Evidence Table 2. Populations

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| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Popova et al., 201012 | Age  Overall:  G1: 60 months  G2: 61 months  Criteria for Diagnosis  Tympanometry (interacoustics AT-235h) - Type B tympanograms with fulid level on otoscopy. Pneumatic otoscopy by validated otoscopist.  Inclusion   * 2007-2009 * Documented bilateral middle effusion for >3 months * 20 db conductive hearing loss   Exclusion   * Previous myringotomy (+/- TT) * Previous adenoidectomy or tonsillectomy * Hx of ear surgery * Cleft palate * Down's syndrome * Congenital malformation of ear * Cholesteatoma or chronic mastoiditis * Perforation of TM * Conductive hearing loss due to destructive changes in ME * Sensoneural hearing loss | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  (500-4000 Hz)  Overall:  G1: 31.4 dB  G2: 32.3 dB  ns p=0.39  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  Overall:  G1: 45  G2: 44  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Williamson et al., 2009;20  Williamson et al., 200921 | Age  Range: 4-11 yrs old  Mean months (SD), (range)  G1: 73.3 (20.2) (49-129)  G2: 72.1 (18.6) (48-125)  Criteria for Diagnosis  Tympanometry  Inclusion   * Dx of bilateral OME by a nurse * In the first yr of study children positive screening entered a 3 month period of watchful waiting. * In yr 2 the protocol was changed and children with histories of bilateral tympanic failure were allowed to be randomized at the first failed screen (50:50).   Exclusion   * Tympanometry screen passed * Large amounts of wax * Uninterpretable tympanogram * Children with cleft palate * Down syndrome * Primary ciliary dyskinesia * Karteagner's syndrom * Immuniodeficiency states * TTs or tympanic perforation * Frequent or heavy epistaxis * Hypersensitivity to mometasone * Hx of steriod use in previous 3 months * Children under 4 yrs | Baseline Tympanometry  Type C2 (middle ear pressure −200 to −399) n=54  Type B (middle ear pressure ≤−400) n=88  Baseline Hearing or Hearing Loss  Scale: Sweep audiometry at 25 dB (pass/fail)  All enrolled children failed audiometric screen  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  History, No. (%)  Adenoidectomy: 51 (24.5)  Tonsillectomy: 23 (11.1)  Cleft palate: 17 (8.2)  Grommets 49 (23.6)  Allergies: 7 (3.4)  Baseline % Female  G1: 48  G2: 68  Baseline % Nonwhite  G1: 3  G2: 4 | Insured Status  NHS England  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Licameli et al., 20087 | Age  Mean months, (range)  Overall: 19 (8-51 )  Criteria for Diagnosis  Not specified  Inclusion   * 3-4 months of medical management for OME prior to randomization   Exclusion   * Previous TT | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  NR  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  Overall: 35.7  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Ragab, 200513 | Age  G1: 4.8 yr  G2: 5.2 yr  Criteria for Diagnosis  Hx, pneumo-otoscopic exam, and tympanograms  Inclusion   * Nov 2002-Jan 2004 patients undergoing surgery for OME   Exclusion   * NR | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  Air Bone Gap:  G1: 24.7 dB  G2: 24.1 dB  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  NR  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Koopman et al., 20046 | Age  Children aged < 11 yrs  Criteria for Diagnosis  Binocular otoscopy in combination with Type B tympanogram or pure tone audiometry used for diagnosis. Bilateral tympanogram Type C1 or C2 (Jerger) considered to support diagnosis of OME. If child was too young or failed at audiometric testing, diagnosis based solely on otoscopic findings and hx  Inclusion   * Children aged less than 11 years * Impaired hearing noticed by parents during at least 3 successive months * Bilateral OME   Exclusion   * Unilateral OME * Ear effusions without fever, otalgia, or otorrhea * Poorly cooperative children * Clinically admitted patients * Asymmetric perceptive hearing loss (HL) * Previously operated ears with other than myringotomy or ventialation tubes | Baseline Tympanometry  Type B: 362 ears (172 bilaterally)  C1: 5 ears  C2: 18 (3 bilateral) ears  Baseline Hearing or Hearing Loss  Mean duration of hearing loss (months [range])  Overall: 6 [3-12]  PTAs NR  # of children referred for TT because of hearing loss NR  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  No. (%)  History of:  Adenoidectomy: 51 (24.5)  Tonsillectomy: 23 (11.1)  Cleft palate: 17 (8.2)  Ever grommets 49 (23.6)  Allergies: 7 (3.4)  Baseline % Female  Overall: 48.1  Baseline % Nonwhite  Overall: 18.3  Mediterranean: 7.7  Black: 6.3  Asian: 1.9  Other: 2.4 | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Ovesen et al., 200011 | Age  Mean (range)  Overall: 38 months (1-7 yrs)  Criteria for Diagnosis  Otomicroscopical exam, tympanometry (middle ear pressure < 200 mm H2O)  Inclusion   * Children undergoing TT insertion bilaterally for the first time due to OME   Exclusion   * Patients with antibiotics within 1 month of surgery * Patients with other diseases * Patients with AOM at time of surgery | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  NR  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  Generally excluded  Baseline % Female  Overall: 36  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Wielinga et al., 199019 | Age  Mean, yrs  Males: 7  Females: 6  Criteria for Diagnosis  Otoscopy, pure tone audiometry, tympanometry  Inclusion   * Bilateral OME * 6 months of unsuccessfull treatment with standard decongestive medications * Mucoid secretion aspiration   Exclusion   * NR | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  Airconduction thresholds >20 dB  G1: 13  G2: 11  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  Overall: 40  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Mandel et al., 19899 | Age  Overall: 7 mos -12 yrs  Groups without hearing loss, by age grp  G1: 7-23 mos n=6 ; 2-5 yrs n=14; 6-12 yrs n=7  G2: 7-23 mos n=8 ; 2-5 yrs n=17; 6-12 yrs n=5  G3: 7-23 mos; n=7; 2-5 yrs n=17; 6-12 yrs n=5  Groups with hearing loss, by age grp  G4: 7-23 mos n=7; 2-5 yrs n= 3; 6-12 yrs n=2  G5: 7-23 mos n=6; 2-5 yrs n=4; 6-12 yrs n =1  Criteria for Diagnosis  Validated otoscopy, tympanometry, middle-ear muscle reflex testing  Inclusion   * Children between 7 mos and 12 yrs of age * Documented MEE of at least 2 mos duration persisting after at least one 14 day course of antimicrobial drug and pseudoephedine hydrochloride-chlorpheniramine maleate syrup.   Exclusion   * Craniofacial malformations * Down syndrome * Systemic illness such as asthma, cystic fibrosis or diabetes * Seizure disorder | Baseline Tympanometry  Acoustic reflex thresholds were estimated for1000 Hz tone ipsilaterally and contralaterally.  Baseline Hearing or Hearing Loss  Audiologic procedures depended upon age.   * < 2.5 yrs: were tested in sound field using a head turn response. Speech awareness thresholds and minimum response levels for warbled pure tones were estimated for these children. * 2.5 – 5 yrs: were tested with play audiometry. * > 5 yrs: traditional clinical protocol was used for chidren older. Bilateral thresholds under earphones from 500 to 4000 Hertz were obtained. * SRT for each ear were obtained using age appropriate responses (picture, id or word rep)   Other Baseline Symptoms  Significant hearing loss for randomization: pure tone avg of >20 dB bilaterallyu or >40 dB unilaterally or a speech awareness threshold >20 dB above the age-appropriate level or otalgia or vertigo unresponsive to medical treatment among those who do not have hearing or speech deficiencies.  Baseline Relevant Comorbidities  Otalgia or vertigo  Baseline % Female  Overall: 33 | Insured Status  NR  Study Population Broadly Applicable?  Yes  Comments  Participants were divided into 2 groups: those with "signifcant" hearing loss (defined arbitrarily as a pure-tone average of >20 dB bilaterally or >40 dB unilaterally, or a speech awareness threshold >20 dB above the age appropriate level) or symptoms consisting of otalgia or vertigo unresponsive to medical treatment, and those who had none of these findings. Within these groups, the subjects were stratified according to age. |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Mandel et al., 19899 | * History of tonsillectomy, adenoidectomy, or TT insertion * Structual middle-ear abnormality such as tympanic membrane perforation or adhesive OM; cholesteatoma; sensorineural hearing loss or conductive loss not attributable to MEE; severe upper airway obstruction; AOM; or purulent rhinitis. | Baseline % Nonwhite  Overall  Black: 25.7 |  |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| McRae et al.,198910 | Age  Mean, years (range)  Overall: 5.8  Range: (2.3 -10)  Criteria for Diagnosis  Otoscopy and impedance audiometry  Inclusion   * Children at head of waiting list for bilateral myringotomy and ventilation tube insertion   Exclusion   * Subsequent surgery in study duration | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  NR  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  Overall: 34  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Lildholdt 19798 | Age  Mean years (range)  Overall: 4 (1-10)  Criteria for Diagnosis  Bilateral middle ear pressure below -150mm H20. If audiogram was possible a maximum 15dB diff at 500, 1000, 2,000 Hz  Inclusion   * Not clearly specified   Exclusion   * Previous use of TT, recurrent acute supperative OM, unequal involvemnt of ears, congenital defects such as cleft palate | Baseline Tympanometry  Bilateral middle ear pressure below -150mm H20.  Baseline Hearing or Hearing Loss  Overall: If audiogram was possible a a maximum 15dB diff at 500, 1000, 2,000 Hz  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  G1: 41  G2: 41  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  No |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Brown et al., 19783 | Age  Range overall, years: 4 to 10  Criteria for Diagnosis  Hx, otoscopy and pure tone audiometry  Inclusion   * Not specified   Exclusion   * Not specified | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  Pure tome audiometry at 500, 1000, 2000, 4000 Hz  G1: 25 dB  G2: 23.1 dB  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  NR  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  No  Comments  The subject population is very marginally described. |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Szeremeta et al., 200016 | Age  Mean years, (range)  G1: 6.52 (2.74 - 12.52)  G2: 7.37 (3.86 - 5.34)  Criteria for Diagnosis  NR  Inclusion   * Children > 4 years with refractory OME or 2nd middle ear intubation * Spring operations   Exclusion   * NR | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  NR  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  NR  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Iwaki et al., 19985 | Age  Overall: range 3-12 yrs  Mean, years  G1: 6.2  G2: 6.5  G3: 5.8  Criteria for Diagnosis  NR  Inclusion   * Continuous conductive hearing loss with over 25 dB air-bone gap * ≥ 6 months resistance to conservative thearpy with medication and politzerization * Retracted and glue-colored tympanic membrane with type B tympanogram   Exclusion   * Craniofacial problems such as cleft palate | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  NR  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  Overall:38  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Austin, 19942 | Age  NR  Criteria for Diagnosis  NR  Inclusion   * Indication for adenotonsillectomy and OME, Resistant to ENT or pediatric management   Exclusion   * NR | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  Air-Bone Gap  G1: 29.9 dB  G2: 26.6 dB  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  NR  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  No  Comments  Regarding applicability: Not enough information on the sample so it is hard to generalize. |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Abdullah et al., 19941 | Age  Mean years (range)  Overall: 6 (3-10)  Criteria for Diagnosis  Inclusion   * De novo OME   Exclusion   * No significant hx of AOM * No evidence of tympanosclerosis | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  NR  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  Overall: 36  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Tos and Stangerup, 198917 | Age  5 years (no range reported) this is not the baseline age of the initial population, but average age of the 146 people in the study conducted in 1984  Criteria for Diagnosis  NR  Inclusion   * Bilateral OME   Exclusion   * NR | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  Specify Scale (mean of 250, 1000, 4000 Hz)  (250 Hz)  G1: 21.7  G2: 19.6  (1000 Hz)  G1: 23  G2: 20.4  (4000 Hz)  G1: 22.8  G2: 20.5  (Mean)  G1: 22.5  G2: 20.2  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  Overall: NR for baseline cohort;  for participants of 1984 study, Overall: 40%  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Slack et al., 198722 | Age  < 16 years  Criteria for Diagnosis  NR  Inclusion   * Children <16 years old * TT inserted for OME in 1983   Exclusion   * NR | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  NR  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  NR  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Shishegar and Hoghoghi, 200714 | Age  Range, years  Overall: 4-8  Criteria for Diagnosis  Physical examinations; otoscopoy, audiometry, tympanometry  Inclusion   * Not specified   Exclusion   * Hx of prior adenotonsillectomy, tympanostomy tube iplacement, dry middle ear, cleft palate, and perforated tympanic membrane | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  Mean pure tone averages in decibels hearing level (db HL) at 500, 1,000 and 2, 000 HZ)  G1: 25.1 db HL  G2: 26.3 db HL  Mean ears difference, dB (SD):  1.15 (3.25)  Decreased hearing level: 30/30 patients Preoperatively 27 of 30 participants had hearing loss  Mean speech Reception Threshold (SRT)  Mean paired ear as difference (SD): 0.83 dB (5.105)  G1: 24.8  G2: 25.6  95%CI=NR  p=NR  Other Baseline Symptoms  N (%):  Nasal obstruction and snoring: 26 (87)  Recurrent otitis media: 24 (80)  Serious otitis media 19 (63)  History of allergy: 4 (13)  Smoking in parents: 10 (33)  Allergic signs: 10 (33)  Adenoid enlargement 23 (77)  Turbinate hypertrophy: 13 (43)  Septal deviation: 5 (17) | Insured Status  NR  Study Population Broadly Applicable?  No  Comments  Unrepresentative comorbidities, but study says "no significant differences in clinical and demographic variables among treatment groups preoperatively." |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Shishegar and Hoghoghi, 200714  (continued) |  | Baseline Relevant Comorbidities  NR  Baseline % Female  Overall: 37 (11/30 children)  G1: 37  G2: 37  Baseline % Nonwhite  NA |  |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| D'Eredità and Shah, 20064 | Age  Mean years (range)  Overall: 3.7 (2-6)  G1:3.8 (2-6)  G2:3.6 (2-6)  Criteria for Diagnosis  Tympanometry  Inclusion   * OME for at least 3 months duration   Exclusion   * Hx of prior middle ear surgery or PE tube insertion or previous pharyngeal surgery * Cleft palate, Down syndrome or other syndrome involving the head and neck * Mental retardation or other known cognitive or psychiatric disorder | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  NR  Other Baseline Symptoms  NR  Baseline Relevant Comorbidities  NR  Baseline % Female  G1: 47  G2: 47  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes  Comments  Total followup was 12 months with post-op evaluations at day 10, 20, 30, 40, 60, and 80 and mo 3,4,6,8, and 12 |

Evidence Table 2. Populations (continued)

|  |  |  |  |
| --- | --- | --- | --- |
| Author, Year | Age  Criteria for Diagnosing OME  Inclusion Criteria  Exclusion Criteria | **Baseline Tympanometry**  **Baseline Hearing or Hearing Loss**  **Other Baseline Symptoms**  **Baseline Relevant Comorbidities**  **Baseline % Female**  **Baseline % Nonwhite** | **Insured Status**  **Study Population Broadly Applicable?**  **Comments** |
| Vlastos et al., 201118 | Age  Mean years (range)  G1: 4.6 (3-7)  G2: 4.4 (3-7)  Criteria for Diagnosis  Otoscopy ,tympanometry, pure tone audiometry  Inclusion   * > 3 yrs * Scheduled adenoidectomy due to sleep-disordered breathing * Presence of bilateral OME (the presence of an opaque or thickened tympanic mem- brane, air–fluid level, or bubbles, or the inability to visualise the incudostapedial joint, were considered signs of OME * Type B tympanogram (compliance <0.2ml). * Audiogram with an air–bone gap of 20 dB or a hearing loss of 30 dB but no more than 55 dB in at least one frequency in both ears.   Exclusion   * No signs of effusion at time of myringotomy * Children with chronic otitis media * Structural changes (e.g. tympanic membrane retraction pockets, ossicular chain erosion or cholesteatoma * Previous ear surgery * Language delays * Behavioural problems * Syndromes | Baseline Tympanometry  NR  Baseline Hearing or Hearing Loss  Mean hearing losses at 250, 500, 1000, 2000 and 4000 Hz (range)  G1: 31.2 dB (21-39)  G2: 32.7 dB (27-37)  Other Baseline Symptoms  OM-6 Score  G1: 2.2  G2: 2.0  Obstructive Sleep Disorders -6 (OSD-6)  G1: 3.3  G2: 3.4  Ears with mucoid fluid  G1: 68%  G2: 61%  Baseline Relevant Comorbidities  Generally excluded  Baseline % Female  G1: 44  G2: 44  Baseline % Nonwhite  NR | Insured Status  NR  Study Population Broadly Applicable?  Yes |