Evidence Table 11. Systematic reviews

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Browning et al., 20101Denmark: Arhus University, Arhus University Research Foundation, University of Southern Denmark, The Foundation for Research in General Practice and the Health Care System; and UK National Institute for Health Research Cochrane Review Incentive SchemeSystematic review | Number of Patients1728 in 10 studies of children with OMEAims of ReviewTo assess the effectivness of grommet insertion compared with myringotmy or non-surgical treatment in children with OMEStudies Included in Analysis or Review10 studies, Maw 1979-862, Black, 19903, Dempster 19934,Gates 19875, Rach 19916, Mandel 19927, Maw 19998, Rovers 20009, MRC: TARGET 200110, Paradise 200111Characteristics of Included Studies RCTs1. Unilateral tubes vs. no surgery OR myringotomy 2. Bilaterial tubes vs. no surgery OR myringotomyCould have short doses of anagesics or antibiotics for AOM in pre-randomization period or decongestants**Criteria for diagnosing OME**OME had to be diagnosed objectively using a combination of otoscopy (pneumatic and microscopic), tympanometry and audiometry **Setting(s):**Referral population, largely to otolaryngology clinics in academic medical centersCharacteristics of Included Populations Children 1-12 years with bilateral OME Characteristics of Interventions* Black 1990: TT vs. myringotomy (adenoidectomy group not included in this review)
* Dempster 1993: unilateral TT vs. WW (adenoidectomy not included)
* Gates 1987: bilateral myringotomy vs. bilateral TT vs. bilateral myringotomy and adenoidectomy vs. bilateral TT and adenoidectomy
* Mandel 1992: bilateral TT vs. bilateral myringotomy vs. no surgery
* Maw 1986:Adenotonsillectomy and unliteral TT vs. adenoidectomy and unilateral TT vs. unilateral TT vs. WW
* Maw 1999: bilateral TT vs. WW
* MRC: TARGET 2001: WW vs. bilateral TT vs. bilateral TT plus adenoidectomy
* Paradise 2001: bilateral TT early vs. WW and bilateral TT delayed
* Rach 1991: bilateral TT vs. WW
* Rovers 2000: bilateral TT vs. WW
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Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Browning et al., 20101(continued) | Main ResultsHearing in dB: Negative result: better in tube group * By child, 3 months (1 study) (N=215)

Bilateral tubes vs. watchful waiting: Mean Difference -11.9 (95% CI, -9.6 to -14.2) * By child, 6 to 9 months (MA:3 studies) (N=523)

Bilateral tubes vs. watchful waiting: Mean Difference - 4.20 (95% CI, -6.00 to -2.39) * By child 12 months (MA: 2 studies) (N=328)

Bilateral tubes vs. watchful waiting: Mean Difference - 0.41 (95% CI, -2.37 to 1.54)* By child 18 mos (MA: 2 studies) N=283

Bilateral tubes vs. watchful waiting: Mean Difference -0.02 [ -3.22 to 3.18 ] * By ear, 4 to 6 months (MA: 3 studies) (N=230 ears)

Unilateral tubes vs. watchful waiting (2 studies) or myringotomy (1 study): Mean Difference -10.08 (95% CI, -19.12 to -1.05)* By ear, 7 to 12 months (MA: 3 studies) (N=234 ears)

Unilateral tubes vs. watchful waiting (2 studies) or myringotomy (1 study): Mean Difference -5.18 (95% CI, -10.43 to 0.07) * By ear, 24 months (1 study) (N=72 ears)

Unilateral tubes vs. myringotomy: Mean Difference -2.1 (95% CI, 2.6 to -6.8) Time (proportion) with effusion: Negative result better in tube group* First year (MA: 3 studies) (N=574)

Bilateral TT vs. myringotomy, delayed treatment or watchful waiting: Mean difference -0.32 (95% CI, -0.48 to -0.17)* First two years (MA: 3 studies) (N=426)

Bilateral TT vs. delayed treatment or watchful waiting: Mean difference -0.13 (95% CI, -0.17 to -0.08) * 1 study 3 mos (N=215) Bilateral TT vs. WW: Mean Diff: -11.9 (95% CI, -9.6 to -14.2) (favors TT)
* 1 study 24 mos (N= 72 ears) Unilateral TT vs. myringotomy: Mean Diff: -2.1 (95% CI, 2.6 to -6.8) (favors TT)

Language: Positive result: better in tube group* Language Comprehension, 6 to 9 months (MA: 3 studies) (N=394)
* Bilateral tubes vs. watchful waiting: Mean Difference 0.09 (95% CI, -0.21 to 0.39)
* Language Expression, 6 to 9 months (MA: 3 studies) (N=393)
* Bilateral tubes vs. watchful waiting: Mean Difference 0.03 (95% CI, -0.42 to 0.49)

Cognitive Development* 1 study (N = 160) 9 mos Griffiths Mental Development Mean Cognitive Index TT vs. WW 106.5 vs. 104.2 (95% CI, -2.58 to 7.04) p=.36
* 1 study (N=393) 3 yrs McCarthy Mental Development Mean General Cognitive Index TT vs. WW 99 vs. 101 (95% CI, -4.1 to 1.1)

Behavior* 1 study (N=393) 3 yrs Child Behavior Checklist Mean Total Problem Score TT vs. WW 50 vs. 99 (95% CI, -0.6 to 3.4)
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Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Browning et al., 20101(continued) | Quality of Life:* Rovers 2001: (N=176) 6 mos The TAIQOL Mean scores in domains
* 6 mos Vitality 3.3 vs. 3.3 Appetite 5.0 vs. 4.7 Communication G1: 6.7 vs. 5.8 Motoric 4.4 vs. 4.4 Social 3.5 vs. 3.5 Anxiety
* 4.3 vs. 4.1 Aggression 11.9 vs. 11.1 Eating 3.3 vs. 3.5 Sleeping 6.8 vs. 6.6 MANOVA Hotelling Trace (p=0.22)
* 12 mos Vitality 3.1 vs.3.2 Appetite 5.3 vs.4.9 Communication 5.9 vs.5.6 Motoric 4.2 vs.4.2 Social 3.5 vs. 3.5
* Anxiety 4.6 vs. 4.3 Aggression 11.8 vs.11.5 Eating 3.3 vs. 3.4 Sleeping 6.4 vs. 6.4 MANOVA Hotelling Trace (p=0.94)

Adverse Events* Tympanosclerosis by ear, 1 year (1 study) (N=78):
* Unilateral tube vs. watchful waiting: 38% vs. 1%
* Tympanosclerosis by child, 24 months (1 study) (N=248):
* Bilateral tubes vs. watchful waiting: 27% vs. 0
* Otorrhoea, 6 months (1 study (N=187)):
* Tubed ears vs. non-tubed ears 49% (95% CI, 39%, 60%) vs. 10% (95% CI, 4%, 16%)
* Perforation and otorrhoea, 24 months (1 study) (N=248):
* Perforation: <1 %
* Otorrhoea: 2%
* AOM (1 study) (n=236):
* Tubed vs. non-tubed 27% vs. 11%
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Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Hellstrom, 201112Swedish Council on Technology Assessment in Health Care - A governmental AuthoritySystematic Review | Number of Patients3218Aims of ReviewThe aim of this review was to study the evidence for effectiveness of VT treatment in SOM (i.e., OME) and rAOM as well as the effect of VT material, the different procedures, and their benefits and complications. Note: only studies of participants with OME are included here. Studies with mixed populations were not included unless OME results were stratified.24 articles in which OME was the focus and there was a comparator of interest: Rovers 20009; Rovers 200113; Paradise 200314; Maw 19998; Maw 19862; Maw 199415; Dempster 19934; Gates 1989; Wilks 2000; Hampal 1991; Dingle 1993; Heaton 1991; Hern 1999; Hampton 1996; Pearson 1996; Salam 1993; Youngs 1988; Kinsella 1994; Bonding 1985; Lildholdt 1983; Mandel 1992; Maw 1994bCharacteristics of Included StudiesOME studies included RCTs (individual or ear), nonrandomized controlled trials, and cohort studies published between 1966 and 2007 of efficacy of tubes on hearing, language development, and quality of life; tube design effects on functioning and complications; tube routines for insertion effects on functioning and complications; prophylaxis and treatment of tube otorrhea; complications and sequelae after tube insertion.**Criteria for diagnosing OME:**Specified only that had to meet international criteria for OME and have OME present for 3 months. Based on methods of underlying studies, OME had to be diagnosed objectively using a combination of otoscopy (pneumatic and microscopic), tympanometry and audiometry**Setting(s):**Referral population, largely to otolaryngology clinics in academic medical centersCharacteristics of Included PopulationsChildren or adolescents with long-term OME defined as a painless inflammation with effusion in the middle ear with impaired hearing for at least 3 months |

Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Hellstrom, 201112(continued) | Characteristics of InterventionsInterventions included trials of: * Efficacy of tubes vs. watchful waiting (late tubes) or myringotomy on hearing, language development, and quality of life: Rovers 2000, Rovers 2001, Paradise, 2003; Maw 1999, Maw 1986; Maw 1994; Dempster 1993; Gates 1989; Wilks 2000
* Tube design effects on functioning and complications: Hampal 1991 (mini shah vs. Shah), Dingle 1993 (Mini Shah vs. Shah); Heaton 1991 (Shepard vs. Sheehy)
* Tube routines for insertion effects on functioning and complications (all randomized ears): Heaton 1991 (anterior/inferior vs. posterior/inferior placement), Hern 1999 (anterior/superior vs. anterior/inferior placement), Hampton 1996 (anterior vs. posterior), Pearson 1996 (otic drops preop vs. no drops), Salam 1993 (otic drops preop vs. no drops), Youngs 1988 (aspiration vs. no aspiration), Kinsella 1994 (touch with surgeon gloves vs. non touch)
* Prophylaxis and treatment of tube otorrhea (ears randomized): Salam 1993 (otitic drops vs. no drops)

Complications and sequelae after tube insertion: * Gates 1989 (Tubes vs. myringotomy vs. adenoidectomy + tubes vs. adenoidectomy + myringotomy), Bonding 1985 (tubes right ear vs. myringotomy left ear), Lildholdt 1983 (tubes vs. control -ears randomized)., Mandel 1992 (tubes vs. myringotomy vs. no tx), Maw 1994 (tube vs. no tube - ears randomized)

Main ResultsFor tubes vs. watchful waiting, outcomes in hearing and language devleopment were reported in the Browning review (same studies).Behavior * 1 study Richman Graham Behavioral Scale
* Richman Behavioral Scale % with Problems9 mos: TT vs. WW 30% vs. 47% (95% CI, -33% to –2%) (p=0.031) (favors tx)
* 18 mos: TT vs. WW 24% vs. 20% (95% CI, -10% to 19%) (p=0.66)

Note: Outcomes varied as to whether they were collected during the treatment or afterAdverse EventsTubes vs. myringotomy or combination treatment, antibiotics, or watchful waiting/controlPerforation* Gates 1989 - Tubes -2.4% vs. myringotomy - 3% vs. adenoidectomy + tubes - 0% vs. adenoidectomy + myringotomy - 0 every 6 weeks for 2 years (no statistical test done)
* Mandel 1992 - tubes vs. myringotomy vs. control monthly for 3 years - tubes 5.6%

Atrophy * Bonding 1985 tubes vs. myringotomy 1-3 years, n.s.
* Lildholdt 1983 - tubes worse than control every 3-6 mos. for 5 yrs. 13% vs. 1.3%
* Maw 1994 tubes worse than control 5 years RR 80%, 10 years RR 80%
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Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Hellstrom, 201112(continued) | Myringosclerosis* Bonding 1985 - tubes worse than myringotomy 1-3 yrs p<.001
* Lildholdt 1983 - tubes worse than control every 3-6 mos. for 5 yrs 33% vs. 6.7%

Granulation* Lildholdt tubes worse than control every 3-6 mos for 5 yrs 4% vs. 0%

Cholesteatoma * Mandel 1992 tubes vs. myringotomy vs. no surgery - monthly for 3 yrs no surgery 5%

Other abnormalitiesTube design effects on functioning and complications: * Hampal 1991 - Shah better than mini Shah in situ 52 wks p<.001, reccurence of OME p<.05
* Dingle 1993 Mini Shah better than Shah tympanosclerosis 2 year p<.001

Heaton 1991 - Sheehy better than Shephard for retention time 15-36 mos p<.0001, complication rate 15-30 mos p=NSTube routines for insertion effects on functioning and complications: Placement* Heaton 1991 - anterior/inferior better than posterior/inferior placement function time 15-36 mos. p=.002
* Hern 1999 - anterior/superior vs. anterior/inferior placement function time 26 mos p=NS.
* Hampton 1996 anterior vs.n posterior placement perforation rate 6 wks to 29 mos p=NS

Drops* Pearson 1996 - otic drops preop vs. no drops tube patency rate 3 mos p=NS
* Salam 1993 otic drops preop vs. no drops obstruction 2 wks n.s., drops better otorrhea p<.01

Other* Youngs 1988 aspiration vs. no aspiration patency 3 mos., p=NS
* Kinsella 1994 - touch with surgeon gloves vs. non touch otorrhea 7-10 days p=NS

Comments* Very difficult to ascertain what kind of statistical test was carried out and not all rates are listed
* Can't use their conclusions for adverse events since they combined studies of rAOM along with OME
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Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Perera et al., 200916University medical Center Oxford, UKSystematic Review | Number of Patients404 in 5 studies of children; 198 adults in 1 study. Total of 602 participantsAims of ReviewTo determine the effects of autoinflation in adults an children with OME.Studies Included in Analysis or Review6, 5 of which were for children and 1 of adults. Children: Brooker 1992; Stangerup 1992; Blanshard 1993; Fraser 1977; Arick 2005. Adults: Lesinskas 2003Characteristics of Included StudiesRCTs. (excluding any form of quasi-experimental trials)1. Any form of autoinflation vs. no autoinflation; other treatments (e.g., analgesics, antiobiotics, decongestants) were permitted as long as given equally to the two groups. 2. Comparison could not include another OME treatmentCriteria for diagnosing OME:OME diagnosis needed to include tympanometerySetting(s):Characteristics of Included Populations* Children and adults with unilateral or bilateral OME and a clinical diagnosis by a primary care physician or specialist using tympanomerty including:
* Arick (2005): 94 children age 4-11 at least 2 month history of MEE and associated hearing loss; absence of enlarged adenoids, AOM or other ear abnormalities at pretest.
* Blanshard (1993): 85 children aged 3-10 with bilateral OME using tympanometry on waiting list for tubes.
* Brooker (1992): 40 children aged 3 to 10 with unilateral or bilateral OME diagnosed by otoscopy, audiometry and tympanometry referred to ENT.
* Fraser (1977): 85 children aged 3 to 12 with bilateral OME using tympanometry.
* Lesinskas (2003): 198 adults aged 16 to 75 with unilateral or bilateral OME diagnosed by tympanometry and PTA.
* Stangerup (1992): 100 children aged 3 to 10 unilateral or bilateral OME for at least 3 mos. diagnosed by tympanometry

Characteristics of InterventionsAny form of autoinflation vs. no autoinflation with other treatments permitted as long as these were provided equally in the 2 groups.* Arick (2005): Modified Politzer (ear popper) device for 7 weeks twice daily alternating nostrils
* Blanshard (1993): Otovent (inflating a baloon) 3 times a day for 3 months
* Brooker (1992): Carnival balloon 3 times a day for 3 weeks
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Evidence Table 11. Systematic reviews (continued)

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| Author, Year CountryFundingStudy Design | Abstraction Form  |
| Perera et al., 200916(continued) | * Fraser (1977): Carnival blower for 6 weeks; factorial design in which autoinflation, Dimotapp Elixir (i.e., an antihistamine and nasal decongestant), Ephedrine nose drops,were assigned so that each individual received one of eight combinations of all three treatments (or control). The group receiving autoinflation with those who had not received autoinflation were similar in respect to the proportion of individuals who received the antihistamine and nose drops.
* Lesinskas (2003): Politzer inflation 2 times a day for 10 days, with or without oral antibiotics; all patients were prescribed nasal decongestants
* Stangerup (1992): Otovent 3 times a day for 2 weeks, extended to 4 weeks in those with persistent OME
* Brooker (1992): Carnival balloon 3 times a day for 3 weeks
* Fraser (1977): Carnival blower for 6 weeks; factorial design in which autoinflation, Dimotapp Elixir (i.e., an antihistamine and nasal decongestant), Ephedrine nose drops,were assigned so that each individual received one of eight combinations of all three treatments (or control). The group receiving autoinflation with those who had not received autoinflation were similar in respect to the proportion of individuals who received the antihistamine and nose drops.
* Lesinskas (2003): Politzer inflation 2 times a day for 10 days, with or without oral antibiotics; all patients were prescribed nasal decongestants
* Stangerup (1992): Otovent 3 times a day for 2 weeks, extended to 4 weeks in those with persistent OME

Main ResultsTympanometry Improvement < 1 month* 3 studies (Blanchard, Brooker, Stangerup): B or C2 to C1 or A RR: 1.65 (95% CI, 0.49 to 5.56)
* 2 studies (Blanshard, Stangerup): B to C1 or A RR: 2.71 (95% CI, 1.43 to 5.12)
* 2 studies (Blanshard, Stangerup) C2 to C1 or A RR: 3.84 (95% CI, 1.94 to 7.59)

Tympanometry improvement > 1 month* 2 studies (Blanshard, Stangerup): B1 or C2 to C1 or A RR 1.89 (95% CI, 0.77 to 4,67)

Mean change in middle ear pressure * 1 study (Fraser): Autoinflation: 12..7 vs. No Autoinflation: 53.3, p = NS.

Mean change in middle ear compliance* 1 study (Frase) Autoinflation: 0.052 vs. No Autoinflation: 0.064, p = NS.

Pure tone threshold average improvement > 10 dB (250 Hz to 2000 Hz) * 2 studies discrete outcome (Blanchard, Brooker) RR 0.80 (95% CI, 0.22 to 2.88)
* 2 studies continuous outcome (Arick, Fraser) Weighted Mean Diff 7.02 (95% CI, -6.92 to 20.96)

Composite improvement in either tympanometry or audiometry (< 1 month) * 4 studies (Blanshard, Brooker, Lesinskas, Stangerup,): RR 2.47 (95% CI, 0.93 to 6.58)

Composite improvement in either tympanometry or audiometry (> 1 month) * 4 studies (Arick, Blanshard, Lesinskas, Stangerup): RR 2.20 (95% CI, 1.71 to 2.82)

Improvement in composite by intervention (< 1 month) Otovent or blower + balloon* 3 studies (Blanshard, Brooker, Stangerup) Risk Ratio 1.65 (95% CI, 0.49 to 5.55)
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Evidence Table 11. Systematic reviews (continued)

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| Author, Year CountryFundingStudy Design | Abstraction Form  |
| Perera et al., 200916(continued) | Improvement in composite by intervention (< 1 month) Politzer * 1 study (Lesinskas): Risk Ratio 7.07 (95% CI, 3.70 to 13.51)

Improvement in composite by intervention (> 1 month) Otovent or blower + balloon* 2 studies (Blanshard, Stangerup) Risk Ratio 1.89 (95% CI, 0.77 to 4.67)

Improvement in composite by intervention (> 1 month) Politzer* 2 studies (Arick, Lesinskas): Risk Ratio 2.25 (95% CI, 1.67 to 3.04)

Adults 16-75 yrs* 1 study (Lesinskas), improvement in composite (pneumo-otoscopy, tympanometry, pure tone audiometry) by ears
	+ End of tx: autoinflation vs. control 49.2% vs.9% (p<.001)
	+ 50 days post tx: autoinflation vs. control 57.8% vs. 11.8% (p<.001)

Adverse Events"No studies demonstrated a significant difference in the incidence of side effects between control or intervention group"AOM * 1 study (Blanchard) stratified by compliance: Control 44%, Low Compliance 30%, High Compliance 36%
* 1 study (Stangerup): 2 week Autoinflation 2%, Control 5.5%; 1 month Autoinflation 0%, Control 6.6%; 2 month Autoinflation 9.1%, Control 5.3%; 3 months Autoinflation 9.1%, Control 4.1%

URTI* 1 study (Blanshard) stratified by compliance: Control 23%, Low Compliance 61%, High Compliance 32%
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Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Simpson, 201117Department of Primary Care and Public Health, Cardiff University, UK.;Wales School of Primary Care Research, UK.;The National Institute For Social Care and Health Research All-Wales (NISCHR)Last search: August 2010 | Number of Patients945 in 12 studiesAims of ReviewTo examine the evidence for treating children with hearing loss associated with OME with systemic or topical intranasal steroids.Studies Included in Analysis or Review* Oral steroids: Schwartz 198018; Niederman 198419; Macknin 198520; Lambert 198621; Berman 199022; Giebink 199023; Podoshin 199024; Hemlin 199725; Mandel 200226
* Topical intranasal steroids: Shapiro 198227; Tracy 199828; Williamson 200929, 30

Characteristics of Included StudiesInclude: * RCTs of oral and topical intranasal steroids. either alone or in combination with another agent such as an oral antibiotic.
* Publications in abstract form only; uncontrolled, non-randomised or retrospective studies; and studies reporting outcomes by ears (rather than children).

Criteria for diagnosing OME A. Air-bone gap of 10 dB or more + 2 or more of: otomicroscopy, pneumatic otoscopy, tympanometry (type B or C2)B. 2 or more of: otomiscroscopy, pneumatic otoscopy, tympanometry (type B or C2)C. 1 of otoscopy alone or tympanometry (type B or C2)D. Poorly or not defined Significant hearing loss defined by:A. Pure-tone audiometry hearing loss of >20 dB at 2 or more times within 3 mos (for example, mean of 500, 1000, and 2000 Hz hearing loss bilaterally)B. Defined, but less strict than AC. Uncertain or not defined**Setting(s):**International; Hospital (secondary or tertiary care) or general practice (primary care)Recruited from the otitis clinic, Departments of Otolaryngology or otolaryngology clinics, hospital based pediatric practices,research centers, private clinics, a hospital and medical centre-based Ambulatory Care Clinic, a Children’s Orthopedic Hospital and MedicalCentre, a Medical Centre-based pediatric Chronic Ear Clinic and general practices |

Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Simpson, 201117 (continued) | Characteristics of Included PopulationsChildren up to the age 12 with the exception of 3 included studies, 2 of which included up to age 14 and one included up to age 15.Berman, 1990: 68 children, 6 months to 5.4 years of age with effusion t for at least 6 weeks and all had 2 previous rounds of antibioticsGiebink, 1990: 76 children, 10 months to 7.9 years of age with continuous OME for at least 8 weeks and at least 3 episodes within previous18 months. All completed a course of antibiotic therapy for most recent acute OM.Hemlin, 1997: 142 children , 2 to 12 years of age with effusion for at least 3 monthsLambert, 1986: 60 children, 2 to 15 years of age with effusion for at least 2 monthsMacknin, 1985: 49 children, 6 months to 14 years of age enrolled 6 weeks after initial presentation with acute OM and completing 10 day course of antibotic therpay Mandel, 2002: 144 children, 1 to 9 years of age with effusion for at least 2 monthsNiederman, 1984: 26 children, 2 to 14 years of age with effusion present for 8 weeksPodoshin, 1990: 150 children 3 to 8 years of age with previsouly untreated OME that was present for at least 2 monthsSchwartz, 1980: 41 children, 1.2 to 10 years of age with effusions present for 3 weeks weeks despite previous antibiotics and/or decongestant treatmentShapiro, 1982: 45 children, 2 to 10 years of age, persistent Eustachian tube dysfunction (documented with abnormal tympanometry)due to allergic rhinitis which failed to respond to 4 weeks of oral antihistamine anddecongestantsTracy, 1998: 61 children (military-dependent population)aged from 3 to 11 years with persistent middle ear effusion for at least 3 months and a minimum of 3 episodes of AOM within past 6 months or 4 episodes within the past year Williamson, 2009: 217 children aged 4 to 11 years with 1 or more episodes of otitis media or ear-related problems in previous 12 months. (33% received active monitoring for 3 months prior to randomization).Characteristics of InterventionsSystemic or topical intranasal steroid compared with control (placebo or non-intervention control). Additional therapy could include antibiotics if it was the same in both arms. **Main Results**OME ResolutionOral Steroids vs. control* MA: 3 studies19, 20, 23: OME resolution (4 to 6 weeks): RR:1.54 ( 95% CI, 0.76 to 3.14)

Oral steroids + antibiotic vs. control + antibiotic* MA: 2 studies24, 26: OME resolution (1-2 months): RR:1.44 ( 95% CI, 0.97 to 2.13)

Intranasal steroid + antibiotic vs. placebo + antibiotic or antibiotic alone* 1 study28: OME resolution (3 months): RR: 1.26 (95% CI, 0.54 to 2.96)

Intranasal steroid vs. control * 1 study29, 30: OME resolution (3 months) RR 1.11 (95% CI, 0.85 to 1.46); (9 months): RR: 0.85 (95% CI, 0.65 to 1.11)
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Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Simpson, 201117 (continued) | Measured HearingOral Steroids vs. control* 1 study20: Hearing not improved by at least 10 dB in either ear (6 weeks): RR:1.09 (95% CI, 0.80 to 1.49 )

Oral steroids + antibiotic vs. control + antibiotic* 1 study24: Hearing loss (at least some conductive loss) (2 months): RR:1.01 (95% CI, 0.73 to 1.40)

Intranasal steroid vs. control * 1 study29, 30: Audiometry failing on ≥ 2 out of 5 frequencies in both ears (1-6 months): RR: 1.17 (95% CI, 0.87 to 1.58)

Adverse effects Oral steroids + antibiotics vs. control + antibiotic* MA: 2 studies25, 26: Mild to moderate adverse effects (2 wks to 6 months): RR: 1.34 ( 95% CI, 0.84 to 2.14)

Intranasal steroid vs. control * 1 study29, 30: Minor adverse effects (3 months): RR: 1.26 (95% CI, 0.80 to 1.99)

Intranasal steroids + antibiotics vs. control + antibiotics * 1 study28: 2 symptom score (3 months): Mean difference:4.5 (95% CI, -10.28 to 1.28), favors treatment group
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Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Thomas et al., 200631University of Wales College of Medicine, NHS Wales Office for Research and Development for Health Nd Social, UKSystematic review: Last search January 2006 | Number of Patients862 in 11 studiesAims of ReviewTo examine evidence for or against treating children with hearing loss associated with OME with systemic or topical intranasal steroids.Studies Included in Analysis or Review* Oral steroids: Schwartz, et al., 198018; Niederman 198419; Macknin 198520; Lambert 198621; Berman 199022; Giebink 199023; Podoshin 199024; Hemlin 199725; Mandel 200026

Topical intranasal steroids: Shaprio 198227; Tracy 199828Characteristics of Included StudiesInclude: * RCTs of oral and topical intranasal steroids. RCTs that included non-intervention controls included with adequate blinding of outcome assessor.
* Include if same co-interventions occuring in all groups.
* 3 Studies had steroids without antibiotics as intervention, 7 studies used antibiotics in both control and intervention groups

Exclude: * Observational studies, studies reporting outcomes only with ears as unit of analysis; studies (or data from arms of studies) comparing steroid + additional treatment vs. treatment with placebo + placebo because effect of steroid could not be isolated.

**Criteria for diagnosing OME:**Diagnosis of OME defined by: A. Air-bone gap of 10 dB or more + 2 or more of: otomicroscopy, pneumatic otoscopy, tympanometry (type B or C2)B. 2 or more of: otomiscroscopy, pneumatic otoscopy, tympanometry (type B or C2)C. 1 of otoscopy alone or tympanometry (type B or C2)D. Poorly or not defined Sig hearing loss defined by:A. Pure-tone audiometry hearing loss of >20 dB at 2 or more times within 3 mos (for example, mean of 500, 1000, and 2000 Hz hearing loss bilaterally)B. Defined, but less strict than AC. Uncertain or not defined |

Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Thomas et al., 200631(continued) | **Setting(s):**International; Hospital (secondary or tertiary care) or general practice (primary care)Recruited from the otitis clinic, Departments of Otolaryngology or otolaryngology clinics, hospital based pediatric practices,research centers, private clinics, a hospital and medical centre-based Ambulatory Care Clinic, a Children’s Orthopedic Hospital and MedicalCentre, a Medical Centre-based pediatric Chronic Ear Clinic and general practicesCharacteristics of Included PopulationsChildren up to the age 12Berman, 1990: 68 children, 6 months to 5.4 years of age with effusion t for at least 6 weeks and all had 2 previous rounds of antibioticsGiebink, 1990: 76 children, 10 months to 7.9 years of age with continuous OME for at least 8 weeks and at least 3 episodes within previous18 months. All completed a course of antibiotic therapy for most recent acute OM.Hemlin, 1997: 142 children , 2 to 12 years of age with effusion for at least 3 monthsLambert, 1986: 60 children, 2 to 15 years of age with effusion for at least 2 monthsMacknin, 1985: 49 children, 6 months to 14 years of age enrolled 6 weeks after initial presentation with acute OM and completing 10 day course of antibotic therpay Mandel, 2002: 144 children, 1 to 9 years of age with effusion for at least 2 monthsNiederman, 1984: 26 children, 2 to 14 years of age with effusion present for 8 weeksPodoshin, 1990: 150 children 3 to 8 years of age with previsouly untreated OME that was present for at least 2 monthsSchwartz, 1980: 41 children, 1.2 to 10 years of age with effusions present for 3 weeks weeks despite previous antibiotics and/or decongestant treatmentShapiro, 1982: 45 children, 2 to 10 years of age, persistent Eustachian tube dysfunction (documented with abnormal tympanometry)due to allergic rhinitis which failed to respond to 4 weeks of oral antihistamine anddecongestantsTracy, 1998: 61 children (military-dependent population)aged from 3 to 11 years with persistent middle ear effusion for at least 3 months and a minimum of 3 episodes of AOM within past 6 months or 4 episodes within the past year Characteristics of InterventionsSystemic or topical intranasal steroid compared with control (placebo or non-intervention control). Additional therapy could include antibiotics if it was the same in both arms. |

Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| Thomas et al., 200631(continued) | Main ResultsPersisting OME (1-2 mos)Oral steroids vs. controlMA: 3 studies (N =106)Peto OR: 0.55 (95% CI, 0.21 to 1.48) (favors tx)Oral steroids + antibiotic vs. control + antibioticMA: 3 studies (N=243)Peto OR: 0.75 (95% CI, 0.45 to 1.27) Persisting OME (3 mos)Topical intranasal steroid + oral antibiotic vs. control + antibiotic or antibiotic alone1 study (Tracy 1998) (N=59)Peto OR: 0.72 (95% CI, 0.21 to 2.44) (favors tx)Persisting OME (6 mos)Oral steroids + antibiotic vs. control + antibiotic 1 study (Hemlin 1997) (N=15)Peto OR: 0.15 (95% CI, 0.00 to 7.80) (favors tx)Symptom score (3 mos)Topical intranasal steroid + oral antibiotic vs. control + antibiotic or antibiotic alone1 study (Tracy 1998) (N=39)Peto OR: -4.50 (95% CI, -10.28 to 1.28) (favors tx)Hearing gain by at least 10 dB (1-2 mos)Oral steroids vs. control 1 study (N=49)Peto OR: 1.47 (95% CI, 0.39 to 5.57) (favors tx)Adverse EventsNo serious or lasting adverse effects reported in 5 studies on oral steroids mentioning adverse events (Niederman, Berman, Giebink, Hemlin, Mandel) or 2 studies on topical (Shapiro, Tracy). Other studies mentioned mild possible adverse effects, such as vomiting, diarrhea, dermatitis, transient nasal stinging and epistaxis. |

Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| van den Aardweg et al., 201032University medical Center Utrecht, Netherlands;Systematic review | Number of Patients1177 in 7 studies of OME patientsAims of ReviewTo assess the effectiveness of adenoidectomy vs. non-surgical management or TTs in children with OMStudies Included in Analysis or Review14, of these, 7 limited to children with OME and 7 either a combination of OME and AOM or AOM aloneOME only studies:* Gates 19875; Filleau-Nikolajsen 198033; Dempster 19934; Black 19903 ; Maw 19862; Casselbrant 200934; Roydhouse 198035

Characteristics of Included StudiesRCTs (excluding quasi-randomized trials) allocation by date of birth or record number; followup of at least 6 months**Criteria for diagnosing OME:** OME had to be diagnosed objectively using a combination of otoscopy (pneumatic and microscopic), tympanometry and audiometry**Setting(s):**Referral population, largely to otolaryngology clinics in academic medical centersCharacteristics of Included PopulationsChildren up to 18 years of age with OM including:* Black (1990): 149 children aged 4-9 with bilateral OME
* Casselbrant (2009): 98 children 24-47 mos, with a history of bilateral middle ear effusion for at least 3 mos, unilateral for 6 mos or longer or unilateral for 3 mos after extrusion of a TT, unresponsive to recent antibiotic
* Dempster (1993): 78 children aged 3-12 with bilateral OME associated with hearing loss
* Fiellau-Nikolajsen (1980): 42 children aged 3 with persistent or recurrent OME
* Gates (1987): 491 children aged 4-8 with persistent bilateral OME
* Maw (1986): 150 children aged 2-9 with persistent bilateral OME
* Roydhouse (1980): 169 children aged 2-14 with persistent OME
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Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| van den Aardweg et al., 201032(continued) | Characteristics of Interventions* Black (1990): Adenoidectomy with bilaterial myringotomy vs. adenoidectomy with a unilateral TT vs. bilateral myringomoty vs. unilateral TT
* Casselbrant (2009): myringotomy and TT vs. adenoidectomy, myringotomy and TT vs. adenoidectomy and myringotomy
* Dempster (1993): adenoidectomy and unilateral TT vs. unilateral TT
* Fiellau-Nikolajsen (1980): myringotomy and adenoidectomy vs. myringotomy
* Gates (1987): bilateral myringotomy vs. TT vs. bilateral myringotomy and adenoidectomy vs. TT and adenoidectomy
* Maw (1986): Adenotonsillectomy and unliteral TT vs. adenoidectomy and unilateral TT vs. unilateral TT
* Roydhouse (1980): TT and adenoidectomy vs. TT vs. control

Main Results* Mean time with Effusion (SD)
* 1 study (Gates, 1987) (N=237)
* Adenoid + Myr: 0.302 (0.250); Myr only: 0.491 (0.252)

SMD: -0.76 (95% CI, -1.02 to -0.49)* 1 study (Gates, 1987) (N=254)
* Adenoid + TT: 0.258 (0.212); TT only: 0.349 (0.235)

SMD: -0.40 (95% CI, -0.65 to -0.15)* 1 study during first 18 mos (Casselbrant, 2009) (N=62)
* Adenoid + Myr + TT: 18%; Myr + TT: 12%

Diff: 6% (95% CI, -12 to 24)1 study during first 36 mos (Casselbrant, 2009) (N=62)* Adenoid + Myr + TT: 21%; Myr + TT: 19%
* Diff: 2% (95% CI, -19 to 23)

Type A tympanogram (normal ears) at 6 mos* 1 study (Fiellau-Nikolajsen, 1980) (N=88)
* Adenoid + Myr: 68%; Myr: 52%

Risk diff: 15% (95% CI, -5% to 46%)Resolution of OME at 6 mos based on otoscopy* (MA: 2 studies) (N=153)
* Adenoid + unilateral TT: 35 of 72 (49%); Unilateral TT: 17 of 81 (21%)

Risk diff: 0.27 (95% CI, 0.13 to 0.42)Resolution of OME at 6 mos based on tympanometry* (MA: 3 studies) (N=297)
* Adenoid + unilateral TT: 56 of 144 (39%); Unilateral TT: 26 of 153 (17%)
* Risk diff: 0.22 (95% CI, 0.12 to 0.32)
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Evidence Table 11. Systematic reviews (continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| van den Aardweg et al., 201032(continued) | Resolution of OME at 12 mos based on tympanometry* (MA: 3 studies) (N=298)
* Adenoid + unilateral TT: 68 of 143 (47%); Unilateral TT: 31 of 155 (20%)

Risk diff: 0.29 (95% CI, 0.19 to 0.39)Resolution of OME at 12 mos based on otoscopy * (Dempster, 1993) (N=72)
* Adenoid: 54%; No intervention: 37%

Risk diff: 17% (95% CI, -6% to 40%)* (Maw, 1986) (N=81)
* Adenoid: 69.4%; No intervention: 27.7%

Risk diff: 42% (95% CI, 22% to 62%)Percentage of ears with effusion at 12 mos* 1 study (Roydhouse, 1980) (N=95)
* Adenoid + TT: 18%; TT: 23%
* Risk diff: -5% (95% CI, -8% to 17%)

Percentage of ears with effusion at 24 mos* 1 study (Roydhouse, 1980) (N=95)
* Adenoid + TT: 15%
* TT: 18%
* Risk diff: -3% (95% CI, -10% to 15%)

Episodes of AOM at 18 mos. * 1 study (Casselbrant, 2009) (N=44)
* Adenoid + Myr + TT: 7
* Myr + TT: 6
* Risk diff: 5% (95% CI, -22 to 32)

Episodes of AOM at 36 mos.* 1 study (Casselbrant, 2009) (N=39)
* Adenoid + Myr + TT: 17
* Myr + TT: 21
* Risk diff: -18% (95% CI, -37 to 1)

Hearing loss (air conduction measured in dB HL) at 6 mos* (Dempster, 1993) (N=72)
* Adenoid (mean): 18.0 (13.0)
* No intervention (mean): 21.1 (11.7)
* SMD: -0.25 dB (95% CI, -0.71 to 0.22)
* (Maw, 1986) (N=81)
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Evidence Table 11. Systematic reviews(continued)

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| **Author, Year** **Country****Funding****Study Design** | **Abstraction Form**  |
| van den Aardweg, 201032(continued) | * Adenoid (mean): 20.4 (11.27)
* No intervention (mean): 36.5 (11.87)
* SMD: -1.37 (95% CI, -1.87 to -0.88)

Hearing loss (air conduction measured in dB HL) at 12 mos* 1 study (Dempster, 1993) (N=72)
* Adenoid (mean): 15.6 (8.4)
* No intervention (mean): 18.4 (10.6)
* SMD: -0.29 (95% CI, -0.76 to 0.17)
* 1 study (Maw, 1986) (N=81)
* Adenoid (mean): 19.7 (10.36)
* No intervention (mean): 27.4 (12.13)
* SMD: -0.67 (95% CI, -1.12 to -0.22)

Change in mean audiometry scores (dB) at 6 mos* 1 study (Black 1990) (N=149)
* Diff adenoid vs. no adenoid: 4.3 (95% CI, 1.4 to 9.9)

Change in mean audiomtry scores (dB) at 12 mos* 1 study (Black 1990) (N=149)
* Diff adenoid vs. no adenoid: 4.3 (95% CI, -3.1 to 11.6)

Mean time with hearing loss >20 dB better ear (SD)* 1 study (Gates, 1987) (N=237)
* Myr + Adenoid: 0.078 (0.13)
* Myr only: 0.186 (0.195)+M3
* 1 study (Gates, 1987) (N=254)
* Adenoid + TT: 0.065 (0.116)
* TT only: 0.101 (0.141)
* SMD: -0.23 (95% CI, -0.48 to 0.02)1 study (Gates, 1987) (N=237)
* Myr + Adenoid: 0.220 (0.239)
* Myr only: 0.375 (0.253)
* SMD: -0.65 (95% CI, -0.91 to -0.39)
* 1 study (Gates, 1987) (N=254)
* Adenoid + TT: 0.224 (0.221)
* TT only: 0.304 (0.227)

SMD: -0.35 (95% CI, -0.60 to -0.11) |

Abbreviations: Adenoid = adenoidectomy; AOM = acute otitis media; CI = confidence interval; dB = decibels; Diff = difference; ENT = Ear = Nose and Throat; Health Nd = \_\_;HL = hearing level; Hz = Hertz; MA = meta-analysis; MANOVA = Multivariate analysis of variance; MEE = middle ear effusion; mos = months; MRC = Medical Research Council; Myr = myringotomy; N = number; NHS = National Health Service; NS = not significant; OM = otitis media; OME = otitis media with effusion ;OR = odds ratio; preop = preoperative; PTA = pure tone audiometry; rAOM = recurrent acute otitis media; RCT = randomized controlled trial; RR = relative risk; SMD = standard mean difference; SOM = secretory otitis media; TAIQOL = TNO-AZL Infant Quality of Life; TARGET = Trial of Alternative Regimens in Glue Ear Treatment; TT = tympanostomy tubes; tx = treatment; UK = United Kingdom; URTI = upper respiratory tract infection; vs. = versus; VT = ventilation tube; wks = weeks; WW = watchful waiting; yrs = years