an abnormal course of rhinosinusitis (exacerbation, ongoing symptoms, respiratory complications, treatment failure) leading to commence or extend antibiotic therapy.

When trials were analyzed by method of rhinosinusitis diagnosis (clinical, radiography, computed tomography), the overall pooled result was very similar to the largest subgroup diagnosed clinically (2101 participants). The subgroup that used computed tomography (190 participants) also showed a benefit of antibiotics, but the subgroup that used radiography showed no statistically significant difference between groups.[5]

Quality of the evidence

The reviewers performed a GRADE assessment of the quality of evidence for this outcome at this time point and stated that the evidence was high certainty. See [Summary of findings from Cochrane Review](#)

Relative effect or mean difference

There was a statistically significant difference between groups, in favor of antibiotics (Peto OR 0.48, 95% CI 0.36 to 0.63).

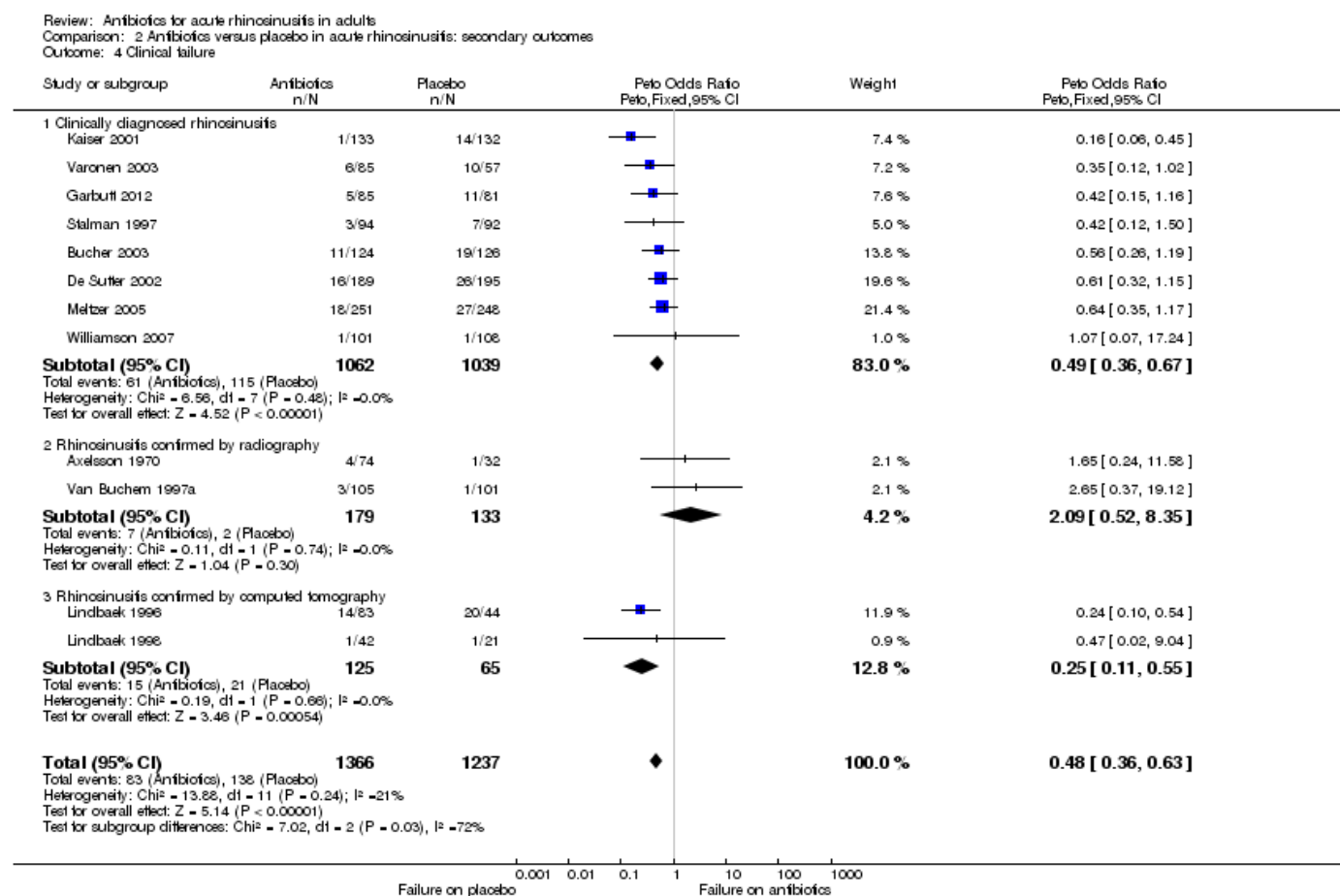


Figure 3

Forest plot from Cochrane Review

[Open in figure viewer](#)

Absolute effect

55 per 1000 people (95% CI 42 to 72) with antibiotics compared with 109 per 1000 people with placebo/no treatment (calculated using median event rate). The number needed to harm was 19 (95% CI 15 to 27).

Reference

Lemiengre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. [Antibiotics for acute rhinosinusitis in adults](#). *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

> OUTCOME 1.6 Activities of daily living

Narrative result

Four RCTs with 986 participants reported on restriction of daily activities due to rhinosinusitis; none showed a statistically significant difference between groups.[6]

Risk of bias of studies

The reviewers did not perform a GRADE assessment of the quality/certainty of the evidence. Of the four studies, one failed to report adequate allocation concealment, but all used appropriate random sequence generation and blinding of participants/carers/outcome assessors and had low numbers of withdrawals.

Relative effect or mean difference

Results were reported narratively.

Reference

Lemiengre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. [Antibiotics for acute rhinosinusitis in adults](#). *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

> OUTCOME 1.7 Analgesic use

Narrative result

Ten RCTs with 1924 participants reported on analgesic use: paracetamol (9 RCTs) and/or ibuprofen (4 RCTs). Four reported no effect of antibiotics on analgesic use. One RCT with 137 participants reported that analgesic use was less frequent with antibiotics than placebo (26% with antibiotic vs 43% with placebo; $P = 0.03$). Results for other trials were not reported.[7]

Risk of bias of studies

The reviewers did not perform a GRADE assessment of the quality/certainty of the evidence. Of the ten studies, two failed to report adequate allocation concealment and one did not report on random sequence generation or blinding of participants/carers/outcome assessors; all had low numbers of withdrawals.

Relative effect or mean difference

Results were reported narratively.

Reference

Lemiengre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. [Antibiotics for acute rhinosinusitis in adults](#). *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

> OUTCOME 1.8 Nasal decongestant use

Narrative result

11 RCTs with 1918 participants reported on use of xylometazoline nose drops; 6 RCTs prescribed nasal decongestants for every participant one of which also permitted use of pseudoephedrine-sustained action. Corticosteroid nose drops were part of the intervention in two RCTs. One RCT specified that concomitant medication that could interfere with the study medication was not permitted. Three RCTs registered use of nose drops (vasoconstrictors), antihistamines or pseudoephedrine-sustained action; none found a statistically significant difference between groups.[8]

Risk of bias of studies

The reviewers did not perform a GRADE assessment of the quality/certainty of the evidence. Of the 11 studies, five failed to report adequate allocation concealment, four did not report on random sequence generation, three did not report blinding of participants/carers/outcome assessors, and one had unclear numbers of withdrawals.

Relative effect or mean difference

Results were reported narratively.

Reference

Lemiengre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. [Antibiotics for acute rhinosinusitis in adults](#). *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

> OUTCOME 1.9 Adverse effects

Narrative result

Ten RCTs with 1816 participants found that more people experienced an adverse effect with antibiotics than with placebo/no treatment. When trials were analyzed by method of rhinosinusitis diagnosis (clinical, imaging) results were similar to the main analysis. The only adverse effect for which data were reported individually was diarrhea; more people had diarrhea with antibiotics than with placebo. Click below for details.[9]

Quality of the evidence

The reviewers performed a GRADE assessment of the quality of evidence for this outcome at this time point and stated that the evidence was high certainty. See [Summary of findings from Cochrane Review](#)

Relative effect or mean difference

There was a statistically significant difference between groups, in favor of placebo/no treatment (OR 2.21, 95% CI 1.74 to 2.82).

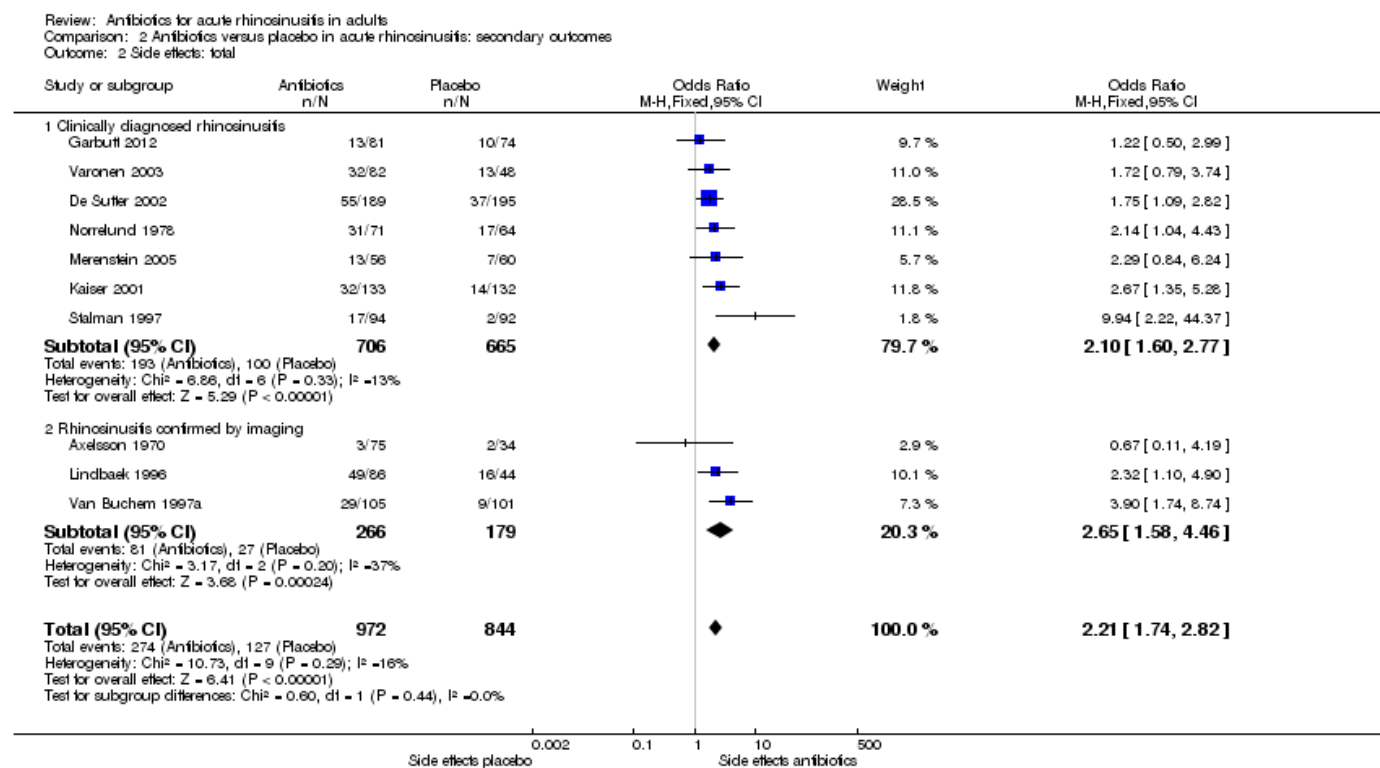


Figure 4
Forest plot from Cochrane Review

[Open in figure viewer](#)

Absolute effect

257 per 1000 people (95% CI 213 to 306) with antibiotics compared with 135 per 1000 people with placebo/no treatment (calculated using median event rate). The number needed to harm was 8 (95% CI 6 to 12).

Reference

Lemiengre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. Antibiotics for acute rhinosinusitis in adults. *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

> Subgroup analysis 1.9.1 Adverse effects – [subgroup: Diarrhea]

Narrative result

Seven RCTs with 1210 participants found that more people had diarrhea with antibiotics than with placebo/no treatment.[10]

Quality of the evidence

The reviewers performed a GRADE assessment of the quality of evidence for this outcome at this time point and stated that the evidence was high certainty. See [Summary of findings from Cochrane Review](#)

Relative effect or mean difference

There was a statistically significant difference between groups, in favor of placebo/no treatment (Peto OR 2.00, 95% CI 1.41 to 2.85).

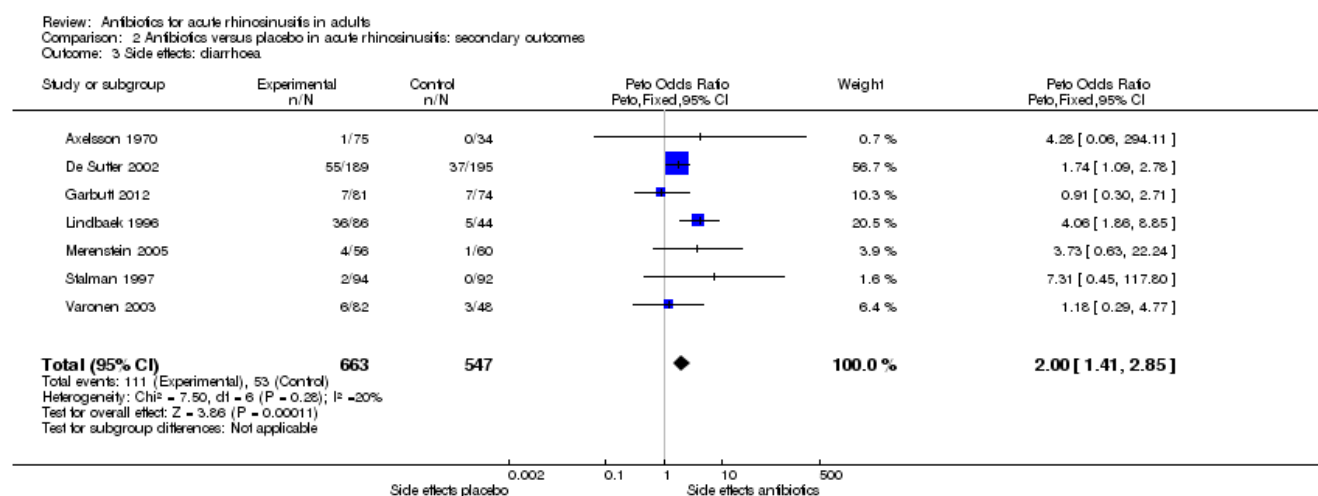


Figure 5

Forest plot from Cochrane Review

[Open in figure viewer](#)

Absolute effect

173 per 1000 people (95% CI 128 to 229) with experimental compared with 95 per 1000 people with placebo/no treatment (calculated using median event rate). The number needed to harm was 13 (95% CI 8 to 29).

Reference

Lemiengre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. [Antibiotics for acute rhinosinusitis in adults](#). *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

› OUTCOME 1.10 Complications of acute rhinosinusitis, Antibiotic resistance

Narrative result

Reviewers did not assess these outcomes.[11]

Reference

Lemiengre MB, van Driel ML, Merenstein D, Liira H, Mäkelä M, De Sutter AIM. [Antibiotics for acute rhinosinusitis in adults](#). *Cochrane Database of Systematic Reviews* 2018, Issue 9. Art. No.: CD006089. DOI: 10.1002/14651858.CD006089.pub5. Search date January 2018

✓ Population, Intervention, Comparator

Population

Adults (where reported, average age 31 to 43 years and 52% to 73% women) showing clinical signs and symptoms of acute rhinosinusitis; diagnosis confirmed using rhinoscopy (5 RCTs), radiography (3 RCTs), computed tomography (CT; 2 RCTs) or unspecified type of radiology (1 RCT). Where reported, duration of symptoms ranged from 4 to 15 days. Of the 15 RCTs, 13 excluded people with recent antibiotic use and 11 excluded people with chronic ear, nose and throat disease and/or comorbid conditions. Trials were published between 1970 and 2012

Intervention

Antibiotics: amoxicillin 500 to 875 mg two or three times daily for 6 to 10 days (10 RCTs), penicillin V 400 to 1320 mg or 1500 IU two or three times daily for 7 to 10 days (4 RCTs), doxycycline 100 to 200 mg once or twice daily for 6 to 7 days (3 RCTs), lincomycin 500 mg three times daily for 8 days (1 RCT), azithromycin 500 mg daily for three days (1 RCT), or pivampicillin 700 mg twice daily for six days (1 RCT); several trials had multiple intervention arms

Comparator

Placebo (14 trials; 2945 participants) or no treatment (1 trial; 112 participants)

Additional Information

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