Evidence Table 4. Benefits KQ 1 and 2, Part 1

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| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| Abdullah et al., 19941 | Recurrence of OME:  G1: 1/17 = 5.9%  G2: 9/17 = 52.9% | NR | NR | NR | NR | NR |
| Austin, 19942 |  | NR | NR | NR | Air Bone Gap  G1: 13.2  G2: 14.4  Mean Improvement in Air-Bone Gap  G1:16 dB  G2: 12.2 dB  p >0.1  Mean Difference Between tx:  1.9 dB | NR |
| Brown et al., 19783 | NR |  | At 5 years, no "significant difference" in fluid level between groups |  | Preoperative HL  G1: 25 dB G2: 23.1 dB 48 hr Postoperative HL  G1: 8.9 dB G2: 24.7 dB 3 month Postoperative HL  G1: 11.4dB G2: 16.6 dB 5 yr Postoperative HL  G1: 17 dB G2: 14 dB | NR |

Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| D'Eredità and Shah, 20064 |  |  | Middle ear ventilation: mean  G1: 3.5 mos  G2: 6.3 mos  (95% CI): NR  p = 0.001  Still ventilated 3 mo followup:  G1: 11 ears, 36.6%  G2: 30 ears, 100% |  | "Normal in both groups at 1 year followup" |  |
| Iwaki et al., 19985 | OME healed, n (%)  G1: 45 (60%)  G2: 25 (64.1%)  G3: 77 (72.6%)  OME recurrence, n (%)  G1: 30 (40%)  G2: 11 (28.2%)  G3: 18 (17%)  G3 vs. G1, P < 0.01  OME recurrence with adenoidectomy  G1: 20 (40%)  G2: 5 (36%)  G3: 12 (24%)  OME recurrence without adenoidectomy  G1: 8 (35%)  G2: 7 (32%)  G3: 8 (17%) | NR | NR | NR | NR | NR |

Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| Koopman et al., 20046 | Success rate defined as the absence of effusion or otorrhea documented by binocular otoscopy.  1 month:  G1: 46.6%  G2: 87.4 %  2 months:  G1: 35.5%  G2: 81.9%  3 months:  G1: 37.1%  G2: 81.5%  4 months:  G1: 38.6 %  G2: 75.5%  5 months:  G1: 41.6%  G2: 68.5%  6 months:  G1: 39.1%  G2: 70.7%  Positive influence on success rate:  Adenoidectomy: p=0.006 | NR | NR | NR | NR | NR |

Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| Licameli et al., 20087 | NR | NR | NR | NR | NR | NR |
| Mandel et al., 19899 | MEE (OME and AOM)  Year 1:  Subjects entering without sig hearing loss or symptoms in G1 (M) and 3 (WW): 56% of the time  G2 (MandT): 16.4% Diff: (P<.001).  Those entering with sig hearing loss or symptoms  G4 (M): 57%  G5 (M and T): 9.8%.  Diff: (P<.001)  YR 2:  G1: 35.2  G2: 20.4  G3:28.2  G4: 39.9  G5: 28.3  YR 3:  G1: 25.5  G2: 25.0  G3:19.2  G4: 14.4  G5: 30.3  G1, 2, 4 may have had tx failure and gotten TT, mostly YR 2 and 3 | AOM (episodes/person-year )  w/o sig HL  G1: 0.58  G2: 0. 18  G3: 0.38  With sigHL  G4: 0.31  G5: 0.41 |  | NR | Speech-recognition threshold (dB) of right ear, during 3-yr study  G1:  Functional TT: 5.1 (2.9)  Intact TM, no MEE: 7.4 (3.8)  Intact TM, MEE: 17.5 (4.7)  G2:  Functional TT: 4.8 (2.5)  Intact TM, no MEE: 6.2 (3.8)  Intact TM, MEE: 19.0 (8.7)  G3:  Functional TT: 5.9 (3.1)  Intact TM, no MEE: 7.1 (4.5)  Intact TM, MEE: 21.3 (5.7)  G4:  Functional TT: 5.8 (3.6)  Intact TM, no MEE: 7.9 (3.7)  Intact TM, MEE: 20.9 (8.7)  G5:  Functional TT: 6.8 (3.5)  Intact TM, no MEE: 5.6 (4.0)  Intact TM, MEE: 26.3 (7.7) | NR |

Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| McRae et al.,198910 | NR | NR | NR | NR | NR | NR |
| Ovesen et al., 200011 | Recurrence of OME:  G1:15/37  G2: 25/38  G3: 52/75 | No. of episodes  G1:0/37  G2: 5/38  G3: 16/75 | NR | NR | NR | NR |
| Popova et al., 201012 | 12 mo  Mean Between-group difference 4% (95% CI):  p = 0.547 | Mean Between-group difference 3% (95% CI): | NR | NR | 1 mo post op. 50-4000 hz  Mean Between-group difference:  0 .2 (95% CI):  p = 0.83  6 mo post op. 50-4000 hz  Mean Between-group difference 0.4 (95% CI):  p = 0.68  12 mo post op. 50-4000 hz  Mean Between-group difference .0.8 (95% CI):  p = 0.24 | NR |
| Ragab, 200513 | Resolution  G1: 59%  G2: 28%  p < 0.01 | NR |  | NR | Air Bone Gap Improvement from pre-op:  G1: 12 dB  G2: 10 dB  p=NS  Both groups improved from pre-op p<0.01) | NR |

Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| Shishegar and Hoghoghi, 200714 | NR | NR | No. (%) of pts with fluid in ears:  G1: 24 (80%)  G2: 24 (80%)  Fluid content of patients ears and No. (%) of patients in each group:  Serous fluid:  G1: 8 (33%)  G2: 8 (33%)  Mucoid fluid:  G1: 14 (58%)  G2: 14 (58%)  Purulent fluid:  G1: 2 (9%)  G2: 2 (9%) | NR | Air-bone gap (pure tone average)  at 1 month:  Mean difference between G1 and G2: 1.43 db  Improvement from baseline:  G1: 16.04 db  G2: 17.47 db  95%Cis: NR  p=NR; NS (not sig)  at 6 mos.:  Mean difference between G1 and G2: 1.37 db  G1: 16.5 db  G2: 17.62 db  95% CIs NR  p=NS  Mean SRT:  at 1 month:  Mean difference between G1 and G2: 1.83 dB  G1: 17 db HL  G2: 18.3 db HL  95%CIs: NR  p=NS  at 6 mos.:  Mean difference between G1 and G2: 2.16 db  G1: 17.16 db HL  G2: 19.33 db HL  95% CIs: NR  p=NS | NR |

Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| Slack et al., 198722 | NR | NR | NR | NR | NR | NR |
| Szeremeta et al., 200016 | NR | NR | At post post-op visit  Me  G1: 4/39  G2: 7/41  p = 0.365 | NR | NR | NR |
| Tos and Stangerup, 198917 | NR | NR | NR | NR | (Mean 250-4000 Hz) Total Gain 1977-1984  Mean between-group difference: 0.6 (Db)  P=NS  G1 Mean Change from Baseline: 17.8 (dB)  G2 Mean Change from Baseline: 16.7 (dB)  data is also broken out by frequency and years | NR |
| Vlastos et al., 201118 | NR | NR | NR | NR | Change in Hearing (6 mo)  G1: -7.41  G2: -4.06  Mean HL Change  3.35 dB (95% CI -6.64 to 10.35)  Change in Hearing at 12 mos  G1: -8.06 dB  G2: -7.40 dB  Mean HL Change  0.66 dB(95% CI -6.82 to 8.15) | NR |

Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| Wielinga et al., 199019 | Resolution:  G1: 53%  G2: 80% | NR | NR | NR | Mean Hearing Loss:  G1: 11 dB  G2: 14 dB | NR |
| Williamson et al., 200920 | Cure rate (A or C1 tympanogram in at least 1 ear)  adjusted results (OR and RR) controlling for season, age, atrophy, and clinical severity score  1 mo.  G1: 39/96 (41%)  G2: 44/98 (45%)  Diff in OR (adj): 0.934 (0.498 to 1.751)  Diff in RR (adj): 0.97 (0.74 to 1.26)  3 mos.  G1: 50/86 (58%)  G2: 44/86 (52%)  Diff in OR (adj): 1.451 (0.742 to 2.838)  Diff in RR (adj): 1.23 (0.84 to 1.80)  9 mos  G1: 40/72 (56%)  G2: 47/72 (65%)  Diff in OR (adj): 0.822 (0.387 to 1.746)  Diff in RR (adj): 0.90 (0.58 to 1.41) | NR | NR | NR | Pass/Fail Criteria on sweep audiometry (fail at 2 or more frequencies at 25 dB in the better ear)  3 mos. failure  G1: 52/83 (63%)  G2: 47/81 = 58% (63%)    At 9 mos failure  G1: 44/74 (59%)  G2: 34/67 (51%)  Hearing loss from tympanograms, median (IQR)  at baseline  G1: 30.97 (23.8-32.65)  G2: 30.94(24.03-2.21)  at 3 months  G1: 19.43 (14.64-1.21)  G2: 21.15 (14.86-0.94) | NR |

Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| Williamson et al., 2009;20  (continued) |  |  |  |  | At 9 months  G1:19.56(14.88-0.84)  G2: 17.89 (14.11-3.55)  Reported hearing  difficulties, median(IQR)  at baseline  G1: 6.06 (2.83-8.57)  G2: 5.88 (2.33-7.60)  at 3 months  G1: 5.54 (0.90-8.43)  G2: 3.92 (0.90-7.60)  at 9 months  G1: 2.33 (0.21 to 7.60)  G2: 2.33 (0.42-6.60)  Days with hearing loss, median (IQR)  At 3 months  G1: 4 (0 to 24.5)  G2: 4 (0 to 18.5)  p=0.45 |  |

Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| Williamson et al., 200921 | OME resolution  at 1 month  OR, unadj (95%CI): 0.84 (0.475 to 1.484)  OR, adj (95%CI): 0.934 (0.498 to 1.751)  at 3 months  OR, unadj (95%CI): 1.265 (0.693 to 2.311)  OR, adj (95%CI): 1.451 (0.742 to 2.838)  at 9 months  OR, unadj (95%CI): 0.665 (0.34 to 1.302)  OR, adj (95%CI): 0.822 (0.387 to 1.746) | NR | NR | NR | Audiometry faiiing, %  at baseline  G1: 69.6  G2: 74.5  at 3 months  G1: 62.7  G2: 58.0  at 9 months  G1: 59.5  G2: 50.7  Hearing loss from tympanograms, median (IQR)  at baseline  G1: 30.97 (23.8-32.65)  G2: 30.94(24.03-2.21)  at 3 months  G1: 19.43 (14.64-1.21)  G2: 21.15 (14.86-0.94)  at 9 months  G1:19.56(14.88-0.84)  G2: 17.89 (14.11-3.55) | NA |

Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **OME** | **AOM** | **Middle Ear Fluid** | **Other Ear Symptoms (Fullness)** | **Hearing (Specify Test)** | **Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)** |
| Williamson et al., 200921  (continued) |  |  |  |  | Reported hearing  difficulties, median(IQR)  at baseline  G1: 6.06 (2.83-8.57)  G2: 5.88 (2.33-7.60)  at 3 months  G1: 5.54 (0.90-8.43)  G2: 3.92 (0.90-7.60)  at 9 months  G1: 2.33 (0.21 to 7.60)  G2: 2.33 (0.42-6.60)  Days with hearing loss, median (IQR)  at 3 months  G1: 4 (0 to 24.5)  G2: 4 (0 to 18.5)  p=0.45 |  |
| 8 | NR | NR | No significant difference between groups in middle ear pressure | NR | No significant difference between groups at entry into the study or at various points post treatment | NR |