



Anti-Bacterials
in
Acute Bacterial Sinusitis
(ABS)



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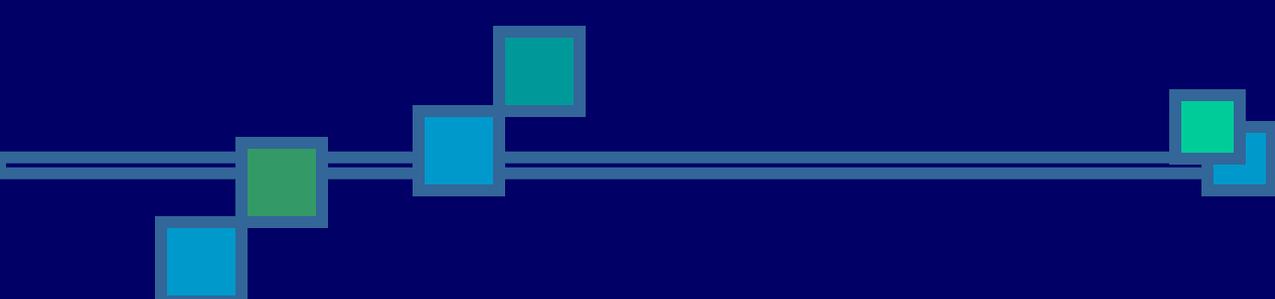
Treatment of acute bacterial sinusitis

- Difficult to differentiate viral from bacterial clinically
- Persistence of symptoms longer than seven days WITHOUT improvement
- Presence of facial pain and pressure AND purulent nasal drainage
- Use a narrow spectrum antibacterial active against likely pathogens: *St. pneumoniae* and *H. influenzae*
- Hickner JM, Bartlett JG et al: Ann Intern Med 2001
- Piccirillo J, NEJM 2004
- SAHP, OTO HNS 2004

Incidence and Complications

- Incidence adults: 20 Million/ yr
 - 2% viral infections
 - 3-4 colds/yr adults
- Complications: rare
 - 1 in 15,000
 - Piccirillo NEJM 2004
 - Intracranial abcess
 - Orbital abcess
 - Cavernous sinus thrombosis
 - ?Chronic Sinus Disease





FDA requirements for ABS trials

- Higher standard than clinical practice
 - Radiographs positive
 - In at least one trial – sinus tap
 - Comparison to an effective approved antibiotic in a non inferiority trial
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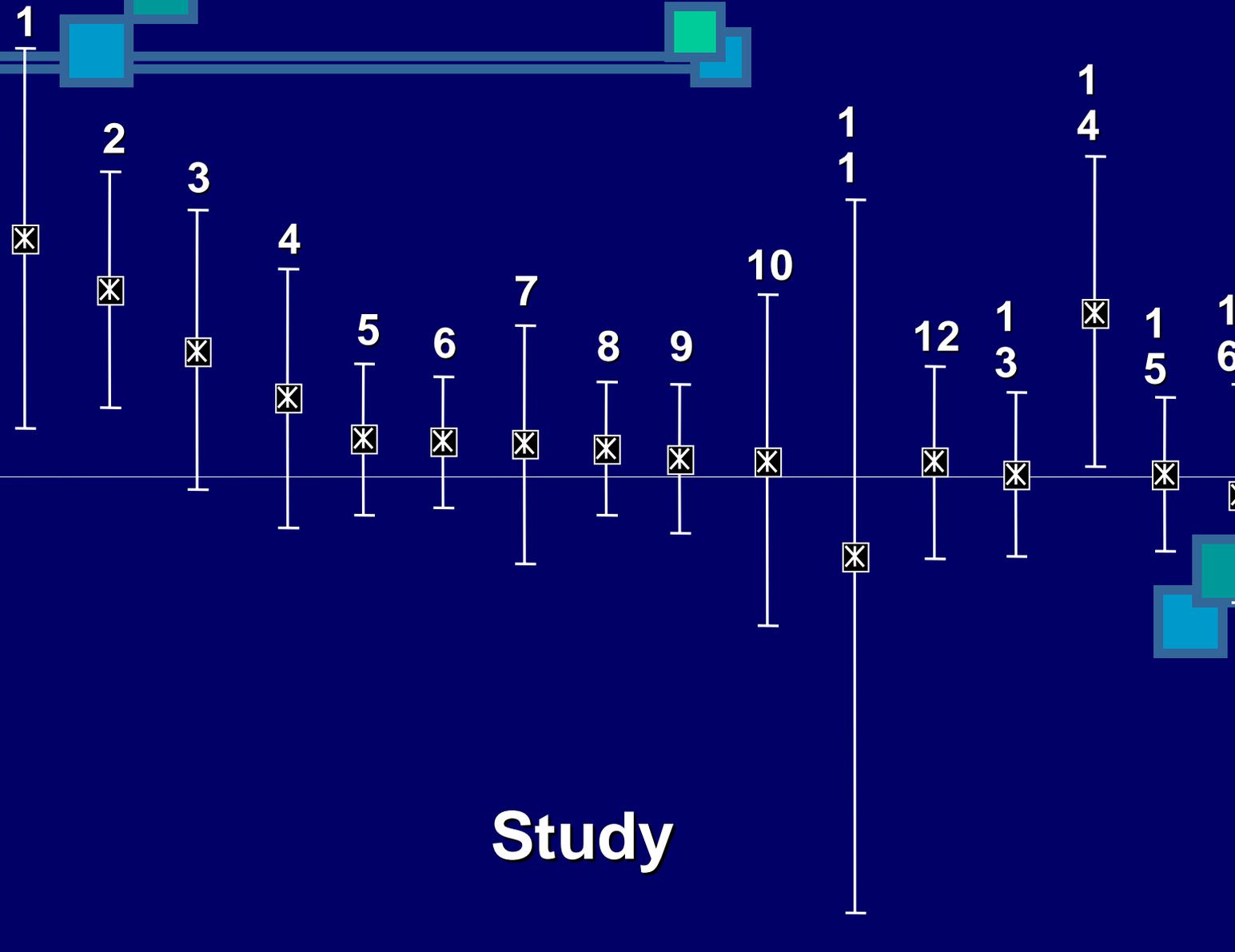
2002 Advisory Committee to FDA - Recommended placebo controlled trials in ABS

- In Sept 2006, Gemifloxacin voted not effective
 - Non inferiority boundary of -10% compared to cefuroxime in tap trials
 - In Oct 2006, Faropenem voted not effective
 - Non inferiority trials
- 

Antimicrobial Efficacy (95% CI)

70
50
30
10
-10
-30
-50
-70

Study



Antibiotics Demonstrate Clinical Benefit in 6 ABRS Studies

Axelsson et al. 1970

Lincomycin/penicillin V N=106

Favors antibiotic

Favors placebo

Gananca et al. 1973

Cyclacillin N=50

Wald et al. 1986

Amoxicillin/Amox-clavulanate
N=93

Lindbaek et al. 1996

Amoxicillin/penicillin N=130

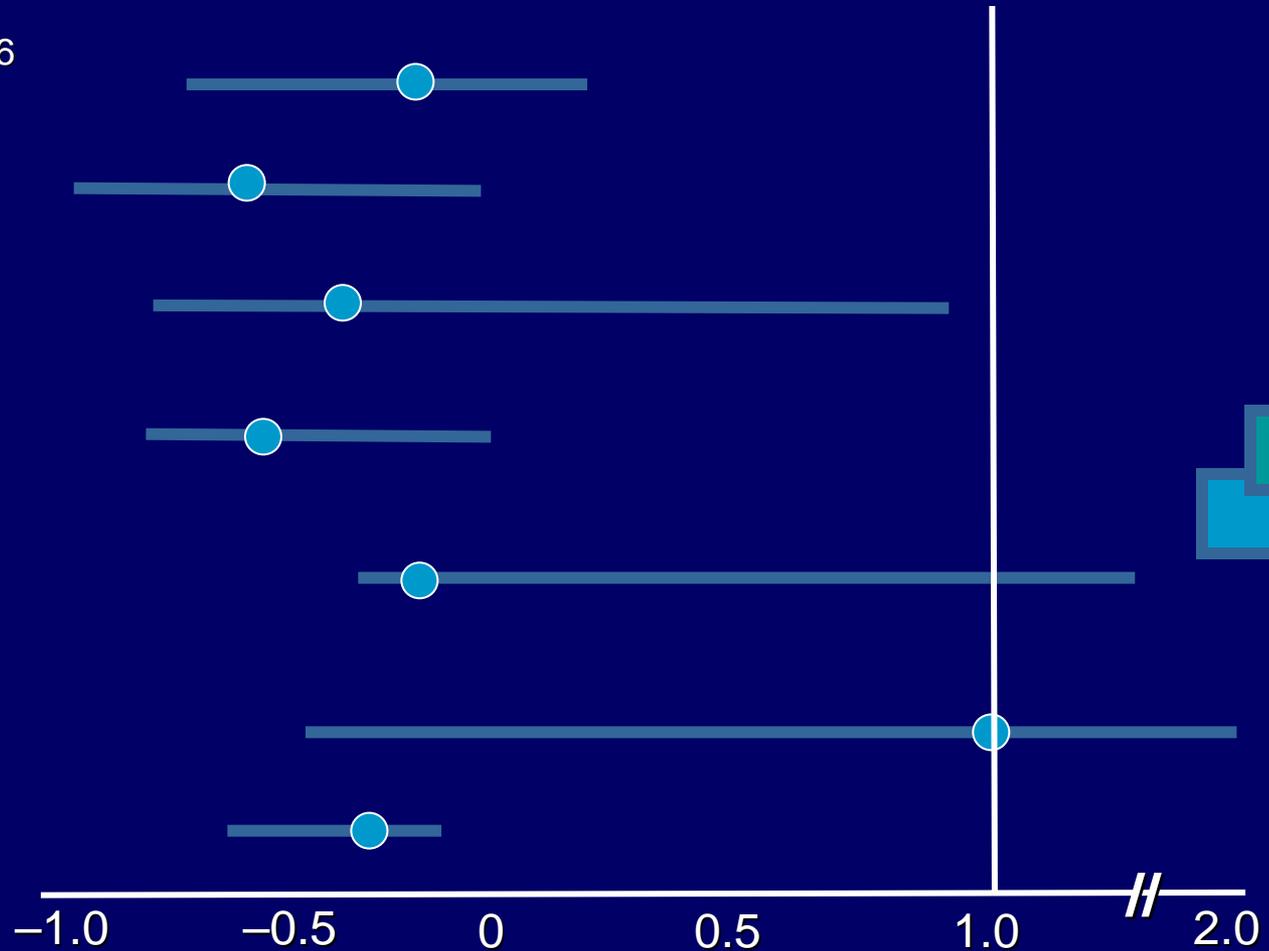
van Buchem et al. 1997

Amoxicillin N=206

Stalman et al. 1997

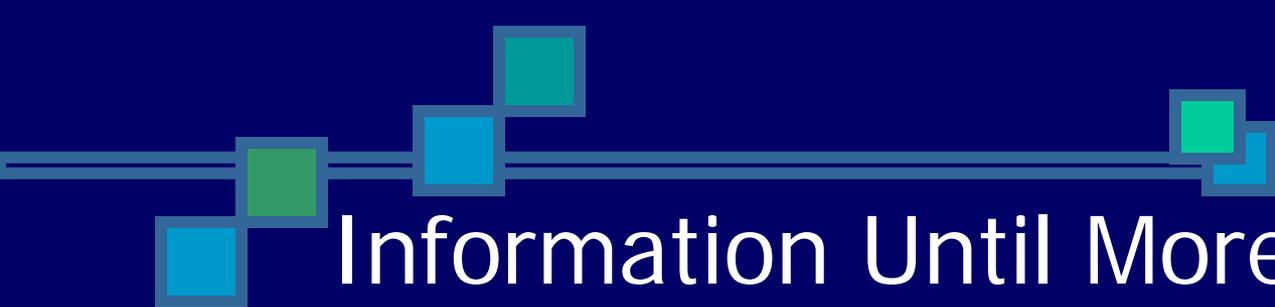
Doxycycline N=176

Overall N=761



Risk Ratio

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Information Until More Arrives

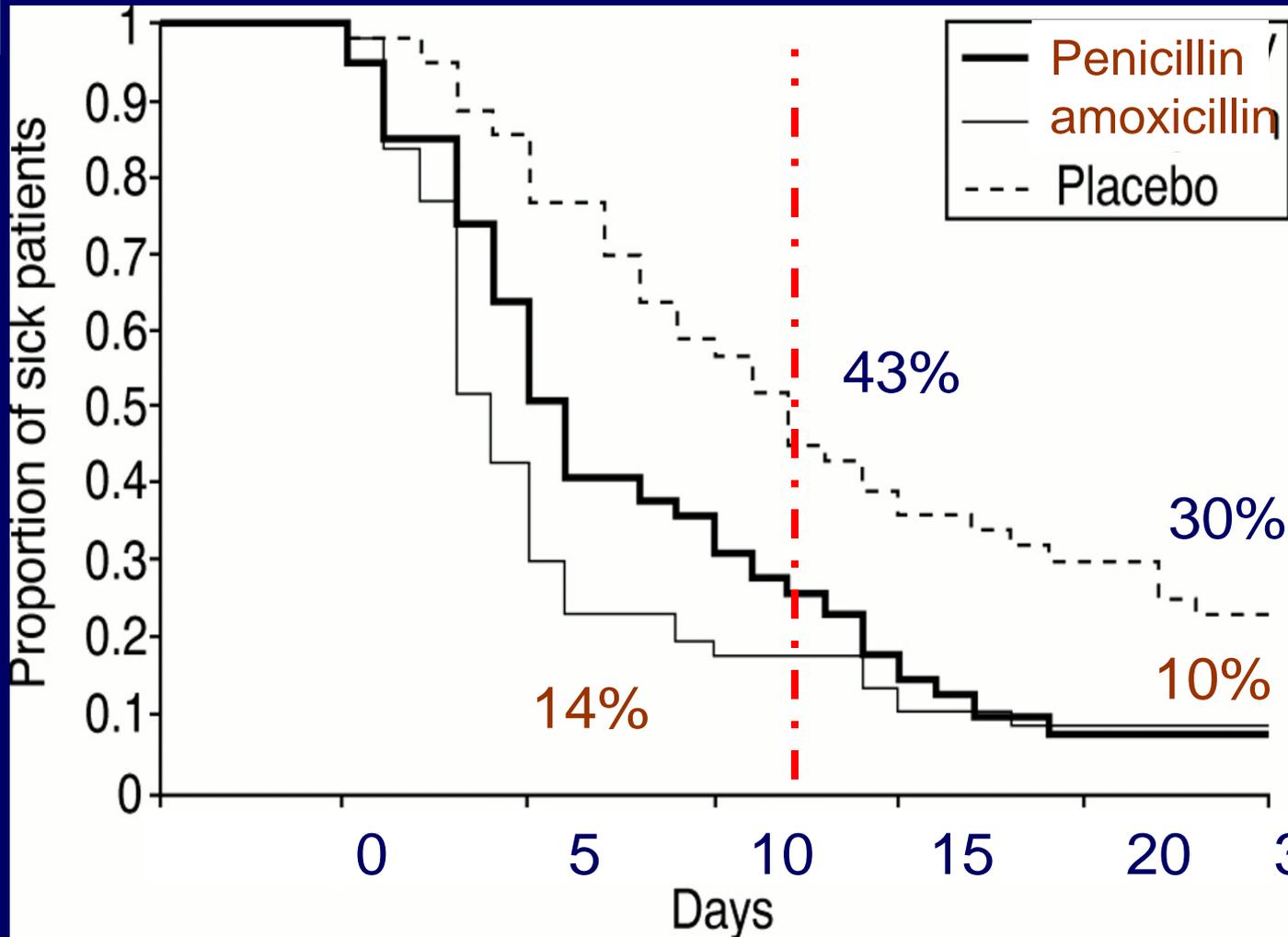
Lindbaek, M. et al. BMJ 1996;313:325-329

- ❑ **No industry sponsorship**
- ❑ **Norwegian Research Council**
- ❑ **Double blind placebo controlled study**
- ❑ **Penicillin (39) vs. amoxicillin (44) vs. placebo (44)**

Conclusion: In appropriately selected patients, antibiotics work



Proportion of 127 patients in three treatment groups by days from start of treatment





Treatment Guidelines

- Patient with persistent signs and symptoms of bacterial sinusitis
 - > 7-10 days, or
 - Worsens after 5-7 days
 - Treatment with narrow spectrum antibacterials is recommended
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- Hickner JM, Bartlett JG et al: Ann Intern Med 2001
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Conclusion– what about telithromycin in ABS

- Efficacy Properties
 - Narrow spectrum
 - In vitro activity against Respiratory Pathogens, including resistant strains
 - Efficacy approved by FDA based on non inferiority comparator trials
 - Risk: must be similar or less than other antibiotics available for ABS
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