Adenotonsillotomy Versus Adenotonsillectomy in Pediatric Obstructive Sleep Apnea: An RCT

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abstract

BACKGROUND: Adenotonsillectomy (ATE) is a well-established and effective treatment of pediatric obstructive sleep apnea (OSA). In recent years, a more conservative method, adenotonsillotomy (ATT), has gained popularity because it is associated with less postoperative morbidity. Yet no previous randomized study has compared these 2 methods regarding their effectiveness in treating pediatric OSA in terms of polysomnographic data, which was the primary aim of this study. The hypothesis was that ATT is noninferior to ATE after 1 year.

METHODS: Seventy-nine children, aged 2 to 6 years, with OSA (Apnea-Hypopnea Index [AHI] 5–30) were randomized to ATT (n = 40) or ATE (n = 39). Polysomnography (PSG) and questionnaire OSA-18 were assessed at baseline and 1 year postsurgery.

RESULTS: Mean difference between groups in the primary outcome, change in AHI, was 0.83, 95% confidence interval –3.2 to 4.9, not exceeding the noninferiority margin of 5. After ATE, AHI decreased from median 12.7 (interquartile range 8.3–19.1) to 2.0 (1.2–3.1) and after ATT from 15.8 (8.5–21.2) to 4.0 (1.2–5.1). For both groups, significant improvements of PSG and OSA-18 questionnaire outcomes were observed, with no significant differences between groups. Five children (13%) in the ATT group needed repeated surgery for tonsil regrowth and recurrence of OSA.

CONCLUSIONS: The results suggest that ATT is noninferior to ATE in treating pediatric OSA regarding PSG outcomes after 1 year. ATT could be considered an alternative to ATE for treatment of pediatric OSA. However, after ATT, there is a nonnegligible risk of recurrence of OSA, and this should be taken into account when selecting surgical method.

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WHAT'S KNOWN ON THIS SUBJECT: Adenotonsillotomy (ATT) is associated with fewer complications than adenotonsillectomy (ATE) and thus is potentially preferable as treatment of pediatric obstructive sleep apnea (OSA). However, it is unknown whether ATT is as effective as ATE in treating OSA because no randomized studies have reported polysomnographic data.

WHAT THIS STUDY ADDS: The polysomnographic results of this randomized blinded trial suggest that ATT is noninferior to ATE in treating pediatric OSA. However, with ATT, there is a nonnegligible risk of tonsil regrowth and need for repeated surgery.

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Pediatric obstructive sleep apnea (OSA) can be considered a major health concern with a prevalence of 2% to 6%[1] and is associated with considerable morbidity and increased need for health care.[2] An important risk factor for OSA in children is adenotonsillar hypertrophy.[3] Adenotonsillectomy (ATE) is considered first-line treatment[3] and is one of the most common surgical procedures throughout the world.[4] ATE is an effective treatment of pediatric OSA but has the disadvantages of risk of postoperative hemorrhage and pain. In recent decades, partial tonsillectomy, or adenotonsillotomy (ATT), with subtotal removal of the tonsils, has gained popularity because it is associated with less postoperative hemorrhage and pain.[5,6] It has also been shown that ATE and ATT equally improve long-term quality of life after surgery.[7,8]

In 2012, a systematic review comparing tonsillectomy (TE) with tonsillotomy (TT) in children with sleep-disordered breathing was published. Of 16 randomized controlled trials (RCTs) included, the conclusion was that TT was equivalent or superior to TE concerning recovery-related outcomes.[9] However, none of the RCTs reported pre- or postoperative data from polysomnography (PSG), which is the gold standard for diagnosing OSA in children, and for grading the severity.[3] Another review concluded that "large well-designed randomized controlled trials with an adequate follow-up are necessary to determine whether the procedure (TT) is capable of replacing TE for resolving upper-airway obstruction."[10] The primary aim of this study was to evaluate ATE and ATT regarding the 1-year effect on pediatric OSA, as measured by PSG and a validated quality-of-life questionnaire, the OSA-18.

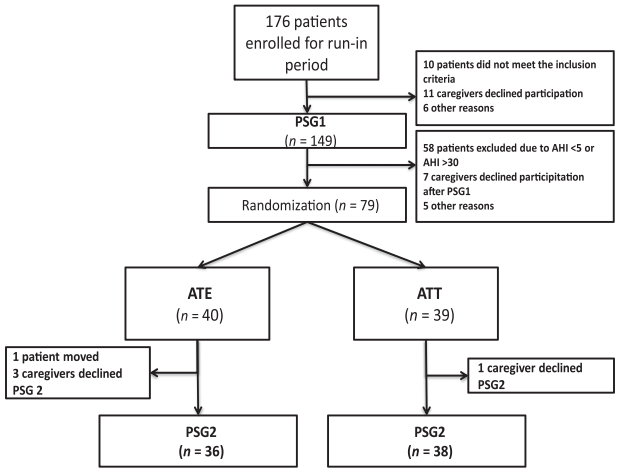

FIGURE 1
Flow of participants.

METHODS

Trial Design and Participants

This prospective, randomized, parallel-group, blinded trial was conducted at the Oto-Rhino-Laryngology Department at Karolinska University Hospital in Stockholm, Sweden, from November 2011 through April 2015. Patients were enrolled by different physicians, including the researchers. Eligible for inclusion were all suitable children referred to the Oto-Rhino-Laryngology Department. This study was approved by the Swedish Regional Ethics Board in Stockholm, Sweden (Dnr 2011/925-32 and 2013/2274-32).

Inclusion criteria for the run-in period were age 2 to 6 years, history or symptoms of OSA, and tonsil hypertrophy 3 or 4 (scale 1–4 according to Brodsky[11]). Exclusion criteria were craniofacial abnormality, neuromuscular disease, chromosomal abnormality, obesity (BMI *z* score >1.67), previous adenotonsil surgery, bleeding disorder, cardiopulmonary disease, history of recurrent tonsillitis, and parents with insufficient knowledge of the Swedish language.

After receiving parental written informed consent to study participation, the children were consecutively enrolled for the run-in period, with a full-night, in-laboratory PSG. Thereafter, the patients who met the final PSG inclusion criterion, Apnea Hypopnea Index (AHI) of ≥5 and ≤30 events/hour sleep, were included (see study flow scheme in Fig 1).

Sample Size and Power Analysis

The sample size calculation was performed by a statistician (Statisticon AB) before the study start. The study was designed as a noninferiority trial, based on 80% power with an α level of .05 to detect an AHI difference of 5 between groups, which was considered to be a clinically relevant difference. No previous data from a similar RCT were available for this population at the start of the study, therefore making it difficult to perform a regular power calculation. The assumed SD of 6.4 was based on another study of 578 children with OSA undergoing ATE.[12] The preceding assumptions yielded a required sample size of 27 patients in each intervention group, for a total of 54 patients. However, to be conservative, a slightly larger sample was chosen, corresponding to a SD of 7.1, yielding a sample size of 33 patients in each intervention group, giving 66 patients total. Also, to

avoid lack of power due to potential limitations in the power analysis and possible dropouts, the sample size was increased to 79 patients.

PSG

The study patients underwent an overnight, in-laboratory attended PSG at baseline (PSG1), with follow-up 1 year after surgical intervention (PSG2). All PSGs performed were using the EMBLA technology (Flaga Medical, Reykjavik, Iceland). The PSG measures sleep stage and respiratory functions using recordings of electroencephalogram, electrooculogram, electromyogram, electrocardiogram, pulse, oronasal airflow, transcutaneous oxygen saturation (Sao_2) and carbon dioxide (Pco_2), respiratory movements (abdomen and thorax), body position, and video and sound recordings. All PSGs were scored manually by a registered polysomnographic technologist. The pediatric scoring rules according to the American Academy of Sleep Medicine were used.[13]

There is no international consensus regarding which AHI cutoff values to use when grading pediatric OSA, but according to clinical practice and several other authors,[14,15] an AHI $\leq$1 is considered normal, AHI >1 to <5 corresponds to mild OSA, AHI 5 to <10 moderate OSA, and AHI $\geq$10 severe OSA. In the current study, the upper limit of AHI 30 was chosen to avoid extreme values because AHI >30 is rare in children.

OSA-18

To assess the quality of life, the caregivers responded to the OSA-18 questionnaire at baseline and at follow-up. The OSA-18 is a disease-specific questionnaire, validated in Swedish[16] with 18 items within 5 domains (Sleep Disturbance, Physical Symptoms, Emotional Distress, Daytime Function, and Caregiver Concerns), where each domain is scored in a 7-point Likert scale assessing the frequency of symptoms (from 1 "none of the time" to 7 "all of the time"). The scores are summed up to a total symptom score (TSS) ranging from 18 to 126 points, where higher scores indicate worse quality of life. The OSA-18 also contains a global rating of health-related quality of life (HRQoL) in a visual analog scale of 1 to 10 points.

Intervention

Study patients were randomly assigned to 1 of 2 groups: ATE or ATT. Surgery was performed 2 to 3 months after PSG1. In the ATE group, tonsils were removed with blunt extracapsular dissection by cold steel technique, whereas ATT was performed by coblation (cold ablation) technique, with partial intracapsular removal of tissue until the limit of the anterior tonsillar pillars.

All procedures were performed by experienced surgeons. In both groups, adenoidectomy with cold steel (ring knife) was always performed during the same session.

Hypothesis

ATT is noninferior to ATE in treating pediatric OSA in terms of differences in AHI changes after 1 year.

Primary Outcome

The primary outcome was the difference in total AHI changes (ΔAHI) between the 2 intervention groups ATE and ATT.

Secondary Outcomes

Secondary outcomes were differences in other PSG variables on respiration and sleep, such as oxygen desaturation index, lowest percentage of oxygen desaturation (nadir Sao_2), and respiratory disturbance index.

The outcomes from OSA-18 were differences in the TSS, the score from the domain of Sleep Disturbance, and the HRQoL.

The need for repeated tonsil surgery due to recurrence of OSA, with return of pronounced OSA symptoms, and/or significant tonsil regrowth and/or AHI >5, was also evaluated.

Randomization and Blinding

Before study start, 90 sealed envelopes were randomly mixed, 45 for ATE and 45 for ATT, giving a 1:1 allocation ratio. The envelopes were placed at the operating room and opened by the surgeon. Only the surgeon and the staff in the operating room knew which surgical method was performed. The surgeon did not meet the patients or parents after surgery; they were discharged by another doctor the day after surgery. Thus patients and care providers were blinded to intervention method, as was the technologist interpreting the PSGs.

Statistical Analysis

The study was designed to test the hypothesis that ATT would be noninferior to ATE for the primary outcome (differences in ΔAHI), with an upper limit of the 95% confidence interval (CI) of AHI 5.

For secondary outcome PSG data, parametrical tests were used for comparisons because PSG variables are continuous data and there was a sample size >30. These included the paired *t* test for within-group comparisons of preoperative and postoperative PSG variables, and the unpaired *t* test for between-group comparisons.

To compare the distribution of success rates (ordinal data) between the groups, the χ^2 test was used.

For OSA-18 outcomes (ordinal data), nonparametric tests were used for comparisons. These included the Wilcoxon signed-rank test within groups and the Mann-Whitney *U* test between groups.

Sensitivity analysis with intention-to-treat was performed for the primary outcome variable ΔAHI; this included

the 5 dropouts with missing values being imputed by using the baseline carried forward. Data were analyzed with IBM SPSS Statistics 20.

RESULTS

Seventy-nine children (53 boys, 26 girls) were included and randomized to either ATE (n = 40) or ATT (n = 39). The 2 groups had similar baseline characteristics (see Table 1). Seventy-four (93.7%) children completed the follow-up with PSG2 1 year after surgery (dropout rate 6.3%). Mean time from intervention to PSG2 was 12.1 ± 1.5 months in the ATE group and 11.8 ± 1.7 months in the ATT group.

Primary Outcome

In the ATE group, the AHI decreased from median (interquartile range [IQR]) 12.7 (8.3–19.1) at PSG1 to 2.0 (1.2–3.1) at follow-up PSG2 (P < .001) and in the ATT group, the AHI decreased from median (IQR) 15.8 (8.5–21.2) to 4.0 (1.2–5.1) (P < .001) (Fig 2) . The ratio of mean was 82% in the ATE group and 71% in the ATT group. The mean difference in AHI changes between the 2 groups was 0.83 (95% CI –3.2 to 4.9).

No patients in the ATE group had increased their AHI, whereas 1 patient in the ATT group had a substantially increased AHI, as seen in Fig 2. Analysis without the outlier in the ATT group showed a mean difference of –0.24 (95% CI –3.7 to 3.2).

The intention-to-treat analysis with 79 patients for AHI changes did not change the results compared with the per-protocol analysis with 74 patients (mean difference –0.06, 95% CI –4.01 to 3.92).

Success rate for 4 levels of AHI at PSG2 were analyzed, with no significant differences in the distribution of success rates between the groups, P = .50 (χ^2 test) (Table 2).

TABLE 1 Baseline Characteristics

	PSG2	PSG2
	n = 40	n = 39
Age at intervention, mo	47 (15)	45 (15)
Male sex, n (%)	29 (73)	24 (62)
Length, cm	98 (13)	99 (10)
Wt, kg	15.7 (3.1)	15.3 (3.3)
Tonsil size, 1–4	3.3 (0.6)	3.5 (0.6)
Adenoid size, 1–4	2.7 (0.8)	3.0 (0.7)
AHI	14.5 (7.3)	15.4 (7.3)

Unless otherwise noted, values are means (SDs).

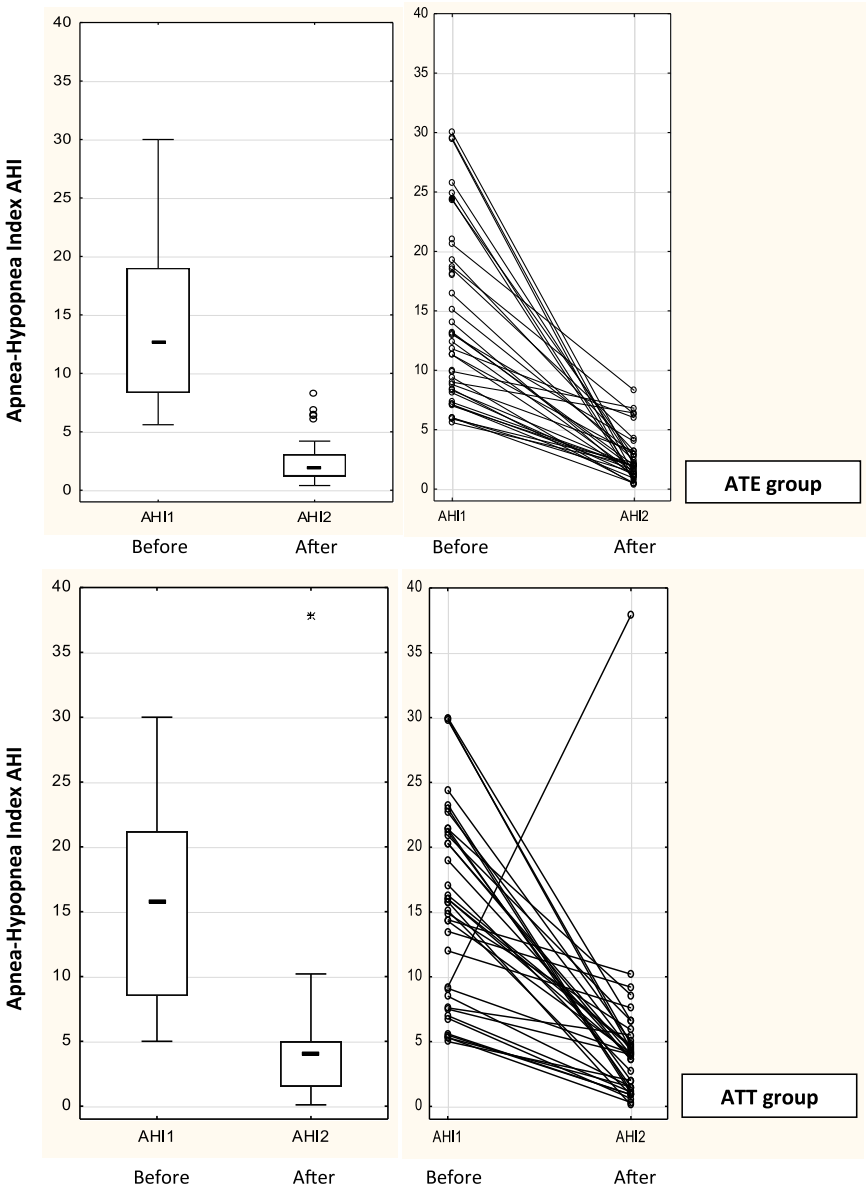

FIGURE 2
Boxplots and lines showing the AHI 1 (before surgical intervention) and AHI 2 (after surgical intervention) in the ATE group and the ATT group. Boxes show the median, 25% and 75% values, whiskers show the non-outlier range and dots represent the outliers. P values for the within-group changes were < .001 for both the ATE and the ATT group.

Secondary Outcomes

The median Obstructive AHI (OAHI) showed significant reductions in both the ATE, from median (IQR) 10.3 (6.7–17.3) to 0.8 (0.3–1.8) ($P < .001$), and the ATT group, from 13.9 (6.0–19.8) to 1.2 (0.6–2.5) ($P < .001$). The mean OAHI values also showed significant reductions in both groups, and the mean difference in OAHI changes between the 2 groups was 0.66 with a 95% CI −3.4 to 4.7; see Table 3.

Except for central AHI, other PSG variables showed significant within-group changes.

No significant differences in change score between groups were observed regarding the PSG variables (Table 3).

The TSS, Sleep Disturbance domain, and HRQL of the OSA-18 showed significant reductions within both groups, with no significant differences between groups (Table 3).

In the ATT group, 5 patients (13%), 4 boys and 1 girl, median age 32 (range 27–63) months, were decided to be in need of repeated surgery (TE) during the follow-up period. The second surgery was performed 14 ± 8.0 (mean ± SD) months after the first surgery. In the ATE group, no patient needed second surgery, whereas 1 patient had postoperative bleeding which needed surgical treatment.

TABLE 2 The Results From Each Group at 4 Levels of AHI at 1-Year Follow-up

AHI at Follow-up	ATE ($n = 36$)	ATT ($n = 38$)
	n (%)	*n* (%)
≤1	8 (22.2)	8 (21.1)
1.1–4.9	23 (63.9)	21 (55.3)
5–10	5 (13.9)	7 (18.4)
>10	0 (0)	2 (5.3)

DISCUSSION

To our knowledge, this is the first randomized study that compares ATT and ATE in pediatric OSA by measuring polysomnographic data. The results from the PSG suggest that ATT is noninferior compared with ATE in treating pediatric OSA, regarding the primary outcome (the difference in total AHI changes), and this was the main finding of the study. However, 5 patients in the ATT group needed repeated surgery (ATE) and thus must be considered failure of ATT.

The changes in AHI showed that the upper limit of the 95% CI did not exceed the noninferiority margin of 5, which was prespecified as a clinically relevant difference. When the outlier in the ATT group was excluded, the upper limit of the CI was even lower, further supporting the noninferiority hypothesis.

Moreover, both groups showed similar success rates for 4 levels of AHI with no significant difference in the distribution between the groups. For follow-up AHI ≤1, success rate was 22.2% in the ATE group and 21.1% in the ATT group. The highest success rates were seen when success was defined as AHI <5, giving 86.1% for ATE and 76.4% for ATT. In comparison, in the Childhood Adenotonsillectomy Trial study where ATE was compared with watchful waiting in children 5 to 9 years of age, the success rate (success defined as AHI <2) for the ATE group was 79%.[17] This is a higher success rate than in the current study, and this might be explained by the lower baseline AHI for the children in the Childhood Adenotonsillectomy Trial study, median 4.8, compared with median 14.3 in our study.

Moreover, a recent review and meta-analysis including 51 studies reported a success rate after ATE of 51% when defining success as AHI <1 and 81% for AHI <5.[18] The included nonrandomized studies evaluated unselected populations of children with various follow-up times and are therefore not directly comparable to our results.

A few studies of ATT have reported follow-up PSG data; 1 study of 20 children who underwent ATT found a reduced mean of 93% (from AHI 14.9 to 1.1).[19] Another study evaluating ATT in 70 children, reports success rates of 30% (success = AHI <1) and 73% (success = AHI <5) after ATT.[20] Another nonrandomized study of ATE versus ATT that included 29 children showed similar improvements after 6 months in both groups,[21] with comparable mean AHI reductions: 96% in the ATT group and 95% in the ATE group. In the current study, the mean reductions were somewhat lower, 82% for ATE and 71% for ATT, but still no significant differences between groups.

Other PSG variables also showed improvements with no significant differences between the groups. This further supports that ATT is no less effective than ATE regarding objective PSG outcomes.

The results of the OSA-18 scores suggest significant improvement of the quality of life in both groups. This is well in line with several previous studies,[7,21] and a recent meta-analysis comparing improvements in OSA-18 in 20 studies of TE and TT concluded that there was no significant difference.[8] The score of the OSA-18 is not correlated to the severity of OSA and has no diagnostic power,[22] but as a measure of quality of life, these improvements must be considered clinically relevant.

Tonsil regrowth and recurrence of OSA are known disadvantages after ATT, and 13% of the children in the ATT group underwent repeated

TABLE 3 Results From PSG Variables and OSA-18 Scores at PSG1 and PSG2 and Mean Difference in Change Score Between Groups

	n	ATE PSG1	ATE PSG2	*P*	*n*	ATT PSG1	ATT PSG2	*P*	Mean Difference in Change Score Between Groups (95% CI)	*P*
AHI	36	14.2 (7.6)	2.5 (2.0)	<.001*	38	15.4 (7.4)	4.5 (6.1)	<.001*	.83 (−3.23 to 4.88)	.69
OAHI	36	12.8 (7.9)	1.2 (1.2)	<.001*	38	13.3 (7.4)	2.3 (4.6)	<.001*	.66 (−3.39 to 4.70)	.75
Central AHI	36	1.3 (1.3)	1.3 (1.4)	.90	38	2.1 (2.1)	2.2 (2.3)	.958	.13 (−0.61 to 0.86)	.73
ODI	36	5.1 (5.2)	1.8 (1.4)	<.001*	37	4.6 (4.6)	2.0 (2.8)	<.001*	.63 (−1.37 to 2.64)	.53
RDI	36	16.4 (7.5)	2.1 (2.0)	<.001*	37	17.3 (7.6)	3.8 (5.0)	<.001*	.84 (−3.11 to 4.78)	.67
Mean Sao_2 (%)	36	95.5 (1.0)	96.9 (0.8)	.04*	37	96.7 (.8)	97.1 (0.8)	.003*	.00 (−0.45 to 0.45)	.99
Nadir O_2 (%)	32	86.5 (6.1)	90.5 (3.3)	.001*	37	86.7 (7.2)	9.1 (4.6)	.004*	−0.42 (3.58 to 2.74)	.79
OSA-18 TSS	34	60 (25–99)	31 (18–72)	<.001*	36	66 (29–103)	31 (20–61)	<.001*	−1.17 (−9.92 to 7.58)	.66
OSA-18 SDS score	34	17.5 (6–28)	5 (4–12)	<.001*	36	17 (7–28)	6 (4–24)	<.001*	1.07 (−3.77 to 1.63)	.37
HRQoL	34	7 (2-10)	9 (4–10)	<.001*	37	7 (2–10)	9 (5–10)	<.001*	0.53 (−0.72 to 1.79)	.40

Data are mean (SD) for polysomnographic (PSG) variables and medain (range) for OSA-18 scores. Between-group comparisons are differences in change scores between groups and presented as mean (95% CI). For PSG variables, parametric tests (paired and unpaired t-tests) were used; for OSA-18 scores, non-parametric tests (Wilcoxon signed-rank test and Mann Whitney U test) were used for within- and between-group omparisons. HRQoL, Healt Related Quality of Life; ODI, oxygen desaturation index; RDI, respiratory disturbance index; Sao_2, oxygen saturation; SDS, sleep disturbance score; TSS, Total Symptom Score.

* Significant difference ($P < .05$).

tonsil surgery within the follow-up period. This figure can be considered high compared with previously reported reoperation frequencies of 0% to 12%.[10,23] Possible explanations for this are the small study sample, the surgical technique, and/or that the study patients were closely followed up with PSG and revisit at the clinic 1 year postoperatively. In our current clinical practice, no such follow-up is possible. Instead, the parents are told to come back with their child if they notice recurrent OSA symptoms, meaning there might be a loss to follow-up.

A recent Swedish study based on >28 000 children reported a 7 times higher risk of reoperation after TT than after TE, with the difference most markedly among the youngest children.[24] In our study, the children undergoing reoperation were also among the youngest (median age 32 months).

The major strength of this study is the randomized design, minimizing the probability of selection bias and confounding. Another strength is that the study included children 2 to 6 years of age. It is unique to include such young children (<5 years) in this kind of study and of high interest because these are the ages when OSA prevalence peaks. The use of PSG and the low dropout rate are other strengths.

One weakness of the study is the homogenous group of study participants: nonobese children with enlarged tonsils, otherwise healthy, and with an AHI <30, thus making the generalizability somewhat limited. However, our study population reflects the typical pediatric OSA population in our country. Also, the generalizability could be limited because ATT was performed with the coblation technique, and there are several other methods for ATT that were not evaluated in this study. Another possible limitation is that follow-up PSG was done after 1 year, whereas previous literature

has suggested that reoccurrence of symptoms and need for repeated surgery may occur later than 1 year.[24] Thus, our 1-year follow-up could underestimate the need for repeated surgery after ATT.

Moreover, a possible weakness is that for the power analysis, a difference in AHI changes of 5 between the groups was chosen to be clinically relevant, and this difference might be high. If a smaller difference was chosen, a much higher sample size would have been needed, which would have been difficult, although we partially compensated for it by adding extra patients.

CONCLUSIONS

The findings of this randomized trial suggest that ATT is not less effective than ATE in treating pediatric OSA, evaluated by both objective PSG and subjective quality-of-life questionnaire. However, with ATT there is a non-negligible risk for tonsil regrowth, OSA recurrence, and repeated surgery, which should be informed to the parents preoperatively and taken into account when deciding surgical method. Furthermore, the long-term regrowth rate needs to be further studied before more widespread use of ATT.

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ABBREVIATIONS

AHI: Apnea Hypopnea Index
ATE: adenotonsillectomy
ATT: adenotonsillotomy
CI: confidence interval
HRQoL: health-related quality of life
IQR: interquartile range
OAHI: Obstructive Apnea Hypopnea Index
OSA: obstructive sleep apnea
PSG: polysomnography
RCT: randomized controlled trial
TE: tonsillectomy
TSS: total symptom score
TT: tonsillotomy

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