

The Use of Prophylactic Antibiotics in Middle Ear Surgery

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Definition

SSI in otologic surgery, outcome reporting seen in all studies (not uniformly reported with respect to either timing post-op or type of infection): Abscess, Cellulitis – post-auricular or external incisions, drainage (otorrhea), TM graft failure

Class	Description	Example
I: Clean	Uninfected operative wound in which no inflammation is encountered and the respiratory or alimentary tract is not entered	Otoplasty
II: Clean-Contaminated	Operative wound in which the respiratory or alimentary tract is entered under controlled conditions and without unusual contamination	Stapedectomy cochlear implant
III: Contaminated	Open, fresh, accidental wounds; operations with major breaks in sterile technique or gross spillage from the aerodigestive tract; incisions in which acute, nonpurulent inflammation is encountered	Tympanoplasty for perforation with otorrhea
IV: Dirty-Infected	Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera	Tympanoplasty for cholesteatoma with keratin debris and exudate

*Modified from Mangram et al.¹

Pierce, Antonelli. The Laryngoscope 2016;126:2363

Clean contaminated (no infection/inflammation, with TM dry perforation i.e., myringoplasty), ossicular reconstruction (excluding cochlear implantation)

Low incidence of post-op SSI and no proven efficacy of antibiotic therapy to reduce SSI in early post-operative period (<3 weeks)

Cochrane review – pooled fixed effect OR = 0.73, NS, 5.1% vs. 6.1% abx vs. prophylaxis (Bagger-Sjoberg 1987, Donaldson 1966, Eschelman 1971, Govaerts 1998, Hester 1998, Pirodda 1994)

No effect on long term (>2 month) in post-op SSI

Cochrane review (Pirodda, Winerman) – 172 patients, 10.5% rate in both placebo and abx group, OR = 1.00 NS

No statistically significant impact seen in otitis externa within 2 months post-op

Cochrane (Lildholdt 1986, Pirodda 1994) – N=126, placebo 12.9% vs. abx 4.7%, OR = 0.29 (NS)

Low incidence of post-op SSI and no proven efficacy of antibiotic therapy to reduce outcome of graft in early or late post-operative follow up (up to 3 months)

Cochrane

Govaerts et al. Laryngoscope 1998;108:107-110. Suggests early (within post-op 1 week) benefit to abx but no difference overall of result

Insufficient studies evaluating outcomes in long-term post-op prophylaxis, but given success low incidence of graft failures and SSI does not suggest strong need for post-op antibiotics

Contaminated (COM +/- cholesteatoma +/- mastoidectomy)

Pre-operative topical treatment with topical ofloxacin does not affect tympanoplasty graft success but does decrease bacterial flora in CSOM-C

Tong, Yue, Ku, van Hassel. Otology & Neurotology 2002;23(1):18-20

- No difference in graft outcomes ofloxacin administered topically between 3 groups: A) 2 weeks pre-op 10min/rx, B) 2 weeks pre-op 3min/rx, C) no treatment

In tympanomastoidectomy for COM with no cholesteatoma, abx does not result in reduced post-op SSI and graft success

Bidkar 2014

Dirty

*CSOM+/-cholesteatoma with purulent discharge (i.e., culture positive for *Pseudomonas aeruginosa*) may benefit from perioperative antibiotics (pre and post-op)*

Lildholdt et al. 1986.

*If not culture directed, choice of antibiotics should cover common agents found in the microbiome of CSOM, in particular *Pseudomonas aeruginosa* and *Staphylococcus sp.**

Ye et al. Bacteriology of CSOM—a multicenter study. *Acta Oto-Laryngologica* 2007;127:1062-1067.

- Multicenter study of 1102 patients throughout Korea in 6 hospitals presenting with purulent or mucopurulent otorrhea +/- cholesteatoma

Adverse effects of antibiotic prophylaxis

Only 2 studies reported adverse drug effects total of 4/428 in abx group and somehow 5/413 in control group (NS) when giving systemic pre-operative antibiotics just prior to surgery+/-topical preparations post-op.

Cochrane Review

Prolonged and extended duration of post-op systemic antibiotic prophylaxis has a statistically significant higher risk of adverse effects in patients undergoing otologic surgery

Bidkar 2014 – no specific types of AE outcomes reported, but mention GI upset as main AE

Timing of antibiotics

Systemic antibiotics should be administered prior to

- Goevarts 1998 examined timing with no evidence to suggest differences (likely secondary to low overall rate of infection or underpowered study) based on administration of prophylactic abx between 2hrs pre and 2hrs post induction

Summary

- Evidence in multiple RCTs supports no identifiable benefit to providing systemic antibiotic prophylaxis in clean or clean contaminated otologic surgery
- The risk of adverse events with perioperative antibiotics given as a single perioperative dose is very low
- No proven efficacy of prolonged post-op systemic antibiotics in clean, clean-contaminated, contaminated otologic surgery
- Most trials report the use of a topical antimicrobial agent +/- topical steroid in post-op packing or topical ear drops, however this is variable and there is no strong evidence to support one option over another
- Perioperative prophylaxis if chosen in contaminated or dirty settings (i.e., chronic suppurative otitis media) microbial coverage should include gram positive flora (i.e., *Staphylococcus ss.*) and *Pseudomonas aeruginosa*
- Despite the existence of randomized control trials with adequate blinding above classifications of surgical wound site is based off original surgical site complication—there is a need for better quality research where there is a standardized definition for diagnosis, classification, and outcome reporting in otologic surgery

APPENDIX

Studies reviewed:

Donaldson 1966

- RCT, myringoplasty (different types)
- Intervention: sulfamethoxazole vs. nil, both had polymyxin B-neomycin-hydrocortisone impregnated sponge
- Outcomes: Post-op SSI on POD 10, 6 weeks, closure of TM/graft success

Eschelmann 1971

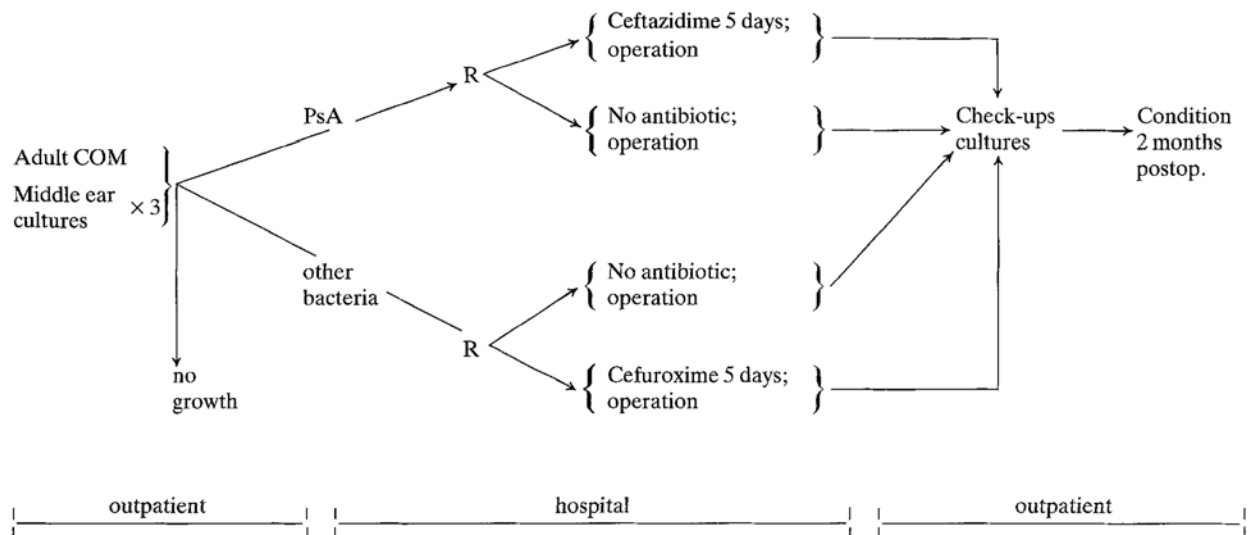
- RCT, grouping I) tympanomastoid+C, II) tympanoplasty and tympanomastoid-C, III) tympanotomy, stapedectomy
- Intervention: 1) penicillin, 2) ampicillin, 3) placebo
- Outcomes: Post-op SSI

Winerman 1981

- RCT, tympanomastoid (closed cavity procedures)
- Intervention: clindamycin + gentamicin vs. placebo
- Outcome: infection within 3 months post-op

Lildholdt 1986 (only reporting one subset, the ceftazidime arm)

- RCT, COM with +ve cultures for Pseudomonas (only study to isolate purulent discharging ears for surgery)
- Intervention: Ceftazidime (starting 24 hours pre-op, then continuing for 5 days post op) vs. none and surgery only; no topical abx reported
- Outcome: post-op discharge, discharge after 2 months, graft failure after 2 months



Bagger-Sjoberg 1987

- RCT, all types of surgery
- Intervention: phenoxymethylpenicillin + hydrocortisone impregnated gauze vs. hydrocortisone impregnated gauze
- Outcome: post-op SSI after 6-8 days

Jackson 1988

- RCT, types of surgical procedures not specified and included neurotological surgery
- Intervention: cephalothin or ancef or oxacillin or vancomycin vs. none
- Outcome: Graft failure after 3 weeks

John 1988

- RCT, tympanoplasty
- Intervention: ampicillin + flucloxacillin vs. none
- Outcome: closure of TM after 8 weeks

Pirodda 1994

- RCT, I – mastoidectomy (different types), II – tympanoplasty (different types)
- Interventions: ceftriaxone vs. nil
- Outcomes: discharge (at 1 week, 1 month, 2 months); perforation of TM (1 week, 1 month, 2 months); stable situation (1 week, 1 month, 2 months)

Govaerts et al. Laryngoscope 1998;108:107-110.

- Prospective, double blind, RCT, N = 750 cases
- Intervention: Cefuroxime 1.5g IV at moment of induction, had post-operative packing with abx ointment
- Control: placebo drug injected
- Outcome: evaluation for SSI at POD 2, 7, 14 and 3 months; SSI fever, wound inflammation, secretion, myringitis, otitis media, evaluated by resident (blinded)
- Results: Overall infection rate 4.7% vs. 3.1% in placebo vs. abx group (NS); on POD 2, 7 RR of 3 for SSI between placebo and cefuroxime groups ($p < 0.05$); ears that sustained infection had longer operative times ($p < 0.05$), all infections in tympanoplasty; some inconsistencies with data reporting, report infection only in tympanoplasty group with allograft but had a RR of infection in normal ears (figure 6), highest RR of infection in wet perforation vs. dry chol or wet chol
- 3 cases of graft necrosis – 1 in placebo, 2 in abx group

Hester 1998

- RCT, population = tympanoplasty, tympanomastoidectomy, radical mastoidectomy
- Intervention:
- Outcome: SSI post-op 3 weeks, graft failure at 3 weeks and 3 months

Tong 2002

- RCT, tympanoplasty only
- Intervention: pre-op ofloxacin 10min/d x2 weeks, pre-op ofloxacin 3min/d x2 weeks or no abx
- Outcome: closure of TM after 8 weeks

Yeo et al. Acta Oto-Laryngologica 2007

Table II. Bacteriologic results of cultured organisms.

Isolated organism	Noncholesteatoma <i>n</i> (%)	Cholesteatoma <i>n</i> (%)	Total <i>n</i> (%)
Gram-positive bacteria			
MRSA	177 (25.6)	47 (20.1)	224 (24.2)
MSSA	122 (17.6)	30 (12.8)	152 (16.4)
CNS	66 (9.5)	43 (18.4)	109 (11.8)
Streptococcus pneumoniae	7 (1.0)	0	7 (0.8)
Corynebacterium	11 (1.6)	6 (2.6)	17 (1.8)
Gram-negative bacteria			
Pseudomonas aeruginosa	219 (31.7)	75 (32.1)	294 (31.8)
Providencia	13 (1.9)	6 (2.6)	19 (2.2)
Acinetobacter	10 (1.5)	5 (2.1)	15 (1.6)
Proteus	7 (1.0)	6 (2.6)	13 (1.4)
Alcaligenes	10 (1.5)	2 (0.9)	12 (1.3)
Klebsiella	7 (1.0)	3 (1.3)	10 (1.1)
Enterobacter	7 (1.0)	3 (1.3)	10 (1.1)
Citrobacter	7 (1.0)	0	7 (0.8)
Serratia	6 (0.9)	0	6 (0.6)
Escherichia coli	4 (0.6)	2 (1.1)	6 (0.6)
Others	19 (2.7)	6 (2.6)	25 (2.7)
Total	692 (100)	234 (100)	926 (100)

MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-sensitive *Staphylococcus aureus*; CNS, coagulase-negative *Staphylococcus*.

Bidkar et al. *Laryngoscope* 2014;124:1459-1463

- RCT, double blind, patients with tympanomastoidectomy, patients with both wet and dry COM-C (whether or not they had at least one episode of ear discharge 1 month prior to surgery); temporalis fascia graft used in all cases; demographics and disease not different between groups
- Intervention: all patients had gel-foam with steroid drops in EAC then abx + steroid drops starting after week 1; I) pre-op cefuroxime II) pre-op cefuroxime + PO cefixime BID x8 days
- Outcomes: N=78 (39 each group), no difference in outcomes (presence of wound infection or graft success between 1 week and 1 month) with overall graft success at 1 month (94.87% and 97.44% between group I and II); adverse events much higher in group II (19/39, n=48.72%) vs. group I (1/39, n=2.56%) no reports of specific type other than mentioning GI disturbance

Pierce, Antonelli. *The Laryngoscope* 2016;126:2363 – data quality insufficient, retrospective cohort of contaminated wounds

Verschuur HP, de Wever, van Benthem. *Cochrane review* 2010