Health outcome measurements in children with sleep disordered breathing

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Objective: To validate the Child Health Questionnaire, measure quality of life in children with obstructive sleep apnoea (OSA) and assess the impact of surgery.
Methods: The primary carer of a consecutive series of 42 patients with sleep disordered breathing referred to a paediatric otolaryngology clinic completed the Child Health Questionnaire (version PF 28). Questionnaires were analysed for data quality and completeness, item/scale correlation, internal consistency and discriminant validity, interscale correlation and reliability. Following overnight pulse oximetry 37 children were diagnosed with OSA and underwent adenotonsillectomy.
Results: Child Health Questionnaire Physical Functioning (CHQ-PF) 28 demonstrated excellent measuring characteristics in our population. Compared with normative data, children with OSA and their carers suffer a significant quality of life deficit, involving 10 of 13 subscales of CHQ. This was most prominent in parental emotional impact, general health perception and family activities. There was no correlation between the severity of OSA and QOL indices. Following surgery, there was a significant improvement in all CHQ subscales, which became equivalent to healthy children.
Conclusion: The CHQ PF 28 is an accurate and reliable way of assessing the impact of Obstructive sleep apnoea on the quality of life in children in Britain. This appears to be significant in most aspects of a child's life, but is fully reversed following surgery.

Sleep disordered breathing (SDB) and obstructive sleep apnoea (OSA) are common conditions in childhood, with prevalence ranging from 3.2% to 12.1% for SDB and 0.7% to 10.3% for OSA.[1–3] Both conditions, but primarily OSA, are associated with significant sequelae, including cognitive and behavioural abnormalities, possible impact on growth and cardiovascular complications, which seem to be reversed with surgical treatment.[4] As a direct result, an increasing number of operations are performed for SDB and OSA whilst the rate of adenotonsillectomies for recurrent tonsillitis has been decreasing.

In addition, both OSA and SBD have a significant psychological impact on the patients and their carers: parents may feel helpless and interpret the disturbed breathing pattern of their child as a sign of impending apnoea, resulting in significant stress and disruption in family relations. This may be further complicated by behavioural changes of the child, resulting directly from OSA.

Child Health Questionnaire (CHQ-PF 28 version) is a sensitive and reliable generic instrument for measuring quality of life in young children through their parents responses,[5]CHQ (PF28) is a 28-item questionnaire evaluating 13 areas of a child's well being. These include physical functioning (PF), role/social–physical (RP), general health (GH) and bodily pain (BP), parental impact in terms of time (PT) as well as emotional impact (PT), family cohesion (FC), family activities (FA), role limitations social–emotional/behavioural (REB), self-esteem (SE), mental health (MH), behaviour–global behaviour (BE) as well as perceived change in overall health status (CH). It has been used extensively in studies assessing QOL in children, including children with epilepsy,[6] asthma[7] and juvenile rheumatoid arthritis.[8]

Although there have been a number of studies in the USA assessing the QOL impact of paediatric OSA using disease specific questionnaires, namely the OSA-18,[9–17] only two studies,[18,19] have used a generic questionnaire. Neither of these two studies used overnight sleep oximetry for OSA diagnosis or validated the CHQ questionnaire in their study sample. Following our use of CHQ in children with adenotonsillar disease in a previous study,[20] we planned this first UK study to assess (i) the measuring characteristics of CHQ as well as (ii) the quality of life and impact of surgery in our study population of British children. Assessment of the measuring characteristics of CHQ was important: Although it has been performed in

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different populations, cultural and social differences as well as divergent attitudes towards health and disease, different health systems and access to health-care mean that their conclusions are not immediately applicable to this particular group of children.

Materials and methods

Design

Prospective observational survey.

Setting

A tertiary, academic paediatric specialty clinic serving an inner city population of multiethnic background (St Mary's Paediatric ENT Clinic, Paddington, London)

Patients

Consecutive series of 42 patients with sleep disordered breathing. Eligibility criteria included age from 1 to 14 years and referral for snoring, apnoeic episodes and disturbed sleep pattern. Exclusion criteria were immunodeficiency, suspicion of neoplasm, other significant comorbidity and non-English speaking primary carer.

Methods

Child Health Questionnaire (PF 28 version) was used. After review of the referral letter by the examining doctor, carers of referred patients were asked to participate in the study. The assisting nurse subsequently collected the completed questionnaires while the examining doctor remained blinded to their responses. The questionnaire was administered again, 3 months after surgery.

Ethical considerations

As this was a non-interventional audit, ethics committee approval was not applied for. All carers of patients provided verbal consent to participate in our study.

Outcome measures

Psychometric validation of CHQ Questionnaire. Psychometric validation of the questionnaire was performed using multi-trait item scaling analysis[21] as described in the CHQ development manual[3] and using routines developed on SPSS (version 13.0) software by the first author.

Quality of Life measurement.

1 Assessment of QOL using CHQ (PF28) subscale scores (comparison of our patients with a normative sample).
2 Impact of surgery on CHQ score.
3 Correlation between OSA indices and CHQ scores.

Power calculations

Assuming 80% statistical power (0.2 type b error) and 0.05 type a error in a bi-directional 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 November 2005 and June 2006. The carer completing the questionnaire was the physical parent in 94% of the children (the mother in 78%) and his/her median age was 35.1 years. Fourteen of 42 (32%) carers worked either part or full time while their median educational level was O'Level/GCSE. All 42 carers completed and returned the questionnaires. The mean age of children was 6.1 years (median: 5.7; range: 1–11). Twenty-two were boys and 20 girls. All 42 children had overnight oximetry. This demonstrated an average of 59 desaturation episodes (range: 0–160). Their average (lowest) oxygen desaturation was 74% (range: 98–60%).

Thirty-seven children had more than five apnoeic episodes per hour and were thus diagnosed with OSA, and subsequently underwent surgery. The postoperative questionnaire was completed by the parents 3 months following surgery.

Psychometric validation of CHQ questionnaire

Questionnaires were analysed for 'completeness and item comparability'. The overall rate of missing responses per item was 2.3% (range 0–11). In all 28 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 standardisation (PF, MH, SE, PE, PT, FA). However, that was not the case for GH and BE (Table 1).

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 items that

Table 1. Psychometric characteristics of CHQ in our group of children (item/scales descriptives)

	Item/scales descriptives		
Scale	No. items	Range of means	Range of standard deviations
PF	3	3.49–3.72	0.66–0.92
RP	1	3.63	0.89
GH	4	2.71–3.84	0.94–1.56
BP	1	4.50	1.53
FA	2	3.84–3.94	1.17–1.24
REB	1	3.86	0.89
PT	2	3.37–3.47	0.97–1.0
PE	2	3.70–3.82	1.32–1.48
SE	3	4.16–4.25	1.05–1.16
MH	3	4.09–4.45	0.89–1.13
BE	4	3.51–4.08	0.92–1.43
CH	1	3.24	1.01
FC	1	2.20	1.08

Table 2. Psychometric characteristics of CHQ in our group of children (item/scale correlations)

	Item/scale correlations	
Scale	Items	Pearson correlation coefficient
PF	2.1 a	0.94
	2.1 b	0.84
	2.1 c	0.82
BE	5.1 a	0.82
	5.1 b	0.85
	5.1 c	0.84
	5.2	0.61
SE	7.1 a	0.92
	7.1 b	0.90
	7.1 c	0.94
GH	8.1 a	0.80
	8.1 b	0.51
	8.1 c	0.75
	8.2	**0.49**
PE	9.1 a	0.94
	9.1 b	0.93
PT	9.2 a	0.95
	9.2 b	0.95
FA	9.3 a	0.94
	9.3 b	0.93

comprise the eight multi-item scales. For seven of eight scales, the items/scale correlation coefficients were very similar, with the exception of GH (Table 2).

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 >0.4 is considered acceptable and >0.6 is excellent. In our sample, all 23 (100%) items contributing to multi-item scales were correlated with their scales with Pearson correlation coefficients >0.4, while 21 of 23 had correlation coefficients >0.6 (Table 2).

Item discriminant validity. 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 one (or preferably two) standard errors higher than its correlation with the other scales. In our sample, Fisher transformation (from r to z) was performed to facilitate comparison. All items (100%) demonstrated acceptable and 79% excellent discriminant validity (Table 4).

Floor and ceiling effects (the frequency of lowest and highest scored answers) were investigated to assess the 'variability of answers'. The floor effect median was 2.5% (range 1.3–7.6) while the ceiling effect median was 38.5% (range 1.3–78.4), with the highest frequency of positive outcomes >50% observed for PT, SE, REB and RP scale items.

'Reliability' was assessed with the use of Cronbach alpha. Cronbach alpha were calculated for all eight multi-item scales. They were >0.7 in seven of eight (87%) scales, failing in the case of GH. Median was 0.85 (range 0.59–0.91; Table 4).

'Interscale correlation' was 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. Seven of eight (87%) constructs met the requirements, the exception being GH (Table 3).

Quality of Life measurement

Pre-treatment QOL. We compared our results with existing normative data, as derived from a recent UK study.[22] Children in our group scored lower in most scales than this sample of healthy British children. After Bonferroni adjustment for multiple comparisons, the difference was statistically significant in 10 of 13 subscales. Most prominent were the differences in emotional impact of the child's problems on the parents ($P = 0.001$), general health perception ($P < 0.001$), family activities ($P = 0.0003$) and parents' time ($P = 0.001$; Fig. 1).

Table 3. Psychometric characteristics of CHQ in our group of children [Interscale correlations (Pearson correlation Sig. two-tailed)]

	PF	BE	MH	SE	GH	PE	PT	FA
PF	1	0.372 (0.001)**	0.466 (0.000)**	0.170 (0.136)**	0.464 (0.000)**	0.537 (0.000)**	0.439 (0.000)**	0.449 (0.000)**
BE	0.372 (0.001)**	1	0.479 (0.000)**	0.167 (0.141)	0.403 (0.000)**	0.560 (0.000)**	0.459 (0.000)**	0.499 (0.000)**
MH	0.466 (0.000)**	0.479 (0.000)**	1	0.198 (0.082)	0.325 (0.004)**	0.417 (0.000)**	0.308 (0.006)**	0.261 (0.022)*
SE	0.170 (0.136)**	0.167 (0.141)	0.198 (0.082)	1	0.335 (0.003)**	0.312 (0.005)**	0.173 (0.130)	0.245 (0.031)*
GH	0.464 (0.000)**	0.403 (0.000)**	0.325 (0.004)**	0.335 (0.003)**	1	0.624 (0.000)**	0.455 (0.000)**	0.617 (0.000)**
PE	0.537 (0.000)**	0.560 (0.000)**	0.417 (0.000)**	0.312 (0.005)**	0.624 (0.000)**	1	0.645 (0.000)**	0.715 (0.000)**
PT	0.439 (0.000)**	0.459 (0.000)**	0.308 (0.006)**	0.173 (0.130)	0.455 (0.000)**	0.645 (0.000)**	1	0.659 (0.000)**
FA	0.449 (0.000)**	0.499 (0.000)**	0.261 (0.022)*	0.245 (0.031)*	0.617 (0.000)**	0.715 (0.000)**	0.659 (0.000)**	1

*Correlation is significant at the 0.05 level (two-tailed). ** Correlation is significant at the 0.01 level (two-tailed).

Table 4. Psychometric characteristics of CHQ in our group of children (distance more than one (two) SE)

	Distance more than one (two) SE		
Scale	Discriminant validity tests (%)	Reliability–Cronbach alpha	Interscale correlation tests
PF	100 (100)	0.85	Pass
GH	100 (25)	0.59	Fail
FA	100 (100)	0.86	Pass
PT	100 (100)	0.91	Pass
PE	100 (100)	0.86	Pass
SE	100 (100)	0.91	Pass
MH	100 (100)	0.80	Pass
BE	100 (50)	0.79	Pass

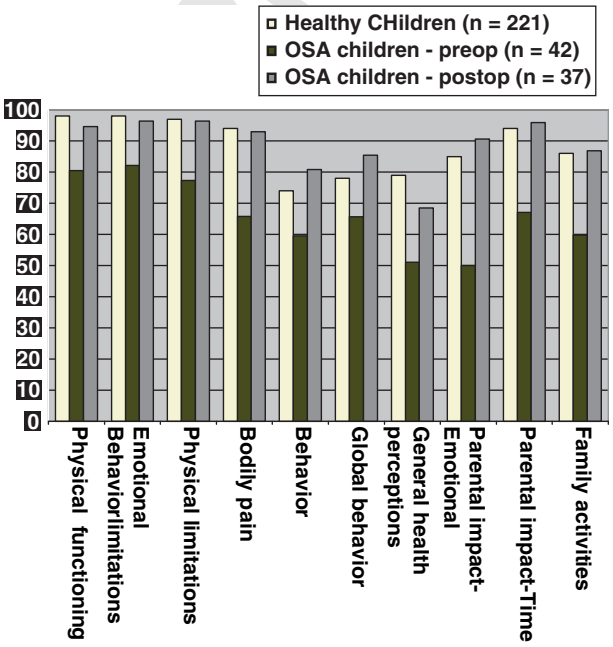

Fig. 1. CHQ (PF 28) Subscale scores in UK children with OSA before and following surgery compared with normative data.

Correlation analysis. Although our sample was small, we felt the excellent scaling characteristics of CHQ could enable us to assess a correlation between OSA indices (lowest O_2 desaturation/Apnoeic episodes and CHQ scores). There was no significant correlation between QOL and OSA indices, as assessed preoperatively.

Post-treatment analysis. CHQ scores improved in all children following surgery. The change was more prominent in areas that demonstrated the greatest deficit. There was no difference in CHQ scores between healthy children and children with OSA who had surgery (Table 5).

Discussion

Psychometric issues

As medicine is adopting a more patient-centred perspective, the use of questionnaires is proving valuable in the assessment of the impact of disease: However, the ability of a questionnaire to measure what it is supposed to be measuring can never be taken at face value: Differences in attitudes towards health and disease, cultural, social, financial disparities, different health systems and different ways of access to health-care mean that one questionnaire that was useful to measure the burden of a condition in one country may be completely useless in a different setting: With this in mind, we performed a psychometric validation of the CHQ in this group of children: We found that all questions were strongly correlated with the concept they were supposed to be measuring (excellent internal consistency) and more so than with the other concepts (acceptable discriminant validity). All concepts demonstrated good reliability (Cronbach alpha) and were clearly distinct between them (lower interscale correlation) with the exception of GH (General Health). In summary, we showed that the scaling characteristics of

Table 5. Comparison of CHQ scores between children with sleep disordered breathing before and after surgery

Scale	Children with SDB preoperatively ($n = 42$) Mean (SD)		Children with SDB after surgery ($n = 37$) Mean (SD)		*P*-value	95% CI of difference
Physical functioning	80.5	23.8	94.6	19.2	0.005	4.4–23.8
Role limitations–emotional behavioural	82.1	30.8	96.4	10.5	0.007	4.0–24.5
Role limitations–physical	77.2	31.1	76.4	17.2	0.001	7.9–30.4
Bodily pain	65.7	31.3	72.9	15.8	<0.001	16.3–38.2
Behaviour	74.1	22.6	88.5	17.1	<0.001	12.4–30.2
Mental health	74.1	20.9	88.5	19.6	0.003	5.1–23.4
Self-esteem	74.5	24.3	86.5	26.3	0.17	−3.4–19.2
Global health	51.1	23.1	68.4	21.4	0.001	7.3–27.3
General health perceptions	**58.5**	27.9	**85.5**	23.1	**<0.001**	**15.5–38.4**
Global behaviour	65.5	24.8	85.4	15.8	<0.001	1−.5–29.0
Family cohesion	73.8	23.9	71.8	20.9	0.12	−2.1–18.1
Parental impact–emotional	**50.0**	30.6	**90.5**	20.0	**<0.001**	**29.0–52.0**
Parental impact–time	**67.6**	35.7	**95.8**	13.4	**<0.001**	**16.8–40.7**
Family activities	59.8	30.6	86.8	16.1	<0.001	15.6–38.3

the CHQ (PF28) in our sample were very satisfactory. The only scale that did not demonstrate consistently good results was Global Health (GH), which has been noted previously[3] and reflects the heterogeneity of this particular subscale.

Clinical issues

This study has shown significant improvements in quality of life following surgery for obstructive sleep apnoea. Although several studies in USA have focused on the quality of life impact of paediatric Obstructive Sleep Apnoea, their results can not be considered directly applicable in the United Kingdom: QOL studies are culture- specific, reflecting the fact that emphasis on disease and aspects of health vary in different countries and cultures. This makes it difficult to extrapolate the results from one such study from one country to another, which prompted us to perform this particular study.

We used a generic questionnaire as we feel that they are generally preferable to disease specific questionnaires for multiple reasons: Firstly, they are designed to measure the patient's overall well being, and not just a small area that is of interest to the clinician, and as a result they are by definition, more relevant to the patient. Secondly, the fact that they can be used to measure health status in patients with different pathologies means that they can provide a common scale for directly comparing the impact of different disease processes. Finally, by producing generic health status data they can be valuable in informing health policy and management decisions such as those based on Quality Adjusted Life Years (QALY) assessment. Their main drawback, however, is that they are generally considered to be a 'crude' way of measuring QOL and are sometimes unable to detect small changes in health status or not sensitive enough to measure the treatment effect. In this study, we have shown that a generic QOL scale can measure the health impact of paediatric OSA while maintaining excellent sensitivity to change following corrective surgery.

This study has demonstrated that paediatric sleep disordered breathing has a significant impact on children and their parents, reflected by the statistically and clinically significant decreases in 10 of 13 subscales of CHQ. The impact, although comparable to that measured in Flannery's study, is more prominent than measured in Stewart's study, which showed change only in Physical but not psychosocial measures. Our results show that these children and their carers suffer significant morbidity, which merits treatment *per se*, and perhaps independently of the neurobehavioural or cardiovascular sequelae of OSA. In terms of QOL, these children and their families suffer as much as children with rheumatoid arthritis or moderate asthma.

Some of the children we assessed preoperatively had been diagnosed with SDB, and not necessarily OSA. The fact that their deficit in terms of QOL was so prominent points towards the conclusion that OSA/SDB are part of a continuum, as reflected in prevalence and sequelae, and are interpreted as such by the parents. This is further supported by the fact that we found no correlation between OSA indices (lowest Saturation/Desaturation

episodes) and CHQ scales. It is of interest that the criteria for the diagnosis of OSA are quite arbitrary – as stated in Paediatrics technical report – 'normative standards for PSG have been chosen on the basis of normative distribution of data but it has not been established that they have any validity as predictors of complications'.[23]

Our results highlight the fact that our population may be more severely affected than previously reported in US studies, with implications for management. This has been shown in other areas, such as OME (where studies in the USA.[24] failed to show a cognitive impact of OME in children, in direct contradiction to similar studies in the UK.[25]) This could be the result of different access to health care in the UK compared with the USA, as NHS constraints and the 'gatekeeper' role of GP mean that only children with significant morbidity reach specialist attention. In terms of specific QOL impact, we found that the subscales which showed the most significant impact were the emotional impact on the parents as well as the impact on family activities and the global health perceptions of the parents.

Two of these three areas were also the ones more affected in Steward's US study. This corroborates our results, and confirms a pattern – namely that parents interpret apnoeic episodes/SDB as potentially life threatening events: while we as clinicians are worried about the long-term sequelae, the parents are worried about their child stopping breathing, and in many cases have to stay awake. This is also reflected in poor health perception and also in disruption in family activities, further complicated by neurobehavioural and growth problems of the child, which can arise as a direct consequence of OSA.

Importantly, we found that all the negative QOL effects of OSA/SDB are reversed after surgery. This has been shown in previous studies, but must be interpreted with caution, as expectation bias from surgery can always skew such findings. However, the scale of improvement is impressive, and more importantly, is almost exclusively in the areas with more significant preoperative decrease, which makes it unlikely to be purely explained by expectation bias, and adds to the arguments for surgery.

We recognise that our study has some limitations: foremost is the small number of patients recruited in our study. However, the number of patients was based on *a priori* power calculations and indeed it was planned as a preliminary study. The patients and their parents were not blinded to treatment, as it would be impossible by definition to have patients and parents unaware of surgery performed, although the doctor administering the questionnaire was blinded as to the intervention applied We appreciate that the open design of this study makes it vulnerable to introduction of bias, specifically expectation bias and the placebo effect of surgery. This is problem that is inherent in most studies of surgical interventions and is only partly addressed by the findings of decreased CHQ scores preoperatively. Additionally, the normative data we used came from a study performed in the UK in 2001 and refer to children older than the ones we studied: we appreciate that this difference in ages could make the comparison problematic. However, the results of children after surgery mirror these normative data, and we feel that differences in age are unlikely to account for the gap between children with SDB and healthy children.

In summary, we found that in a British cohort of children with SDB, there is a significant impact in almost all areas of Quality of life that is fully reversed by surgery. Although this was only a preliminary study, we hope that it will generate further research in this area, that will help us understand better these vulnerable patients and their carers.

Conflict of Interest

None to declare.

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Change to capitals	≡ under matter to be changed	≡
Change to small capitals	= under matter to be changed	=
Change to bold type	~ under matter to be changed	~
Change to bold italic	≈ under matter to be changed	≈
Change to lower case	Encircle matter to be changed	≠
Change italic to upright type	(As above)	⌐
Change bold to non-bold type	(As above)	⌐
Insert 'superior' character	/ through character or ⌐ where required	Y or Y under character e.g. Y^{3} or Y^{3}
Insert 'inferior' character	(As above)	⌐ over character e.g. Y_{2}
Insert full stop	(As above)	⊙
Insert comma	(As above)	,
Insert single quotation marks	(As above)	Y or Y and/or Y or Y
Insert double quotation marks	(As above)	Y or Y and/or Y or Y
Insert hyphen	(As above)	⊢
Start new paragraph	⌐	⌐
No new paragraph	⌐	⌐
Transpose	⌐	⌐
Close up	linking ⁀ characters	⁀
Insert or substitute space between characters or words	/ through character or ⌐ where required	Y
Reduce space between characters or words	| between characters or words affected	⊤