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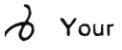
	TAKE OUT CHARACTER INDICATED	 Your proof.
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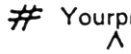
	INSERT SPACE	 Yourproof.
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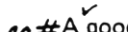
	EVEN SPACE	 A good proof.
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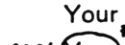
	CAPITALS	Your proof.  Your proof.
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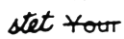
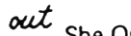
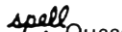
	DELETE, SEE COPY	 She Our proof.
	SPELL OUT	 Queen Eliz.
	START PARAGRAPH	 read. Your
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Measuring Quality of Life in Children with Adenotonsillar Disease with the Child Health Questionnaire: A First U.K. Study

Christos Georgalas, MRCS, DLO; Jeeve Kanagalingam, MRCS, DLO; Neil Tolley, MD, FRCS, DLO; Jeevendra Kanagalingam, MRCS, DLO; Jeevendra Kanagalingam, MRCS, DLO

Key Words: **Adenotonsillar disease, quality of life, child health questionnaire.**

INTRODUCTION

Adenoidectomy is among the most common operations performed on children worldwide. In 1999, in the United Kingdom, a total of 60,000 patients underwent tonsillectomy with or without adenoidectomy, whereas another 9,000 underwent adenoidectomy alone.[1] The indications for these procedures, however, remain controversial and are based (in the vast majority of cases) on relative indices of morbidity (recurrent infections or upper airway obstruction) as assessed by the surgeon. A recent Cochrane Review[2] article concluded that there is paucity of data originating from high-quality, blind, randomized studies regarding the efficacy of tonsillectomy.

Medical need is defined by the presence of morbidity and does not always correspond with the actual demand for medical services, which is influenced by external bias. Generic quality of life questionnaires present us with a way to assess the health needs of a population; however, these have not been widely used in children with adenotonsillar disease. Part of the problem is that the patients are too young to use traditional outcome measures and to express their suffering as well as their satisfaction with the results of an intervention in a clear and articulate way. The Child Health Questionnaire (CHQ) PF 28 version is a sensitive and reliable instrument for measuring global quality of life in young children through their parents' responses.[3] This questionnaire has been used extensively in the United States for the assessment of a variety of conditions including childhood cancer, asthma,[4] and juvenile rheumatoid arthritis, and a slightly adapted version of it was recently introduced in the United Kingdom.[5,6] The first study to examine the health status of children with adenotonsillar disease using a validated questionnaire in the United States was published in 2000.[7] This study showed a significant impact of adenotonsillar disease, although it failed to validate the scales and questionnaire used in their study population. We planned this preliminary study to assess the measuring characteristics of the CHQ questionnaire as well as explore different aspects of adenotonsillar disease in our study population of British children.

MATERIALS AND METHODS

Design

The study design is as a prospective observational survey.

Setting

The setting for the study was a tertiary academic pediatric specialty clinic serving an inner city population of multiethnic background (St. Mary's Pediatric ENT clinic, Paddington, London).

Patients

A consecutive series of 43 patients were referred by their general practitioners for adenotonsillar disease. Eligibility criteria included age from 1 to 14 years and referral for recurrent/chronic tonsillitis, history of peritonsillar abscess, nasal obstruction, snoring, mouth breathing, and disturbed sleep pattern. Exclusion criteria included rhinitis, obstructive sleep apnea, immunodeficiency, suspicion of neoplasm, other significant comorbidity, and non–English-speaking primary caretaker.

Methods

The CHQ (PF 28 version) was used. CHQ (PF28) is a 28 item questionnaire evaluating 15 areas of a child's well being. These are divided in two main categories: Physical Health, which includes Physical Functioning (PF), Role/Social-Physical (RP), General Health (GH/GGH), and Bodily Pain (BP), and Psychosocial

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Health, consisting of Parental Impact in terms of Time (PT) as well as Emotional Impact (PT), Family Cohesion (FC), Family Activities (FA), Role limitations Social-Emotional/Behavioral (REB), Self-Esteem (SE), Mental Health (MH), Behavior-Global Behavior (BE/GBE), as well as perceived Change in overall Health status (CH).

After vetting of the referral letter by the examining doctor, carers of referred patients were asked to participate in the study. Written informed consent was obtained from all carers. The assisting nurse subsequently collected the completed questionnaires, whereas the examining doctor remained blinded to their responses.

Outcome Measures

Main outcome measures. The main outcome measure was a psychometric validation of CHQ questionnaire. The CHQ (PF28) subscale and summary (Physical and Psychosocial) scores of our patients were compared with healthy children and children with rheumatoid arthritis.

Secondary outcome measures. The secondary outcome measure was a CHQ score comparison between two patient subgroups: children placed on the waiting list for adenoidectomy with or without tonsillectomy and children placed in a nonsurgical arm. CHQ scores were compared between children with predominantly infective and children with mainly obstructive symptoms.

Statistics

A psychometric validation of the questionnaire was performed using a multitrait item scaling analysis,[8] as described in the CHQ development manual[3] and using routines developed on SPSS (version 8.0, Chicago, IL). Questionnaires were analyzed for completeness and item comparability. Scores in multi-item scales were assessed for equivalence of means and variance (equal items-scale correlation). It is important that each item contributes equally to the individual construct being measured. This was assessed by comparing the item-scale Pearson correlation coefficients between the scores that comprise the eight multi-item scales (items internal consistency [linearity]). The absolute values of correlation coefficients between items and scales is a measure of the internal consistency of the scale. Generally a Pearson item-scale correlation greater than 0.4 is considered acceptable, and greater than 0.6 is very good. Item discriminant validity evaluates the specificity of an item as a measure of a particular construct. It requires that the correlation of the item with its scale is at least 1 (or preferably 2) standard errors higher than its correlation with the other scales. In our sample, Fisher transformation (from r to z) was performed to facilitate comparison. Floor and ceiling effects (the frequencies of lowest and highest scored answers) were investigated to assess the range of answers. Reliability estimates/consistency (a measure of test-retest variability assessed with the use of Cronbach alpha) were also calculated. Interscale correlation is used to evaluate how much each scale is distinct from the other scales and requires that the correlation coefficients between two scales are less than their reliability coefficients.

Power calculations. Assuming 80% statistical power (0.2 type b error) and 0.05 type a error in a bidirectional hypothesis, a sample of 45 children was estimated to be sufficient for detecting a 10 point difference in any subscale between our group and normative data. Two tailed t tests with Bonferroni adjustments for multiple comparisons were used for comparisons between groups.

RESULTS

The study took place between June and November 2000. The caretaker completing the questionnaire was the physical parent in 92% of the children (the mother in 81%) and his/her mean age was 36.7 (median 35). Fifteen of 35 (40%) carers worked either part or full time, whereas their median educational level was O'Level/GCSE. Fifty-three percent of responders defined themselves as white/British, whereas 47% belonged to ethnic minorities. All 43 carers completed and returned the questionnaires. The mean age of children was 6.3 (median 5.4, range: 1–14) years. Twenty-three were boys and 20 girls. Symptoms suggestive of nasopharyngeal/oropharyngeal obstruction were predominant in 53% of children, whereas 33% had mixed symptoms, and 10% were referred for recurrent/chronic infection. AQ: 1

Psychometric Issues

Because the CHQ questionnaire was used in this population for the first time in the United Kingdom, we evaluated its psychometric properties using multitrait/multi-item analysis. The overall rate of missing responses per item was 7.3% (range 0–18). In all 29 questions, the responses had a normal distribution. Items in six multi-item scales had similar means and standard deviations and as a result did not require standardization (PF, MH, SE, PE, PT, FA); however, that was not the case for GH and BE (see Table I for explanation of abbreviations). AQ: 2 T1

Equal Items

Scale correlations were for seven of eight (87%) scales, and the items/scale correlation coefficients were very similar, with the exception of GH(Table I).

TABLE I.
Psychometric Characteristics of Child Health Questionnaire in Our Group of Children.

	Item/Scales Descriptives (First and Second Likert Assumptions)			
Scale	Number of Items	Range of Means	Range of Standard Deviations	Range of Item Scale Correlations
PF	3	3.42–3.59	0.75–0.79	0.85 –0.93
RP	1	3.63	0.89	N/A
GH	4	2.73–3.33	0.94–1.56	0.52 –0.67
BP	1	4.50	1.53	N/A
FA	2	3.89–3.74	1.19–1.22	0.89 –0.91
REB	1	3.86	0.89	N/A
PT	2	3.30–3.20	1.06–1.17	0.93 –0.94
PE	2	3.45–3.63	1.42–1.48	0.84 –0.85
SE	3	4.20–4.29	0.81–0.93	0.79 –0.80
MH	3	4.07–4.29	0.87–1.12	0.77 –0.83
BE	4	2.30–4.24	0.95–1.26	0.69 –0.76
CH	1	3.24	1.01	N/A
GGH	1	2.93	0.75	N/A
GBE	1	2.30	1.08	N/A
FC	1	2.20	1.08	N/A

PF = physical functioning; RP = role/social-physical; GH = general health; BP = bodily pain; FA = family activities; REB = role limitations social-emotional/behavioral; PT = parental impact in terms of time; PE = ●●●; SE = self-esteem; MH = mental health; BE = behavior; CH = change in overall health status; GGH = global general health; GBE = global behavior; FC = family cohesion.

Items Internal Consistency (Linearity)

In our sample, all 23 (100%) items contributing to multi-item scales were correlated with their scales with Pearson correlation coefficients greater than 0.4, whereas 92% had correlation coefficients greater than 0.6 (Table II). T2

Item discriminant validity. All items (100%) demonstrated acceptable and 79% excellent discriminant validity (Table II).

Range of answers. The floor effect median was 4.7 (range 0–27.9), whereas the ceiling effect median was 38.3 (range 2.3–74.4), with the highest frequency of positive outcomes greater than 50% observed for PT, REB, PF, and RP scale items.

Consistency/reliability estimates. Cronbach alpha were calculated for all eight multi-item scales. They were greater than 0.7 in six of eight (75%) scales, failing in the case of PE and BE. Median was 0.75, and range was 0.07 to 0.86 (Table II).

Interscale correlation. Seven of eight (87%) constructs met the requirements, the exception being BE (Table II).

In summary, we showed that the scaling characteristics of the CHQ (PF28) in our sample were very satisfactory. The only scale that did not demonstrate consistently good results was BE, which has been noted previously[3] and reflects the heterogeneity of this particular subscale.

Clinical Issues

We compared our results with existing normative data, as derived from a recent United Kingdom study.[6] Children in our group scored lower in most scales than a sample of healthy British children. After Bonferroni adjustment for multiple comparisons, the difference was statistically significant in 11 of 15 subscales. Most prominent were the differences in global health ($P < .001$), general health perception ($P < .001$), bodily pain, and discomfort experienced ($P < .001$), emotional impact of the child's problems on the parents ($P = .001$) on family activities($P = .0003$) as well as on parents' time ($P = .001$) (Table III) (Fig. 1). T3 F1

A comparison with a group of British children with the persistent oligoarticular form of rheumatoid arthritis was then performed.[6] For most constructs, no significant difference was found. However, children with adenotonsillar disease had significantly lower subscale scores on the global health scale ($P = .009$) and the summary physical score ($P = .02$) (Table IV) (Fig. 1). T4

Subgroup Analysis

Although our sample was small, we felt the excellent scaling characteristics of CHQ could enable us to make comparisons between subgroups. Referral symptoms were divided into two general categories: predominately obstructive or predominately infective symptoms. Children in the recurrent infection/tonsillitis group scored worse in 13 of 15 subscales, although the difference was statistically significant only in the Change (CH) subscale ($P = .03$). Subsequently, we analyzed the quality of life of children who were booked for adenoidectomy/tonsillectomy with those treated medically. In 12 of 15 subscales, the mean scores of the children who were booked for an operation were lower than those treated medically, with the difference reaching statistical significance only in the case of emotional/behavioral role limitations (REB) ($P = .03$) (Fig. 2) (Table V). AQ: 3 F2/T5

DISCUSSION

Tonsillectomy or adenoidectomy in children has an absolute indication in pediatric obstructive sleep apnea and relative indication in recurrent infections or obstructive symptoms. There is, however, paucity of well-organized studies to assess the health impact of adenotonsillectomy in these cases. Although two randomized, controlled trials have evaluated its efficacy and shown that it can be effective in reducing the incidence of recurrent tonsillitis,[9,10] a recent meta-analysis showed no clear evidence of benefit.[2] This is in contrast with the experience of many clinicians as well as with the Scottish tonsillectomy audit of more than 9,000 patients that showed a 98% satisfaction rate with the procedure.[11] Essentially, the argument of its opponents is that episodes of recurrent tonsillitis and symptoms of enlarged adenoids may repre-

TABLE II.
Psychometric Characteristics of Child Health Questionnaire in Our Group of Children.

Scale	Internal Consistency Tests, Success Rate (%)	Discriminant Validity Tests, Distance More than One (Two) SE (%)	Reliability-Cronbach Alpha	Range of Interscale Correlations	Interscale Correlation Tests
PF	100	100 (100)	0.86	0.11–0.61	Pass
GH	100	100 (25)	0.81	0.16–0.38	Pass
FA	100	100 (100)	0.77	0.12–0.45	Pass
PT	100	100 (100)	0.87	0.04–0.73	Pass
PE	100	100 (100)	0.62	0.18–0.56	Pass
SE	100	100 (100)	0.74	0.07–0.24	Pass
MH	100	100 (100)	0.73	0.12–0.52	Pass
BE	100	100 (50)	0.07	0.04–0.52	Fail

See Table I for abbreviations.

TABLE III.
Comparison of Child Health Questionnaire Scores between Healthy U.K. Children and Children with Adenotonsillar Disease.

	Children with Adenotonsillar Disease (n = 43)		Healthy U.K. Children (n = 221)			
Scale	Mean	SD	Mean	SD	*P* Value	95% CI of Difference
Physical functioning	86.0	24.1	97.9	9.6	<.0001	7.6–16.1†
Role limitations, emotional behavioral	85.3	29.8	97.8	10	<.0001	7.4–17.5†
Role limitations, physical	87.8	26.6	97.2	11.9	.0003	4.3–14.4†
Bodily pain	70.0	30.6	94.3	13.8	<.0001	18.6–29.9†
Behavior	67.5	20.6	74.3	17.5	.02	0.9–12.7†
Mental health	81.1	19.3	80.8	10.9	.88	−3.8–4.4
Self-esteem	80.3	19.8	78.6	14.9	.52	−3.5–6.9
General health perceptions	57.2	20.4	79.5	13.7	<.0001	17.4–27.2†
Global health	65.0	25.1	93.3	9.5	<.0001	23.9–32.7†
Global behavior	73.8	25.4	78.4	20.9	.24	−2.5–11.7
Family cohesion	76.0	25.9	76.9	22.0	.81	−6.5–8.3
Parental impact, emotional	63.7	31.1	85.2	15.9	<.0001	15.2–27.8†
Parental impact, time	75.6	35.0	94.5	10.4	<.0001	13.3–24.5†
Family activities	72.6	26.2	86.5	15.9	<.0001	8.0–19.8†
Change	56.1	25.5	57.7	15.6	.59	−7.4–4.3
Physical score	35.5	16.9	55.4	4.2	<.0001	17.3–22.4†
Psychosocial score	53.1	7.2	51.6	7.1	.20	−0.8–3.8

* Significant at .05 level; † significant at <.001 level.

sent a stage of normal development and as such are not associated with significant morbidity. If that was the case, it is logical to assume that these children would be almost equivalent to other healthy children in terms of their overall well-being.

Over the recent years, there has been an expansion in methodologic research on quality of life, with the development of various quality of life questionnaires (instruments) that assess quality of life, with more than 100 devised for use in adults.[12] Such questionnaires can form

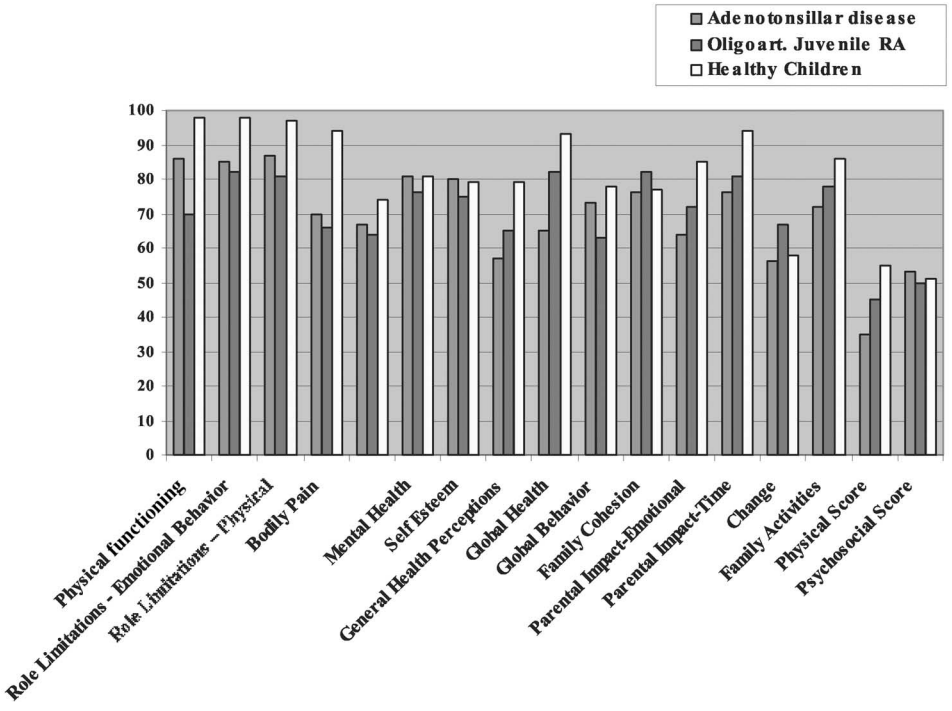

Fig. 1. Child Health Questionnaire (PF28) subscale scores in U.K. children with adenotonsillar disease, rheumatoid arthritis, and healthy controls

TABLE IV.
Comparison of Child Health Questionnaire Scores between Children with Adenotonsillar Disease and Children with Oligoarticular Juvenile Rheumatoid Arthritis.

	Children with Adenotonsillar Disease (n = 43)		OligoartJuvenile Rheumatoid Arthritis (n = 19)			
Scale	Mean	SD	Mean	SD	*P* Value	95% CI of Difference
Physical functioning	86.0	24.1	70.7	36.4	.05	−.3–30.9
Role limitations, emotional behavioral	85.3	29.8	82.7	31.5	.75	−14.1–19.3
Role limitations, physical	87.8	26.6	81.5	31.3	.41	−9.1–21.7
Bodily pain	70.0	30.6	66.0	28.5	.63	−12.5–20.5
Behavior	67.5	20.6	64.7	27.1	.65	−9.7–15.3
Mental health	81.1	19.3	76.2	17.2	.34	−5.4–15.2
Self-esteem	80.3	19.8	75.8	20.7	.41	−6.5–15.5
General health perceptions	57.2	20.4	65.3	20.1	.15	−19.2–3.0
Global health	65.0	25.1	82.5	20.2	.009	−30.5–4.4*
Global behavior	73.8	25.4	63.3	31.6	.16	−4.6–25.6
Family cohesion	76.0	25.9	81.7	17.1	.38	−18.7–7.3
Parental impact, emotional	63.7	31.1	72.8	23.9	.26	−25.1–6.9
Parental impact, time	75.6	35.0	81.5	27.4	.51	−24.0–12.2
Family activities	72.6	26.2	78.5	29.7	.43	−20.9–9.1
Change	56.1	25.5	66.7	27.8	.15	−25.1–4.0
Physical score	35.5	16.9	45.0	11.5	.02	−18.0–0.9*
Psychosocial score	53.1	7.2	50.3	10.6	.22	−1.8–7.4

* Denotes difference significant at .05 level.

the basis for the assessment of the need for intervention and subsequently can validate efficacy as well as assess its relative and absolute cost effectiveness (quality adjusted life years [QALY]). However, only recently have similar endeavors been undertaken in children, with only a handful of instruments developed for use in children.[13,14] For young children, it is accepted that their parents are in a position to act as proxies for their needs and that quality of life questionnaires completed by them can reflect accurately and reliably their children's true health status.[15] CHQ is the most widely used of these questionnaires and has recently been validated in the United Kingdom.

We undertook this study to explore the burden of adenotonsillar disease in the community. We looked at children with adenotonsillar hypertrophy considered severe enough to warrant referral but not necessarily an operation. CHQ has never before been used in this population of children, and its robustness has not yet been fully explored in the United Kingdom. For that reason, we undertook psychometric analysis of CHQ in our popula-

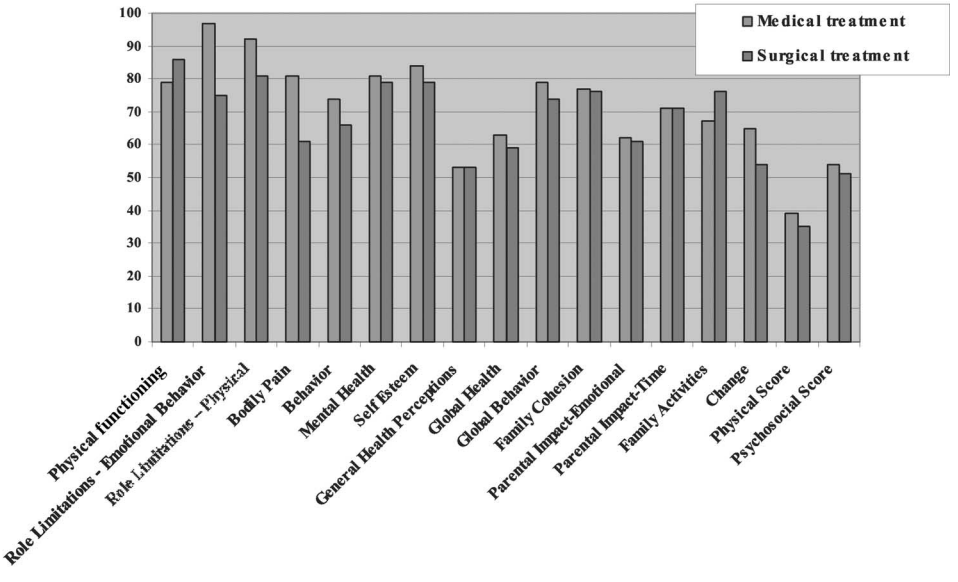

Fig. 2. Child Health Questionnaire (PF28) subscale scores in U.K. children with adenotonsillar disease listed for surgery and treated medically.

TABLE V.
Comparison of Child Health Questionnaire Scores between Children Listed for Surgery and Children Treated Conservatively.

	Children Listed for Adenotonsillectomy (n = 14)		Children Treated Conservatively (n = 17)			
Scale	Mean	SD	Mean	SD	*P* Value	95% CI of Difference
Physical functioning	78.9	25.9	85.7	27.3	.77	−29.1–16.1
Role limitations, emotional behavioral	81.2	29.7	97.4	9.2	.03	2.9–41.9*
Role limitations, physical	87.8	26.6	92.3	19.9	.24	−7.9–30.1
Bodily pain	61.2	37.5	81.5	22.3	.08	−2.5–43.4
Behavior	66.3	22.1	74.1	16.3	.33	−8.3–24.0
Mental health	79.1	16.5	80.7	23.1	.83	−14.2–17.4
Self-esteem	79.1	20.8	84.1	18.6	.41	−6.5–15.5
General health perceptions	53.0	22.7	53.9	18.0	.93	−17.7–16.3
Global health	59.3	29.5	62.6	21.8	.73	−17.0–23.8
Global behavior	74.7	25.0	78.8	27.3	.67	−15.5–23.8
Family cohesion	75.8	24.7	77.3	19.5	.86	−15.6–18.5
Parental impact, emotional	60.7	35.3	61.5	36.6	.95	−27.6–29.3
Parental impact, time	71.1	39.0	70.8	40.2	.98	−31.8–31.3
Family activities	75.9	25.7	67.7	29.8	.43	−31.2–14.7
Change	54.4	28.2	64.5	22.5	.31	−10.0–30.3
Physical score	35.1	16.8	38.6	13.3	.35	−13.9–20.9
Psychosocial score	51.5	7.3	53.7	5.6	.52	−5.7–10.1

* Denotes difference significant at .05 level.

tion, taking into account that it was an inner city population of a mixed ethnic background. The item-internal consistency (the ability of items to measure a particular construct) was higher than 0.4 for all items in all 11 scales. The discriminant validity (the ability of answers to differentiate between different scales) was also excellent for all items in the questionnaire. More important, its reliability (measured by Cronbach's alpha, i.e., the measure of the proportion of answers than could be caused by random error, as opposed to true variance) was higher than 0.7 for almost all scales and validates its use for group comparison.

We were then able to proceed to the next step, namely comparison of our group with other groups of children. We found that children referred for adenoidectomy with or without tonsillectomy scored poorly in almost every area of well being, with the exception of mental health, self-esteem, and family cohesion. The difference from healthy children was quite marked in the areas of Bodily Pain and the overall health perception of their parents, as well as in terms of both emotional and time impact for their parents. When we compared these children with children with a monoarticular form of rheumatoid arthritis, they were roughly equal in most areas in terms of well-being, although they scored lower in the general health perception of their parents as well as the overall physical scale.

Although both in the United Kingdom[16] and the United States,[17] national guidelines exist regarding tonsillectomy in children, in practice, the management of these children varies greatly between general practitioners, pediatricians, and otolaryngologists and even between different otolaryngologists, according to their training.[18] In our sample, despite the fact that surgeons were blinded to the questionnaire's answers, it appears that children's overall quality of life was intuitively taken into account in the decision for surgery. Although it is difficult to reach conclusions because of the small sample, in 13 of 15 subscales, these children scored lower than their counterparts who were managed with medical treatment or a wait and see policy. It also appears that parents are more worried about infective symptoms (recurrent or chronic sore throats) than obstructive symptoms (snoring, mouth breathing), a fact that has potential implications in our management of these children.

There are several limitations in our study. It was planned as a preliminary study, that is, a feasibility study to examine whether this questionnaire could be used to assess the quality of life deficit in children with adenotonsillar disease. Our number of patients as well as the design of our study precluded the conclusive assessment of the different components of adenotonsillar disease, the surgical decision process, or the potential benefits of intervention. Lack of an age, sex, and socioeconomic status-matched control group weakens the validity of comparison with healthy subjects. However, the normative data that already existed from healthy British subjects was quite robust and permitted a gross comparison, whereas our main aim was primarily the psychometric evaluation of the questionnaire in children suffering from adenotonsillar disease. The presence of comorbidity (albeit minor) could have influenced the overall assessment of these children. Also, we only studied a selected sample referred to a specialty clinic and as such it is possible that only children with the most severe forms of disease were seen.

However, our definition of adenotonsillar disease was not very strict: essentially it was made by the general practitioner and confirmed by the ENT surgeon on the basis of a credible history of tonsillitis and adenoid hypertrophy symptoms after the exclusion of other conditions causing the symptoms and consistent physical examination. This was a conscious decision because this was designed as a pragmatic study, assessing a group of children who make frequent use of medical services with considerable health implications, although they may not fit the standard criteria for adenotonsillectomy.

Overall, it appears that the impact of adenotonsillar disease is significantly greater than previously thought, involving most aspects of a child's life. Although our criteria for tonsillectomy have become more strict, none of the published guidelines actually take into account quality of life issues. We feel that validated techniques for measuring changes in life quality will play a role in surgical decision-making in the future. More research is needed to understand the factors that contribute to this impact on quality of life and to measure the effect of surgery on such patients. Such studies would need a much larger number of patients and adequate control groups. The North of England Study of Tonsillectomy and Adenotonsillectomy in Children (NESTAC) was undertaken under the NHS Health Technology Assessment program and is an excellent step in that direction.

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AUTHOR QUERIES

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AQ2—'Please spell out PE here and in Table I.'

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