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 GapG1: 13.2G2: 14.4Mean Improvement in Air-Bone Gap G1:16 dBG2: 12.2 dBp >0.1Mean Difference Between tx:1.9 dB | NR |
| Brown et al., 19783 | NR |  | At 5 years, no "significant difference" in fluid level between groups |  | Preoperative HLG1: 25 dB G2: 23.1 dB 48 hr Postoperative HLG1: 8.9 dB G2: 24.7 dB 3 month Postoperative HLG1: 11.4dB G2: 16.6 dB 5 yr Postoperative HLG1: 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: meanG1: 3.5 mosG2: 6.3 mos(95% CI): NRp = 0.001Still 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 < 0.01OME recurrence with adenoidectomyG1: 20 (40%)G2: 5 (36%)G3: 12 (24%)OME recurrence without adenoidectomyG1: 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: 35.2G2: 20.4G3:28.2 G4: 39.9G5: 28.3YR 3:G1: 25.5G2: 25.0G3:19.2 G4: 14.4G5: 30.3G1, 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 studyG1: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:G1:15/37G2: 25/38G3: 52/75 | No. of episodesG1:0/37G2: 5/38G3: 16/75 | NR | NR | NR | NR |
| Popova et al., 201012 | 12 moMean Between-group difference 4% (95% CI): p = 0.547 | Mean Between-group difference 3% (95% CI): | NR | NR | 1 mo post op. 50-4000 hzMean Between-group difference: 0 .2 (95% CI): p = 0.836 mo post op. 50-4000 hzMean Between-group difference 0.4 (95% CI): p = 0.6812 mo post op. 50-4000 hzMean Between-group difference .0.8 (95% CI): p = 0.24 | NR |
| Ragab, 200513 | ResolutionG1: 59% G2: 28%p < 0.01 | NR |  | NR | Air Bone Gap Improvement from pre-op: G1: 12 dB G2: 10 dBp=NSBoth 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 dbImprovement from baseline: G1: 16.04 db G2: 17.47 db 95%Cis: NRp=NR; NS (not sig)at 6 mos.:Mean difference between G1 and G2: 1.37 dbG1: 16.5 dbG2: 17.62 db95% CIs NRp=NSMean SRT: at 1 month: Mean difference between G1 and G2: 1.83 dB G1: 17 db HLG2: 18.3 db HL95%CIs: NRp=NSat 6 mos.: Mean difference between G1 and G2: 2.16 dbG1: 17.16 db HLG2: 19.33 db HL95% CIs: NRp=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 visitMeG1: 4/39G2: 7/41  p = 0.365 | NR | NR | NR |
| Tos and Stangerup, 198917 | NR | NR | NR | NR | (Mean 250-4000 Hz) Total Gain 1977-1984Mean between-group difference: 0.6 (Db) P=NSG1 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: -7.41G2: -4.06Mean HL Change3.35 dB (95% CI -6.64 to 10.35)Change in Hearing at 12 mosG1: -8.06 dBG2: -7.40 dBMean 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 dBG2: 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. failureG1: 52/83 (63%) G2: 47/81 = 58% (63%) At 9 mos failureG1: 44/74 (59%) G2: 34/67 (51%) Hearing loss from tympanograms, median (IQR)at baselineG1: 30.97 (23.8-32.65)G2: 30.94(24.03-2.21)at 3 monthsG1: 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 monthsG1:19.56(14.88-0.84)G2: 17.89 (14.11-3.55)Reported hearing difficulties, median(IQR)at baselineG1: 6.06 (2.83-8.57)G2: 5.88 (2.33-7.60)at 3 monthsG1: 5.54 (0.90-8.43)G2: 3.92 (0.90-7.60)at 9 monthsG1: 2.33 (0.21 to 7.60)G2: 2.33 (0.42-6.60)Days with hearing loss, median (IQR)At 3 monthsG1: 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 resolutionat 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 baselineG1: 69.6G2: 74.5at 3 monthsG1: 62.7G2: 58.0at 9 monthsG1: 59.5G2: 50.7Hearing loss from tympanograms, median (IQR)at baselineG1: 30.97 (23.8-32.65)G2: 30.94(24.03-2.21)at 3 monthsG1: 19.43 (14.64-1.21)G2: 21.15 (14.86-0.94)at 9 monthsG1:19.56(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 baselineG1: 6.06 (2.83-8.57)G2: 5.88 (2.33-7.60)at 3 monthsG1: 5.54 (0.90-8.43)G2: 3.92 (0.90-7.60)at 9 monthsG1: 2.33 (0.21 to 7.60)G2: 2.33 (0.42-6.60)Days with hearing loss, median (IQR)at 3 monthsG1: 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 |