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Patient reported outcome measures (PROMs) in children with sleep-disordered breathing undergoing adenotonsillectomy

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Abstract. *Patient reported outcome measures (PROMs) in children with sleep-disordered breathing undergoing adenotonsillectomy. Objectives*: Patient reported outcome measures (PROMs) asses the health status or health related quality of life from the patient's perspective. The aims of this study were to assess the effect of adenotonsillectomy on symptoms and daily functioning in children with sleep-disordered breathing (SDB) using an electronic questionnaire, and to determine if this is a feasible method to evaluate treatment outcome in this patient population.
Methods: The electronic questionnaire was administered to the parents of children undergoing adenotonsillectomy for SDB on the day of surgery (T0), and two weeks (T1) and six months (T2) after surgery. The questionnaire scored symptoms in 5 different fields (snoring, sleepiness, behaviour, appetite, and apnoea). Higher scores indicated more pronounced symptoms. The score on T0 measured the preoperative symptoms. The main outcome measure (the change in scores between the postoperative measurements and the preoperative measurement) was analysed using the Wilcoxon signed-rank test.
Results: Eighty-eight percent of invited patients participated in the study. Six percent had no access to internet, and another 6% did not wish to participate. Language problems were not reported. Response rates for T1 and T2 were 82.6% and 79.7% respectively. The T1 and T2 scores were significantly lower than the scores on T0 for snoring, behaviour, apnoea, and sleepiness. The T2 appetite score was significantly higher than on T0, which indicates an improvement of appetite.
Conclusion: A comparison of pre- and postoperative results from an electronic disease-specific questionnaire indicated significantly improved symptoms and daily functioning in children undergoing adenotonsillectomy for SDB. High participation and response rates indicated it was feasible to assess treatment outcome by means of an electronic questionnaire.

Introduction

Childhood sleep-disordered breathing (SDB) has been described to range from primary snoring (isolated snoring without obstructive apnoea, arousals, or gas exchange abnormalities) to obstructive sleep apnoea syndrome (OSAS).[1] Habitual snoring is the predominant feature in every condition. Lumeng *et al*. estimated that approximately 7.45% of children snore regularly. According to their meta-analysis, OSAS has a prevalence of 1-4% in children without comorbidities.[1] Untreated OSAS in children may lead to a series of developmental and medical problems, such as behavioural and neurocognitive dysfunction, failure to thrive, and cardiovascular complications.[2]

Upper airway obstruction in children with SDB is most commonly caused by adenotonsillar hypertrophy; therefore, adenotonsillectomy (ATE) is the treatment of choice. It is among the most frequently performed surgical procedures in the daily practice of the ENT specialist. The most important indications are recurrent tonsillitis and upper airway obstruction. In Belgium, approximately 23,000 ATEs are performed every year, an amount that has remained stable over the past decade (The Belgian Federal Government RIZIV, RijksInstituut voor Ziekte- en InvaliditeitsVerzekering. Available at:

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www.riziv.fgov.be). Many studies have demonstrated the medical effectiveness of ATE performed for recurrent throat infections.[3,4] Sleep-disordered breathing affects a child's functioning. Therefore, evaluating treatment outcome in these cases is less straightforward. Various disease-specific questionnaires have been validated to evaluate the effect of SDB and its treatment on a child's daily activities, physical symptoms, social interactions, and emotional well-being.[5-7]

In recent years, "Patient Reported Outcome Measures" (PROMs) have become increasingly important. These PROMs are typically short, self-completed questionnaires that measure health status or health related quality of life from the patient's perspective. They can be used to evaluate quality of health care and functional treatment outcome. In addition, they can also be used to evaluate and support clinical practice as they indirectly evaluate a surgeon's diagnostic approach and decision-making.

The aim of our study was to set up a PROM to evaluate the effect of adenotonsillectomy on symptoms and daily functioning in children with SDB. We conducted a prospective study in Ziekenhuis Oost-Limburg, Genk, Belgium, in which we asked the parents of children undergoing surgery to complete an electronic disease-specific questionnaire based on the Paediatric Sleep Questionnaire before and after surgery. This questionnaire was developed to investigate the presence of childhood sleep-related breathing disorders and prominent symptom complexes, including snoring, daytime sleepiness, and related behavioural disturbances.[5] Our second aim was to assess if electronic questionnaires were a feasible means for evaluating treatment outcome in this patient population. As 40% of the population in the testing area is from a foreign country and speaks Dutch as a second language, we thought we might encounter some difficulty in administering a Dutch questionnaire. We also suspected that access to the internet would limit participation in our study.

Materials and methods

The study was conducted at the otorhinolaryngology department of Ziekenhuis Oost-Limburg in Genk, Belgium in cooperation with the hospital's outpatient surgery centre. Between 29 October 2009 and 28 October 2010, the parents of consecutive children aged 0 to 16 years undergoing adenotonsillectomy for SDB were invited to participate. Patients were selected for surgery based on a history of SDB (habitual snoring, witnessed apnoeas, mouth breathing, difficulty swallowing, daytime sleepiness, etc.) in combination with clinical findings of adenotonsillar hypertrophy. In our practice, tonsillar size is graded on a scale from zero (tonsils within the tonsillar pillars) to three (kissing tonsils). Children undergoing adenotonsillectomy for recurrent throat infections were not included.

On the day of the surgery, nurses in the outpatient surgery centre invited the parents of selected children to participate. After obtaining proper written consent, the nurse asked one of the caregivers to complete a disease-specific quality of life questionnaire on a computer in the centre. Informed consent sheets were also collected for parents who did not wish to participate and the reason for not participating was noted. The score on the day of the surgery (T0) measured preoperative symptoms. Two weeks (T1) and 6 months postoperatively (T2), the same questionnaire was sent to the parents by e-mail. If no response was obtained within one week, a friendly reminder was sent once.

The electronic questionnaire used in this study contained 21 questions and scored symptoms in 5 different fields: snoring, sleepiness, behaviour, appetite, and apnoea (Appendix). All questions but one had a yes/no response format. A positive answer was scored as one point, a negative answer as zero points. Question number 15 concerning appetite was the only one that had to be answered on a scale from 1 to 10, with a higher score indicating a greater appetite.

The difference between preoperative (T0) and postoperative (T1 and T2) total scores (sum of all questions except number 15) was analyzed using the Wilcoxon signed-rank test, as was the difference between pre- and postoperative scores for the 5 individual fields: snoring score (sum of all questions concerning snoring), sleepiness score (sum of questions concerning sleepiness), behavioural score (sum of questions concerning behaviour), appetite score (question number 15), and apnoea score (sum of questions concerning apnoea). All statistical analyses were performed using Stata MP/10.1 software.

Results

Of all invited patients, 88% participated in the study. Six percent of invited patients wished to

participate but couldn't because they had no internet access. Another 6% refused to participate for non-specified reasons. Inability to participate due to language problems was not reported. Parents of 69 children completed the questionnaire on the day of the surgery (T0) while 57 (82.6%) and 55 (79.7%) questionnaires were completed respectively two weeks (T2) and 6 months (T2) postoperatively. A reminder was sent for 24 patients at T1 and for 23 patients at T2. The median age was 4 years (IQR 3-5), with a range from 2 to 16 years. Sixty-two percent of children were male and 38% were female.

Pre- and postoperative questionnaire scores are shown in Tables 1 and 2. Higher scores indicated more pronounced symptoms. Total scores and scores for snoring, behaviour, and apnoea were significantly lower at T1 and T2 than on T0 ($p<0.0001$ and $p<0.0001$, respectively) and there was no significant difference between T1 and T2 scores. The sleepiness scores at T1 and T2 were significantly lower than on T0 ($p = 0.003$ and $p = 0.0001$, respectively) and the scores at T2 were also significantly lower than at T1 ($p = 0.04$). The appetite score at T2 was significantly higher than on T0 ($p = 0.01$), with higher scores indicating greater appetite. There was no significant difference between scores at T2 and T1, nor between T1 and T0 scores. The difference between the total score at T2 vs. T0 was calculated and the median difference (IQR) in was -7 (-10;-5).

Discussion

Adenotonsillectomy is one of the most commonly performed surgical procedures in the daily practice of the ENT specialist. The most important indications are recurrent tonsillitis and upper airway obstruction secondary to adenotonsillar hypertrophy. In a survey among Belgian ENT specialists, Jacobs *et al*.[8] estimated that, for children older than 5 years old, approximately 75% of ATEs are performed for recurrent throat infections. The other 25% are performed for upper airway obstruction. For younger children, the distribution tends to be more equal.[8]

Many studies have demonstrated the medical effectiveness of ATE performed for recurrent throat infections.[4,6] Recent retrospective analysis studies of 11,114 patient files obtained from the largest mutual health insurance company in Belgium demonstrated a 55% reduction in the use of antibiotics, a 31% reduction in the number of visits to the paediatric physician and general practitioner, and a 51% reduction in the use of respiratory medication in the year after surgery compared with the year before.[9,10]

Upper airway obstruction and SDB have an important functional impact. Meta-analysis studies by Friedman *et al*.[11] and Brietzke *et al*.[12] evaluated the effect of ATE in childhood OSAS using objective measures obtained with polysomnography (PSG) as a measure of cure. These studies showed that, although complete normalization of respiratory sleep parameters is not always achieved, ATE still offers significant improvements.[11,12] PSG objectively measures episodes of apnoea and hypopnoea in SDB, but it fails to relate disease and treatment with functional impact and outcome.

In this study, we set up a "Patient Reported Outcome Measure" (PROM) to evaluate the functional impact of adenotonsillectomy in children with SDB, as perceived by their parents. We asked the parents to complete an electronic questionnaire that measures the effects of disease on a child's breathing and sleeping patterns, general well-being, and functioning. Measurements were made on the day of the surgery (T0, scoring preoperative symptoms), as well as 2 weeks (T1) and 6 months (T2) postoperatively. Score changes were statistically significant for the overall scores and for the different fields of the questionnaire (snoring, sleepiness, behaviour, appetite, and apnoea), indicating substantial postoperative improvement in SDB-related symptoms. Scores remained significantly improved 6 months after surgery, suggesting a long-term effect of treatment.

We selected children for surgery based on their history of SDB and clinical findings of adenotonsillar hypertrophy. No additional preoperative technical investigations were performed. The American Academy of Paediatrics and American Thoracic Society recommend preoperative PSG to distinguish OSAS from primary snoring, as it is difficult to distinguish these two components of the SDB spectrum by clinical evaluation.[13-15] However, a survey among Belgian ENT specialists demonstrated that the current ATE practice in Belgium differs from these guidelines, as the majority of Belgian physicians consider ATE for upper airway obstruction to be indicated in children with clinically enlarged tonsils and a history suggestive of sleep

Table 1

Questionnaire scores for T0 (scoring preoperative symptoms), T1 (2 weeks postoperatively), and T2 (6 months postoperatively)

Question		**T1**	**T2**	**T3**
1. While sleeping, does your child snore more than half the time?	Yes (%)	64 (92.75)	3 (5.26)	3 (5.45)
2. While sleeping, does your child always snore?	Yes (%)	55 (79.71)	1 (1.75)	1 (1.82)
3. While sleeping, does your child snore loudly?	Yes (%)	46 (66.67)	1 (1.79)	2 (3.77)
4. While sleeping, does your child have heavy or loud breathing?	Yes (%)	58 (85.29)	6 (10.71)	4 (7.27)
5. Does your child have trouble breathing, or struggle to breathe during sleep?	Yes (%)	32 (47.06)	2 (3.57)	2 (3.64)
6. Have you ever seen your child stop breathing during the night?	Yes (%)	25 (36.76)	1 (1.79)	1 (1.82)
7. Does your child tend to breathe through the mouth during the day?	Yes (%)	57 (82.61)	17 (30.91)	16 (29.63)
8. Does your child often wake up during the night?	Yes (%)	46 (66.67)	10 (17.86)	11 (20.00)
9. Does your child occasionally wet the bed?	Yes (%)	27 (39.13)	19 (33.33)	15 (27.27)
10. Does your child have a problem with sleepiness during the day?	Yes (%)	31 (44.93)	12 (21.82)	9 (16.36)
11. Has a teacher or other supervisor commented that your child appears sleepy during the day?	Yes (%)	20 (29.41)	7 (12.73)	6 (10.91)
12. Is it hard to wake your child up in the morning?	Yes (%)	15 (21.74)	10 (17.86)	7 (12.73)
13. Does your child wake up with headaches in the morning?	Yes (%)	4 (5.88)	0 (0)	0 (0)
14. Has your child ever been found to be too small for his/her age?	Yes (%)	7 (10.14)	6 (10.53)	8 (14.55)
15. How is your child's appetite on a scale from 1 to 10?	see Table 2			
16. Does your child often not seem to listen when spoken to directly?	Yes (%)	31 (44.93)	10 (17.54)	14 (25.93)
17. Does your child have difficulty organising tasks and activities?	Yes (%)	12 (17.65)	6 (10.53)	4 (7.27)
18. Is your child easily distracted by extraneous stimuli?	Yes (%)	36 (52.17)	19 (33.33)	16 (29.09)
19. Does your child fidget with his/her hands or feet or squirm in his/her seat?	Yes (%)	36 (52.17)	15 (26.32)	22 (41.51)
20. Does it often seem as though your child is "on the go" or "driven by a motor"?	Yes (%)	32 (46.38)	16 (28.57)	14 (26.92)
21. Does your child often interrupt or intrude on others?	Yes (%)	31 (44.93)	28 (50.00)	20 (36.36)

apnoea. Only 8% of respondents considered a positive PSG to be necessary in the decision to operate.[9] These results are comparable to those from a survey among the members of the American Society of Paediatric Otolaryngologists (ASPO), which showed that the majority of respondents rely on a clinical diagnosis rather than PSG when recommending ATE for SDB in children.[16] The American Academy of Otolaryngology Head and Neck Surgery recently published less stringent guidelines, which recommend

Table 2
Median scores for T0, T1, and T2. IQR: inter-quartile range

	T0 Median (IQR)	T1 Median (IQR)	T2 Median (IQR)	score change T1-T0	score change T2-T0	score change T2-T1
Total score	9 (8-12)	3 (1-5)	2 (1-4)	P<0.0001	P<0.0001	P = 0.5
Snoring score	4 (3-4)	0 (0,0)	0 (0-0)	P<0.0001	P<0.0001	P = 0.8
Sleepiness score	1 (0-2)	0 (0-1)	0 (0-0)	P = 0.003	P = 0.0001	P = 0.04
Behavioural score	2 (1-4)	1 (0-2)	1 (0-3)	P<0.0001	P<0.0001	P = 1
Appetite score	7 (5-8)	7 (6-8)	7 (6-8)	P = 0.1	P = 0.01	P = 0.2
Apnoea score	1 (0-2)	0 (0-0)	0 (0-0)	P<0.0001	P<0.0001	P = 0.7

pre-operative PSG for children with symptoms of SDB and obesity (BMI ≥95th percentile), Down syndrome, craniofacial abnormalities, neuromuscular disorders, sickle cell disease, mucopolysaccharidoses, as well as for children without any of these comorbidities for whom the need for surgery is uncertain or when there is discordance between tonsillar size on clinical examination and the reported severity of SDB.[17]

Polysomnography is expensive and time-consuming. It gives no information on the level of obstruction. To our knowledge, there is no validated PSG threshold for clinically significant disease, as no studies have linked the criteria used with outcome.[18] Recent research suggests that milder forms of SDB may not be benign and that clinical benefits of ATE are not limited to children with OSAS.[19,20] Furthermore, there is a lack of standardization in PSG acquisition between centres, undermining its additional value.[21] Finally, PSG fails to quantify the impact of SDB on a child's general well-being, including emotional health and behaviour. Thus, the decision for surgery in children with SDB should first be based on thorough clinical evaluation rather than on PSG. This study clearly demonstrated improvement in SDB-related symptoms, supporting the current clinical practice.

The present study is an observational study in which all enrolled children underwent adenotonsillectomy. As the study did not contain a control group, it is not possible to exclude a certain bias in the reporting of postoperative improvement by the parents. Although it is likely to be the case, we cannot conclude with absolute certainty that the observed changes in questionnaire scores are purely the result of surgical treatment. Another limitation of our study is the lack of information on the, albeit limited, number of children whose parents did not consent to participate in the study or did not respond at T1 and T2. Finally, we used a translated and adapted version of the Paediatric Sleep Questionnaire, which has not yet been validated.

The second aim of our study was to assess if electronic questionnaires are a feasible method for evaluating treatment outcome in this patient population. We obtained a high participation rate and high response rates at T1 and T2 thanks to the nurses in the outpatient surgery centre who thoroughly explained the aim of the study and the meaning of the questionnaire. A minority (6%) of invited patients could not participate due to lack of internet access. Language problems were not reported. These findings demonstrate that the use of electronic questionnaires is a feasible method to evaluate treatment outcome in this patient population.

Conclusion

Quality of life is an important aspect in children with SDB. This study is an example of a "Patient Reported Outcome Measure" and demonstrates statistically significant improvements after adenotonsillectomy for all areas of an electronic disease-specific questionnaire. The method of using an electronic questionnaire to evaluate treatment outcome proved to be feasible and could be applied in other fields of study for evaluating clinical practice and quality of health care.

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Appendix – electronic disease-specific quality of life questionnaire (adapted from the Paediatric Sleep Questionnaire[6])

1. While sleeping, does your child snore more than half the time?
2. While sleeping, does your child always snore?
3. While sleeping, does your child snore loudly?
4. While sleeping, does your child have heavy or loud breathing?
5. Does your child have trouble breathing, or struggle to breathe during sleep?
6. Have you ever seen your child stop breathing during the night?
7. Does your child tend to breathe through the mouth during the day?
8. Does your child often wake up during the night?
9. Does your child occasionally wet the bed?
10. Does your child have a problem with sleepiness during the day?
11. Has a teacher or other supervisor commented that your child appears sleepy during the day?
12. Is it hard to wake your child up in the morning?
13. Does your child wake up with headaches in the morning?
14. Has your child ever been found to be too small for his/her age?
15. How is your child's appetite on a scale from 1 to 10?
16. Does your child often not seem to listen when spoken to directly?
17. Does your child have difficulty organising tasks and activities?
18. Is your child easily distracted by extraneous stimuli?
19. Does your child fidget with his/her hands or feet or squirm in his/her seat?
20. Does it often seem as though your child is "on the go" or "driven by a motor"?
21. Does your child often interrupt or intrude on others?

Total score: sum of all questions, except question 15
Snoring score: sum of questions 1-4
Sleepiness score: sum of questions 10-13
Behaviour score: sum of questions 16-21
Apnoea score: sum of questions 5-6
Appetite score: question 15