

Psychometric performance of EQ-TIPs and PedsQL in infants and toddlers with congenital defects post-surgery in China

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Abstract

Objective

EQ-TIPS is an experimental EuroQol instrument for infants and toddlers younger than four years. To date evidence on the psychometric performance of EQ-TIPS is only available from South Africa. The aim of this study was to compare the psychometric performance of EQ-TIPS and the PedsQL Generic Core Module (PedsQL) in young children who had received surgery for congenital defects.

Methods

Parents of children with Omphalocele (abdominal wall defects) or Tetralogy of Fallot (TOF, combination of four heart defects) who attended the Children's Hospital, Zhejiang University School of Medicine in China since 2018 were contacted and recruited in September and October 2023. In this cross-sectional study, EQ-TIPS and PedsQL were administered online, in a fixed order, to parents of children aged between one month to four years via proxy report. Response distribution, ceiling effects, known-group validity and convergence were assessed for both instruments in the two clinical samples respectively and by child age (1-12 months, 13-24 months, 2-4 years).

Results

This study included 115 children (mean age =1.73) with Omphalocele and 123 children with TOF (mean age =1.73). Over 95% of the parents reported their children had good recovery and prognosis post-surgery. For the Omphalocele and TOF samples respectively, we observed ceiling effects of 65.2% and 72.4% on EQ-TIPS (11111), 24.4% and 34.2% on EQ VAS scores (100), and 19.1% and 12.2% on PedsQL (100). Mean (SD) EQ VAS scores were 87.1 (12.7) and 90.0 (13.9), respectively, and mean (SD) PedsQL total scores were 82.0 (17.4) and 81.8 (15.8). We found statistically significant differences in PedsQL scores between age groups but not in EQ-TIPS level sum scores (LSS) and EQ VAS. In the Omphalocele sample, EQ-TIPS LSS and PedsQL total scores showed small to large effect sizes (ES) in differentiating the presence of other birth defects (ES=0.381 and 0.295 for EQ-TIPS and PedsQL respectively) and children's general growth & development (ES=0.709 and 0.217 respectively). Similarly in the TOF sample, the presence of any cardiac symptoms (ES=0.423 and 0.768 respectively) and children's general growth & development (ES=0.664 and 0.813 respectively) showed medium to large ES. We found moderate correlations between EQ-TIPS LSS and PedsQL total scores, and moderate associations on 1-2 item pairs of 13 EQ-TIPS item and PedsQL item pairs hypothesised to be correlated in children aged under 2 years old.

Conclusion

The EQ-TIPS, EQ VAS, and PedsQL total scores exhibited high ceiling effects in this study. Despite the children's severe congenital health issues, a majority of parents reported relatively good health-related quality of life (HRQOL) of their children post-surgery. Anecdotally, it was observed that parents had generally low expectation to their children's HRQOL prior to surgery, which may explain the high HRQOL scores reported post-surgery. Both the EQ-TIPS and PedsQL GCM demonstrated good known-group validity, with the EQ-TIPS showing better differentiation in the Omphalocele sample and the PedsQL GCM performing better in the TOF sample. Additional qualitative research could be useful in better understanding why parents rated their children's HRQOL so high in these clinical populations. Future research should consider HRQOL at multiple time points including prior to surgery, immediately after the surgery, and 6-12 months following the surgery to evaluate responsiveness.

1. Introduction

Despite remarkable progress in child survival rates globally over the last three decades, there remains a substantial burden of disease among younger children [1, 2]. The focus of promoting child health is not just survival, but also thriving. As a result, there is a growing emphasis on assessing and improving health-related quality of life (HRQOL) in children within both research and healthcare settings. A multitude of instruments exist for assessing HRQOL in children aged five and above; however, until recently, there has been a notable lack of instruments designed for younger children, specifically those under the age of five. The assessment of HRQOL in children under the age of five has attracted growing interest in recent years due to advancements in developing new measures and the reassessment of existing guidelines [3, 4]. Several newly developed HRQOL instruments that are accompanied by preference weights have emerged for assessing HRQOL in preschool-aged children, facilitating the calculation of health utility scores to inform decision-making processes. This includes the Health Status Classification System-Preschool (HUPS) [5], the Infant Health-related Quality of Life Instrument (IQI) [6, 7], and the EuroQoL Toddler and Infant Populations (EQ-TIPS) [8, 9]. EQ-TIPS is an experimental EuroQol instrument for children aged between one month to three years with recent exploration of use in children aged four years [10, 11]. EQ-TIPS has been developed as a concise, generic instrument that will facilitate the provision, in future, of preference weights to accompany it; at present value sets are not available. To date published literature on the psychometric performance of the EQ-TIPS is only available from South Africa, with ongoing research in Australia [12] and China [13]. More data and evidence from countries other than South Africa and across different conditions are needed.

The present study collected data using the EQ-TIPS among young children aged between one month to four years with congenital defects, specifically Omphalocele and Tetralogy of Fallot (TOF) post-surgery in China. Omphalocele is a congenital anomaly characterized by herniation of abdominal viscera through a defect in the abdominal wall, with a prevalence ranging from 1 in 6000 to 1 in 4000 in newborns [14, 15]. It is often detected during the second and third trimesters of pregnancy. More than half of the children with Omphalocele also have other birth defects including, spine, heart, gastrointestinal related problems [16, 17]. Minor omphalocele can usually be effectively treated with primary surgical intervention, which is usually implemented shortly after birth. In contrast, for children with giant omphalocele, a staged surgical strategy or conservative management is often required over a few days to weeks [18]. TOF is a congenital heart defect characterized by four distinct structural abnormalities in the heart, resulting in altered blood flow and decreased oxygen levels in the body. Individuals with this condition typically present with cyanosis, or bluish discoloration of the skin, due to insufficient oxygenation. Surgical intervention is necessary to correct the defects which is usually implemented during the first year of age, and lifelong monitoring and follow-up care are essential for individuals diagnosed with TOF [19]. There was limited evidence on HRQOL in very young children affected by the two conditions, however studies have found the HRQOL in adults affected by TOF are notably diminished [20], while mixed evidence on HRQOL in adolescents and adults affected by Omphalocele [21-23].

This study aimed to comprehensively evaluate the psychometric performances of EQ-TIPS and PedsQL in young children with congenital defects post-surgery in China.

2. Method

2.1 Participants and procedure

Participants were identified from two established patient databases that includes children with Omphalocele or TOF managed at Department of Neonatal Surgery and Department of Cardiac Surgery respectively, at the Children's Hospital, Zhejiang University School of Medicine, Hangzhou, China since

2018. Parents of patients who have undergone the surgical repairs of Omphalocele or TOF were included. All parents are routinely invited to join an online support group (via WeChat, a commonly used social media software in China) organised by corresponding departments, which enables the provision of ongoing support from the departments and peer support. An online survey link with consent form was shared with parents in the WeChat groups. Parents of patients aged between one month to four years old and who gave consent were included in the present study. Only one parent completed the survey questionnaire for each patient. Data collection was carried out in September and October 2023. No incentive was given to participants.

Ethics approval was granted by the Medical Ethics Committee of the Children's Hospital, Zhejiang University School of Medicine (Ethics approval number: 2023-IRB-00154-P-01).

2.2 Survey questionnaire and HRQOL instruments

The survey included the following parts: general characteristics such as socio-demographic characteristics, medical insurance, social benefits; parent-reported disease and surgery related information, and proxy-reported HRQOL using EQ-TIPS and PedsQL in a fixed order (EQ-TIPS first).

2.2.1 EuroQol Toddler and Infant Populations (EQ-TIPS)

The EQ-TIPS was initially developed for children aged 1-36 months for proxy report [9], and recently the development team explored its use within four years [10, 11]. Therefore, the simplified Chinese EQ-TIPS was used in this study. The EQ-TIPS uses the recall period of 'today'. The EQ-TIPS includes a descriptive system consisting of six dimensions/items: movement, play, pain, communication, social interaction and eating, and a Visual Analogue Scale (EQ VAS) on a 0 (worst) to 100 (best) scale. Each dimension/item has three levels: level 1 (no problems), level 2 (some problems) and level 3 (a lot of problems) [8]. The health state measured by the EQ-TIPS descriptive system can be summarized as a six-digit string, representing the level of each dimension in the order presented in the questionnaire. The best health state is described as 111111 and the worst as 333333. As the EQ-TIPS does not currently have a utility score we reported level sum score (LSS) as the summary scores for the descriptive system, which ranges from 6 to 18. We also reported EQ VAS scores. A lower LSS suggests better HRQOL, and a higher EQ VAS score suggests better HRQOL.

2.2.2 PedsQL Generic Core Module (PedsQL)

The proxy-reported version of PedsQL for infants aged 0-12 months, 13-24 months, and toddlers aged 2-4 years was used in this study [24]. The recall period was 'past one month'. The PedsQL for infants and toddlers (1-12 months and 13-24 months) includes 36 and 45 items respectively, covering five domains: physical functioning (PF), physical symptoms (PS), emotional functioning (EF), social-functioning (SF) and cognitive-functioning (CF). The PedsQL for children aged 2-4 years includes 21 items, covering PF, EF, SF and school functioning (School). Each item has a raw score ranging from 0 (never a problem) to 4 (always a problem), which is converted to a 0 to 100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0 [25]. Domain level scores were calculated by the summation of item scores (on a 0-100 scale) over the number of completed items in each domain. The total PedsQL score was calculated as the sum of all the items over the number of completed items [25]. A higher score indicates better HRQOL.

2.3 Data analysis

Descriptive statistics were used to summarize the general and clinical characteristics of patients and their parents who filled in the questionnaire.

At the item/dimension level, we examined response distribution by reporting the frequency of responses to each level of EQ-TIPS items and PedsQL items and presented the distribution in figure. We examined the differences in response distribution by age group (1-12 months, 13-24 months, 2-4 years) using Pearson's Chi-squared test. At the instrument level, we reported means and standard deviations (SD), median and interquartile range (IQR) of EQ-TIPS LSS, EQ VAS scores, PedsQL domain scores and total scores for each condition and by age group within each condition. We examined differences in scores by age group using Kruskal-Wallis tests.

The ceiling and floor effects were assessed by reporting the proportion of the sample choosing the highest and lowest levels across all dimensions for EQ-TIPS (111111), and by reporting the proportion of a score of 100 or a score of 0 on EQ VAS and PedsQL total scores. The analysis was performed in each sample and by age group. Following literature, the 15% threshold was used for examining ceiling and floor effect [26, 27].

Known-group validity assesses the extent to which an instrument detects differences between groups where responses are expected to differ. Group differences were assessed at the instrument level by comparing EQ-TIPS LSS, EQ VAS score and PedsQL total scores. For each condition, we hypothesized that there would be differences between the following groups: parent-perceived prognosis after surgery (very good, good, fair/poor/very poor), parent-rated children's general growth & development (Very good, good, fair/poor/very poor). In addition, we compared differences in scores by the presence of other birth defects in the Omphalocele group, and by the presence of any cardiac symptoms in the TOF groups. The statistical significance of the difference across groups in our sample was tested using non-parametric Mann-Whitney U tests or Kruskal-Wallis tests as the summary scores were not normally distributed. The magnitudes of the difference across groups were assessed using the Cohen's d effect size. Effect sizes of 0.2–0.49 were considered as small, 0.50–0.79 moderate, and ≥ 0.80 large [28, 29]. A mean difference with a p value of < 0.05 and a large effect size (≥ 0.8) was considered as good performance.

Convergent validity is evaluated by examining the extent to which a specific dimension of the instrument demonstrates significant correlations with dimensions that are theoretically expected to be related. In this study, we examined the correlations between EQ-TIPS items, EQ-TIPS LSS, and EQ VAS scores with PedsQL domain scores and total scores, anticipating moderate to strong correlations[10, 11]. We also assessed the correlations between EQ-TIPS items and PedsQL items by age groups. As indicated in grey shaded cells in Tables S1-S2 in the appendix, we hypothesized that in age group 1-12 months and 13-24 months, moderate to strong correlations would be identified between the following 13 pairs: 'movement' vs 'participating in active play'; 'play' vs 'participating in active play'; 'pain' vs 'having hurts or aches'; 'social interaction' vs 'not smiling at others', 'social interaction' vs 'not laughing when tickled', 'social interaction' vs 'not making eye contact with caregivers'; 'social interaction' vs 'not laughing when cuddled'; 'communication' vs 'not imitating caregivers actions'; 'communication' vs 'not imitating caregivers facial expression'; 'communication' vs 'not imitating caregiver sounds'; 'eating' vs 'spitting up after eating'; 'eating' vs 'difficulty swallowing', 'eating' vs 'vomiting'. In the 2-4 years old age group, we hypothesize that the following 7 pairs to be at least moderately correlated: 'movement' vs 'walking'; 'movement' vs 'running'; 'play' vs 'active play or exercise'; 'play' vs 'playing with other children'; 'play' vs 'keeping up when playing with other children'; 'pain' vs 'having hurts or aches'; 'social interaction' vs 'playing with other children'. The analysis was conducted separately for each condition, with correlations computed using Spearman's correlation coefficient. Correlations falling within the range of 0.1 to 0.29 were classified as weak, those between 0.3 and 0.49 as moderate, and those equal to or exceeding 0.5 as strong [29].

3. Results

3.1 General and clinical characteristics of the study population

This study included 115 children with Omphalocele and 123 children with TOF. Table 1 displays the demographic and clinical features of the study cohort across both conditions. A majority of the afflicted children in our sample were between the ages of 2 and 4, and were male. Nearly 95% of parents indicated, on retrospection, that their child's postoperative recovery and prognosis were either good or very good.

[Table 1]

3.2 Distribution of responses

Figure 1 shows the response distribution for EQ-TIPS in two conditions. In Omphalocele, the proportion of respondents reporting at least some problems (level 2 or level 3) for movement, play, pain, social interaction, communication and eating were 1.7%, 3.4%, 13.6%, 5.1%, 5.9% and 25.4% respectively. Only 2 parents reported 'a lot of problems' (level 3) on pain while no level 3 responses were obtained on any other items. We did not find statistically significant differences in the distributions by age groups except for eating: more than 80% of parents of patients aged 1-24 months reported no problems on eating while 63.6% of parents of patients aged 2-4 years reported no problems. In TOF, the proportion of respondents reporting at least some problems (level 2 or level 3) for movement, play, pain, social interaction, communication and eating were 5.3%, 3.8%, 6.1%, 8.4%, 13.0% and 17.6% respectively. We observed responses on level 3 across all items except for pain. We did not find statistically significant differences in the distributions by age groups.

[Figure 1]

Figures S1-3 in the appendix show the distribution of PedsQL items for each age group in two conditions. Across all three age groups, more problems were reported on items in the domain of Emotional Functioning compared to other domains in both conditions. For children aged 1-12 months, more frequent problems were reported on Physical Symptoms domain in the Omphalocele sample (e.g. 'having gas'; 'spitting up after eating') while more frequent problems were reported on Emotional Functioning domain (e.g. 'feeling angry'; 'crying or fussing when left alone') in TOF sample. Similarly, more frequent problems were reported on these items in children aged 13-24 months. In addition, we found nearly 20% and 10% of parents of children with Omphalocele and TOF reported 'often' or 'always a problems' on 'difficulty naming familiar objects' and 'difficulty repeating words' on Cognitive Functioning domain. For 2-4 years old group, overall, less problems were reported compared to younger age group. Response on 'always a problem' were reported only on the School Functioning domain in children affected by Omphalocele, whereas it was reported on all domains except for School Functioning domain among children affected by TOF.

For the Omphalocele and TOF samples respectively, we observed ceiling effects of 65.2% and 72.4% on EQ-TIPS (111111), and 24.4% and 34.2% on EQ VAS scores (100). We observed ceiling effects of PedsQL in Omphalocele (19.1%) but not in TOF (12.2%). The ceiling effects for EQ-TIPS were slightly lower in 2-4 years group in both conditions compared to younger age groups but differences were not statistically significant. However, the pattern was the opposite for PedsQL and the proportion reporting 100 were significantly different across age groups. Mean EQ VAS scores were 87.1 and 90.0 in Omphalocele and TOF, and mean PedsQL total scores were 82.0 and 81.8 respectively. We found statistically significant differences in PedsQL scores between age groups within each condition, i.e., at 1% significance level in the Omphalocele sample and 10% significance level in the TOF sample, but not in EQ TIPS LSS and EQ VAS.

[Table 2]

3.3 Known group validity

Both EQ-TIPS and PedsQL showed good known-group validity in differentiating groups within each condition. EQ-TIPS LSS and PedsQL total scores showed small to strong effect sizes in differentiating the presence of other birth defects ($ES=0.381$ and 0.295 for EQ-TIPS and PedsQL respectively) and children's general growth & development ($ES=0.709$ and 0.217 respectively) in Omphalocele sample, in differentiating the presence of any cardiac symptoms ($ES=0.423$ and 0.768 respectively) and children's general growth & development ($ES=0.664$ and 0.813 respectively) in the TOF sample.

[Tabel 3]

3.4 Convergent validity

As shown in Tables 4 and 5, at the instrument level, we found moderate correlations between EQ-TIPS LSS and PedsQL total scores, and weak to moderate correlations between EQ VAS and PedsQL total scores. At the item level (see Appendix tables S1-S6), in the age group 1-12 months, among the EQ-TIPS item and PedsQL item pairs ($n=13$) hypothesized to be correlated, we only found moderate association between eating and 'difficulty swallowing' in Omphalocele sample, and between eating and 'vomiting', between pain and 'having hurts or aches' in TOF sample. Because 100% of parents of both conditions reported no problem on social interaction and communication items of EQ-TIPS, there were strong monotonic correlations measured by Spearman's rank correlations ($\rho=1$) between these two dimensions and all PedsQL items. In the age group 13-24 months, among the 13 pairs hypothesised to be correlated, we found moderate correlation between eating and 'difficulty swallowing' in Omphalocele sample, moderate correlations between play and 'difficulty participating in active play', communication and 'not imitating caregivers' actions' and 'not imitating caregivers' facial expressions'. In the age group 2-4 years old, moderate associations were found among four of the seven pairs hypothesised to be correlated, i.e., movement and 'running', play and 'active play or exercise', 'playing with other children', and 'keeping up when playing with other children' in Omphalocele sample, but only one pair in TOF sample (social interaction and 'play with other children').

[Table 4 & 5]

We also found strong correlations in pairs that were not hypothesized to be correlated in Omphalocele sample, i.e., 'pain' and 'feeling tired'; 'pain' and 'crying a lot' (1-12 months); 'play' and 'bathing'; 'play' and 'hurts or aches'; 'eating' and 'running' (2-4 years). Play was moderately associated with 20 out of 21 items in PedsQL in 2-4 years, and eating was moderately-to-strongly associated with all items on physical functioning domains in the same age group. In children with TOF aged 13-24 months, play was weakly to moderately associated with all items on domains of physical functioning, social functioning and cognitive functioning; communication was moderately-to-strongly associated with eight out of nine items on physical functioning domains.

4. Discussion

This study provides novel findings regarding the validity of the EQ-TIPS and PedsQL in young children (aged one month to four years) with two congenital defects, specifically, Omphalocele and TOF following surgical intervention in China. The EQ-TIPS exhibited very high ceiling effects in both groups and PedsQL exhibit ceiling effects in children with Omphalocele, with high EQ VAS and PedsQL scores observed in both groups. However, both instruments demonstrate good known-group validity in both conditions, with EQ-TIPS showing better performance in distinguishing between groups in the

Omphalocele sample and PedsQL performing better in the TOF sample. Moderate correlations were observed between EQ-TIPS level sum scores and PedsQL total scores in both conditions.

The EQ-TIPS demonstrated ceiling effects in both samples, specifically 65.2% in Omphalocele and 72.4% in TOF, exceeding the reported rates in children with health conditions in South Africa (28%-46%) [10, 11], children with medical conditions or disabilities in Australia (29.2%) [12] and a recent study on children affected by COVID-19 in China (30.4%) and their healthier non-infected counterparts (61.0%)[13]. At the individual item level, 'eating' had the highest proportion of reporting problems in both samples (74.6% to 82.4%), followed by 'pain' in the Omphalocele sample (86.4%) and communication in the TOF sample (87.01%). Consistent with previous studies, a similar trend was observed where eating, communication, and pain items had higher rates of reported problems compared to other items. However, the proportions reporting no problems on EQ-TIPS items in the present study were notably higher than those reported in prior research. One possible explanation, which were found to be attributed to the high ceiling effects of adult EQ-5D instruments observed in China in comparison to other countries [30], is cultural-specific issues and reporting styles [31]. Nevertheless, we observed an elevated proportions in this study compared to the other EQ-TIPS study in China. This may be explained by the nature of conditions investigated in our study, which we discussed in more detail in the following paragraphs. Alternatively, it may be influenced by variations in data collection procedures and modes of administration [13]. The sample in their study was gathered from children receiving medical care in hospitals, either upon admission or during outpatient visits.

In our sample, PedsQL also demonstrated ceiling effects in Omphalocele (19.1%) but not in TOF (12.2%), and the mean scores were 82.0 and 81.8 respectively. There was limited evidence on HRQOL measured by PedsQL or other generic measures among infants and toddlers affected by Omphalocele or TOF, and most existing studies focused on older children aged 4 years and above. One study reported a mean PedsQL total score of 88 among children aged 4-17 years old born with Omphalocele in the Netherlands [32]. Two studies used PedsQL to measure HRQOL in children with repaired TOF aged 8-18 years which reported a mean PedsQL total score of 75 in Swedish children [33], and 85.3 and 77.4 by self and parent proxy report in the United States [34]. A few more evidence was available on younger children with congenital heart disease, where the PedsQL total score ranged from 76 in infants aged 13-24 months and 77.7 in toddlers 2-4 years in Australia [35] to 86.1 in children aged 2-4 years in India [36]. Children affected by TOF aged 2-4 years in our sample reported a mean score of 83.9 which seemed to be comparable with other countries. When comparing our results with healthy children in China which was 81.2 among 2-7 years old [37] and 80.7 among 2-18 years old by parent report, the mean PedsQL total score in both samples were comparable to healthy children. This is in line with existing studies in children with Omphalocele in the Netherlands [32], and children with TOF or other congenital heart diseases in the United States [34] and Indonesia [38].

EQ-TIPS showed high ceiling effects whereas PedsQL also demonstrated ceiling effects, which may be a true reflection of parents' perceived health of their children. Though the children in our sample were with serious birth defects, they had undergone surgeries and over 95% of parents reported good prognosis of their children's condition. Most of Omphalocele and TOF are detected during pregnancy and parents experience significant psychosocial and financial burden by the diagnosis [39]. Anecdotally, it was observed that parents generally had accepted their children's diagnosis and had very low expectations to their children's HRQoL pre-surgery. With efficient surgical interventions that repaired these defects and survived their children, parents are satisfied, which may explain the high HRQOL scores reported post-surgery. In addition, parents in our sample may be well supported by the hospital and peers through the online chat groups. Studies have found that peer support for parents of children

with birth defects have positive impact on psychosocial well-being, through emotional and informational support, particularly when health professionals are involved [40, 41]. This may also impact on parent's perceived health of their children. However, an alternative explanation relates to potential sample selection bias, as we sampled from those who voluntarily participated in the peer support group.

Comparing the ceiling effect between EQ-TIPS and PedsQL, it is not surprising that EQ-TIPS demonstrated much higher rate compared to PedsQL. This can be explained by the number of items, items and domains covered and recall period. Particularly, more frequent problems were reported on PedsQL Physical Symptoms domains (e.g. 'having gas'; 'spitting up after eating') in Omphalocele and on Emotional Functioning domain (e.g. 'feeling angry'; 'crying or fussing when left alone') in TOF sample, which may be specifically relevant to these conditions but not covered in EQ-TIPS. Compared to that EQ-TIPS uses a recall period of 'today', PedsQL used a recall period of 'one month', which are more likely to pick up the normal fluctuations in health and temperament experienced by year children and lead to more problems reported.

We also found different patterns in the proportion of ceiling effects across age groups between the two instruments. The EQ-TIPS had lower ceiling effects and lower EQ VAS score in children 2-4 years compared to younger age in both samples. The differences across age groups in proportion of reporting full health and in response distributions on EQ-TIPS items were not statistically significant, suggesting these no age-related changes in reporting of problems when using EQ-TIPS. On the contrast, PedsQL had statistically significant higher total scores in 2-4 years, which was largely driven by the increasing scores in the Emotional Functioning and School Functioning domains. One study found similar results among children dependent on Technology for Breathing in South Africa [10]. One explanation might be that, while EQ-TIPS used the same questionnaire covering the same 6 items, PedsQL used different versions for children under 4 years old, with questionnaires covering more and varying items for infants 1-24 months old (36 and 45 items) compared to the version for toddlers 2-4 years old (21 items). Furthermore, items in the domains of Physical Symptoms and Cognitive Functioning were only asked in 1-24 months, where these domain scores were relatively lower compared to scores of the Physical Functioning domain and School Functioning domain.

EQ-TIPS LSS, EQ VAS and PedsQL showed good known-group validity in differentiating groups within each condition, exhibiting significant effect sizes. PedsQL performed better in differentiating groups by parent-perceived condition prognosis after surgery, even between 'very good' and 'good' groups. For other known-groups, in general EQ-TIPS performed better in differentiating groups in Omphalocele sample while PedsQL performed better in TOF sample. Previous studies showed EQ-TIPS was able to discriminate between levels of severity of health conditions [9-11]. We also found EQ VAS showed better discriminatory capacity compared to EQ-TIPS which was not seen in previous studies [9, 10]. This might be explained by that EQ VAS captures parent's rating of their children's overall current health.

We found moderate correlations between EQ-TIPS LSS and PedsQL total scores, and moderate associations on limited number of EQ-TIPS item and PedsQL item pairs hypothesised to be correlated. Existing studies compared EQ-TIPS and PedsQL found moderate to strong correlations in most EQ-TIPS item and PedsQL domains [10-12], particularly movement and Physical Functioning, communication and Social Functioning which were not seen in this current study. In our study, the convergence performance was inconsistent by conditions and age groups., which were stronger in Omphalocele children aged 2-4 years, children aged 13-24 months affected by TOF. Specifically, we found that EQ-TIPS play, movement were weakly to strongly correlated with all PedsQL items, including those on Emotional Functioning domain. Two studies reported item level correlation among children aged 2-4

years old and found no relevant correlations between EQ-TIPS items and items on the Emotional Functioning domain of PedsQL [11, 12], which may be explained by that in EQ-TIPS, emotional aspects were not explicitly included as a dimension [8, 10]. Our results suggest emotional aspects may be captured indirectly through play. However, given such correlations were only found in Omphalocele but not TOF, further exploration is needed.

Overall, we presented new evidence on the psychometric performance of the EQ-TIPS and the PedsQL GCM in young children with congenital defects post-surgery in China. Our study benefited from using a relatively large sample in two rare conditions and the inclusion of infants, toddlers, and children, which enabled the assessment of HRQOL across different ages in early years of childhood. However, there are also several limitations. First, our sample only included children post-surgery, among whom both instruments demonstrated overall high HRQOL scores. We did not collect HRQOL data pre-surgery which limited our assessment of how HRQOL change and responsiveness. However, it is arguably very challenging to measure HRQOL in newborn with birth defects or severe conditions that require immediate intervention and care. For example, children with Omphalocele typically require surgical repair within 72 hours of birth. It is difficult to collect proxy report HRQOL data from parents who may not have many opportunities to be with the child. If not feasible, future research could consider measure HRQOL shortly after surgery and 6-12 months post-surgery to measure responsiveness. Second, in our known-group analyses, the sample size for some subgroups was doubtful or inadequate, and we used parent-reported outcome rather than clinical indicators to classify different groups. Finally, it was noted that there were significant ceiling effects observed in the EQ-TIPS and high HRQOL scores on the EQ VAS and PedsQL. This may have constrained our ability to thoroughly analyze the convergent validity between specific EQ-TIPS items, such as communication and social interaction, and the PedsQL within certain age groups. This limitation arose from the fact that all parents reported no problem, resulting in a lack of variability in responses and consequently a strong monotonically-related Spearman's rank correlations with all PedsQL items. Additional qualitative research is necessary to investigate the content validity and high ceiling effects observed in the utilization of EQ-TIPS within these clinical populations.

5. Conclusion

The EQ-TIPS, EQ VAS, and PedsQL scores exhibited high ceiling effects in this study. Despite the children being born with severe health issues, a majority of parents reported relatively good health-related quality of life (HRQOL) of their children post-surgery. Anecdotally, it was observed that parents had generally accepted their children's diagnosis which were usually detected during pregnancy and had low expectations to children's HRQOL prior to surgery, which may explain the high HRQOL scores reported post-surgery along with cultural tendencies in responding. Both the EQ-TIPS and PedsQL demonstrated good known-group validity, with the EQ-TIPS showing better differentiation in the Omphalocele sample and the PedsQL performing better in the TOF sample. Additional qualitative research is necessary to investigate the content validity and high HRQOL scores observed using both instruments in these clinical populations. Future research should consider longitudinal research with HRQOL responses at multiple time points including prior to the surgery, immediately after the surgery, and 6-12 months following the surgery, to evaluate responsiveness.

Reference

1. World Health Organization. *Child mortality and causes of death*. 2024 [cited 2024 10 July]; Available from: <https://www.who.int/data/gho/data/themes/topics/topic-details/GHO/child-mortality-and-causes-of-death>.
2. UNICEF. *Under-five mortality*. 2024 [cited 2024 10 July]; Available from: <https://data.unicef.org/topic/child-survival/under-five-mortality/#:~:text=This%20translates%20to%2013%2C400%20children,birth%20and%20intrapartum%2Drelated%20complications>.
3. Kwon, J., et al., *Systematic Review of Conceptual, Age, Measurement and Valuation Considerations for Generic Multidimensional Childhood Patient-Reported Outcome Measures*. Pharmacoeconomics, 2022. **40**(4): p. 379-431.
4. Schouten, E., et al., *Standardized Outcome Measures for Preterm and Hospitalized Neonates: An ICHOM Standard Set*. Neonatology, 2022. **119**(4): p. 443-454.
5. Saigal, S., et al., *Development, reliability and validity of a new measure of overall health for pre-school children*. Qual Life Res, 2005. **14**(1): p. 243-57.
6. Jabrayilov, R., et al., *A descriptive system for the Infant health-related Quality of life Instrument (IQI): Measuring health with a mobile app*. PLoS One, 2018. **13**(8): p. e0203276.
7. Jabrayilov, R., et al., *Valuing Health Status in the First Year of Life: The Infant Health-Related Quality of Life Instrument*. Value Health, 2019. **22**(6): p. 721-727.
8. Verstraete, J., L. Ramma, and J. Jelsma, *Item generation for a proxy health related quality of life measure in very young children*. Health and Quality of Life Outcomes, 2020. **18**(1): p. 11.
9. Verstraete, J., L. Ramma, and J. Jelsma, *Validity and reliability testing of the Toddler and Infant (TANDI) Health Related Quality of Life instrument for very young children*. Journal of Patient-Reported Outcomes, 2020. **4**(1): p. 94.
10. Verstraete, J., et al., *Fighting to Breathe and Fighting for Health-Related Quality of Life: Measuring the Impact of Being Dependent on Technology for Breathing on the Child and Their Caregiver*. Patient, 2024. **17**(1): p. 65-82.
11. Verstraete, J., A.J. Lloyd, and J. Jelsma, *Performance of the Toddler and Infant (TANDI) Health-Related Quality of Life Instrument in 3–4-Year-Old Children*. Children, 2021. **8**(10).
12. Pan, T., et al., *Psychometric performance of EuroQol Toddler and Infant Populations Instrument (EQ-TIPS) compared with the Pediatric Quality of Life Inventory™ (PedsQL) in young children (Manuscript ready to submit)*. 2024.
13. Zhou, W., et al., *Psychometric validation of the Chinese versions of EQ-5D-Y-3L and the Experimental EQ-TIPS in children and adolescents with COVID-19* European Journal of Health Economics, 2024. **Accepted**.
14. Bauman, B., et al., *Management of giant omphaloceles: A systematic review of methods of staged surgical vs. nonoperative delayed closure*. J Pediatr Surg, 2016. **51**(10): p. 1725-30.
15. Whitehouse, J.S., et al., *Conservative management of giant omphalocele with topical povidone-iodine and its effect on thyroid function*. J Pediatr Surg, 2010. **45**(6): p. 1192-7.
16. Children's Hospital of Philadelphia. *Omphalocele*. 2024 [cited 2024 10 July]; Available from: <https://www.chop.edu/conditions-diseases/omphalocele#:~:text=More%20than%20half%20of%20all,gastrointestinal%20issues%20or%20genitourinary%20problems>.
17. Verla, M.A., C.C. Style, and O.O. Olutoye, *Prenatal diagnosis and management of omphalocele*. Seminars in Pediatric Surgery, 2019. **28**(2): p. 84-88.
18. Ein, S.H. and J.C. Langer, *Delayed management of giant omphalocele using silver sulfadiazine cream: an 18-year experience*. J Pediatr Surg, 2012. **47**(3): p. 494-500.
19. Mayo Clinic. *Tetralogy of Fallot*. 2024 [cited 2024 9 July]; Available from: <https://www.mayoclinic.org/diseases-conditions/tetralogy-of-fallot/symptoms-causes/syc-20353477>.

20. Malik, M., et al., *Health-related quality of life in adults with tetralogy of Fallot repair: a systematic review and meta-analysis*. Quality of Life Research, 2021. **30**(10): p. 2715-2725.
21. Flucher, C., et al., *Long-term motor activity, cardiopulmonary performance and quality of life in abdominal wall defect patients*. Pediatric Research, 2024. **95**(4): p. 1101-1109.
22. van Eijck, F.C., et al., *Minor and giant omphalocele: long-term outcomes and quality of life*. J Pediatr Surg, 2009. **44**(7): p. 1355-9.
23. Hijkoop, A., et al., *Omphalocele at school age: What do parents report? A call for long-term follow-up of complex omphalocele patients*. Early Human Development, 2019. **137**: p. 104830.
24. Varni, J.W., et al., *The PedsQL™* 4.0 as a Pediatric Population Health Measure: Feasibility, Reliability, and Validity*. Ambulatory Pediatrics, 2003. **3**(6): p. 329-341.
25. Varni, J.W., *Scaling and scoring for the acute and standard versions of the PedsQL 2023*, Mapi Research Trust,: France.
26. Terwee, C.B., et al., *Quality criteria were proposed for measurement properties of health status questionnaires*. Journal of Clinical Epidemiology, 2007. **60**(1): p. 34-42.
27. McHorney, C.A. and A.R. Tarlov, *Individual-patient monitoring in clinical practice: are available health status surveys adequate?* Quality of Life Research, 1995. **4**(4): p. 293-307.
28. Sullivan, G.M. and R. Feinn, *Using Effect Size-or Why the P Value Is Not Enough*. J Grad Med Educ, 2012. **4**(3): p. 279-82.
29. Cohen, J., *A power primer*. . Psychological Bulletin, , 1992. **112**(1): p. 155–159. .
30. Cheng, L.J., et al., *The Ceiling Effects of EQ-5D-3L and 5L in General Population Health Surveys: A Systematic Review and Meta-Analysis*. Value in Health, 2024. **27**(7): p. 986-997.
31. Pan, T., et al., *What explains differences in ceiling effects in EQ-5D and other HRQoL instruments between countries? An investigation into possible reasons, existing evidence, and future research directions and priorities in 2024 EuroQol Academy Meeting*. 2024: Copenhagen, Denmark.
32. Hijkoop, A., et al., *Omphalocele at school age: What do parents report? A call for long-term follow-up of complex omphalocele patients*. Early Hum Dev, 2019. **137**: p. 104830.
33. Svensson, B., et al., *Health-Related Quality of Life in Children With Earlier Surgical Repair for Right Ventricular Outflow Tract Anomalies and the Agreement Between Children and Their Parents*. Front Cardiovasc Med, 2020. **7**: p. 66.
34. Kwon, E.N., et al., *Children and Adolescents with Repaired Tetralogy of Fallot Report Quality of Life Similar to Healthy Peers*. Congenital Heart Disease, 2011. **6**(1): p. 18-27.
35. Denniss, D.L., et al., *Need for Routine Screening of Health-Related Quality of Life in Families of Young Children with Complex Congenital Heart Disease*. The Journal of Pediatrics, 2019. **205**: p. 21-28.e2.
36. Raj, M., et al., *Health-related quality of life (HRQOL) in children and adolescents with congenital heart disease: a cross-sectional survey from South India*. BMJ Paediatr Open, 2019. **3**(1): p. e000377.
37. Yang, X., N. Xiao, and J. Yan, *The PedsQL in pediatric cerebral palsy: reliability and validity of the Chinese version pediatric quality of life inventory 4.0 generic core scales and 3.0 cerebral palsy module*. Quality of Life Research, 2011. **20**(2): p. 243-252.
38. Atmadja S, T.T., Evalina R, Sofyani S, Ali M. , *Quality of life in children with congenital heart disease after cardiac surgery*. . Paediatrica Indonesiana, 2018. **5**(6): p. 285.
39. Lemacks, J., et al., *Insights from parents about caring for a child with birth defects*. Int J Environ Res Public Health, 2013. **10**(8): p. 3465-82.
40. Carlsson, T. and E. Mattsson, *Peer Support Experienced by Mothers of Children With Congenital Heart Defects in Sweden*. Journal of Family Nursing, 2022. **28**(2): p. 142-150.
41. Carlsson, T., A. Klarare, and E. Mattsson, *Peer support among parents of children with congenital heart defects: A qualitative analysis of written responses submitted via an online survey*. Journal of Advanced Nursing, 2020. **76**(12): p. 3528-3536.

Tables

Table 1 Sample characteristics

	Omphalocele		Tetralogy of Fallot	
	N	%	N	%
Age				
1-12m	28	24.35	21	17.07
13-24m	33	28.7	50	40.65
2-4y	54	46.96	52	42.28
Sex				
Male	61	53.04	73	59.35
Female	54	46.96	50	40.65
Parent's highest level of educational attainment				
Primary or below	2	1.74	2	1.63
Junior High	2	1.74	8	6.5
Senior High	23	19.13	25	20.33
Bachelor's degree	76	66.09	78	63.41
Master's degree or above	13	11.3	10	8.13
Annual Household income (after tax)				
<50,000 CNY	10	8.7	27	21.95
50,001 - 100,000 CNY	36	31.3	45	36.59
100,001 - 200,000 CNY	34	29.57	31	25.2
200,001 - 500,000 CNY	21	18.26	16	13.01
>500,000 CNY	14	12.17	4	3.25
Parental perceived prognosis after surgery				
Very good	52	45.22	67	54.47
Good	58	50.43	51	41.46
Fair	5	4.35	5	4.07
Other birth defects*				
No	53	46.09	-	-
Congenital heart disease	24	20.87	-	-
Pulmonary hypertension	27	23.48	-	-
Bronchopulmonary dysplasia (BPD)	7	6.09	-	-
Other birth defects	31	26.96	-	-
Current discomfort or symptoms				
No	-	-	103	83.74
Chest tightness	-	-	0	0
Shortness of breath	-	-	2	1.63
Palpitation	-	-	1	0.81
Decreased level of activity	-	-	4	3.25
Other	-	-	18	14.63
General growth and development	-	-		
Very good	28	24.35	40	32.52
Good	47	40.87	48	39.02
Fair	33	28.7	30	24.39
Poor	7	6.09	4	3.25
Very poor			1	0.81

*Children may have multiple defects

Table 2 Distribution of summary scores

	Total sample	1-12m	13-24m	2-4y	p-value
Omphalocele	N=118	N=28	N=33	N=54	
EQTIPS					
Ceiling effect (111111)	65.22%	71.43%	72.73%	57.41%	0.235
Floor effect (333333)	0	0	0	0	
LSS (mean, SD)	6.58(1.03)	6.43(0.79)	6.42(0.83)	6.76(1.21)	0.242
LSS (median, IQR)	6 (6 -7)	6 (6 -7)	6 (6 -7)	6 (6 -7)	
EQ VAS (mean, SD)	87.05(12.73)	88.89(11.17)	87.61(12.01)	85.76(13.94)	0.741
EQ VAS (median, IQR)	90 (80 – 99)	90 (83.5 -99.5)	90 (80 – 100)	90 (80 – 96)	
% of EQ VAS =100	24.35%	25.00%	27.27%	22.22%	0.864
PedsQL					
Ceiling effect (100)	19.13%	7.14%	6.06%	33.33%	0.001
Floor effect (0)	0	0	0	0	
Physical Functioning	86.81(17.75)	82.29(18.83)	80.72(21.12)	92.88(12.49)	<0.001
Physical Symptoms	70.86(17.98)	70.09(16.81)	71.52(19.14)		0.486
Emotional Functioning	77.32(20.22)	68.15(19.75)	69.63(19.96)	86.76(16.37)	<0.001
Social Functioning	81.05(20.68)	83.48(24.01)	85.61(15.9)	90.28(14.87)	<0.001
Cognitive Functioning	76.07(23.4)	75.45(26.29)	76.6(21.04)		0.808
School Functioning	89.88(21.88)			89.88(21.88)	
Total (mean, SD)	82.01(17.37)	73.56(17.82)	75.44(17.22)	90.4(13.09)	<0.001
Total (median, IQR)	84.52 (71.43 – 96.43)	(76.73 (63.54 - 82.64)	72.78 (68.89 – 87.22)	95.24 (88.10 - 100)	
Tetralogy of Fallot	N=123	N=21	N=50	N=52	
EQTIPS					
Ceiling effect (111111)	72.36%	71.43%	82.00%	63.46%	0.111
Floor effect (333333)	0	0	0	0	
LSS (mean, SD)	6.64(1.57)	6.38(0.67)	6.46(1.43)	6.92(1.91)	0.113
LSS (median, IQR)	6 (6 -7)	6 (6 -7)	6 (6 -7)	6 (6 -7)	
EQ VAS (mean, SD)	89.95(13.89)	92.43(7.08)	89.42(16.89)	89.46(12.82)	0.665
EQ VAS (median, IQR)	93 (84-100)	91 (90 – 100)	95 (80-100)	90 (83-100)	
% of EQ VAS =100	34.15%	38.10%	36.00%	30.77%	0.784
PedsQL					
ceiling effect (100)	12.20%	4.76%	8.00%	19.23%	0.116
Floor effect (0)	0	0	0	0	
Physical Functioning	85.6(17.07)	82.14(16.62)	86.89(17.62)	85.76(16.84)	0.424
Physical Symptoms	82.18(13.54)	79.29(13.88)	83.4(13.34)		0.172
Emotional Functioning	74.86(19.24)	66.67(22.24)	74.67(16.33)	78.37(19.87)	0.063
Social Functioning	78.83(18.26)	89.88(14.18)	88.3(17.63)	84.9(22.63)	<0.001
Cognitive Functioning	79.85(22.47)	78.57(23.1)	80.39(22.42)		0.855
School Functioning	91.41(13.63)			91.41(13.63)	
Total (mean, SD)	81.79(15.82)	76.65(14.72)	81.71(14.31)	83.93(17.36)	0.062
Total (median, IQR)	83.33 (72.22 – 94.44)	72.92 (68.05 - 89.58)	80.56 (75- 94.44)	88.69 (74.4 – 96.83)	

LSS: level sum score; SD: standard deviation. IQR: interquartile range

Kruskal-Wallis test was used for testing differences in EQ-TIPS LSS, EQ VAS and PedsQL scores between age groups, Pearson's chi squared test was used to test differences in proportion of reporting no problems.

Table 3. Known group validity

EQ-TIPS Level sum scores						EQ VAS				PedsQL total scores			
Group	N	Mean	SD	p-value	effect size	Mean	SD	p-value	effect size	Mean	SD	p-value	effect size
Omphalocele Sample													
Parent perceived prognosis after Surgery				0.052				0.0001				0.005	
Very good	52	6.44	0.73		0.157	90.88	10.84		0.445	86.45	14.35		0.407
Good	58	6.59	1.08		0.880	85.88	11.66		2.245	79.65	18.74		1.008
Fair	5	8.00	2.00			60.80	10.66			63.17	13.54		
Other birth defects				0.029				0.0033				0.060	
Yes	62	6.76	1.15		0.381	83.55	14.37		-0.634	79.67	17.74		0.295
No	53	6.38	0.81			91.15	9.03			84.74	16.67		
General growth & development				0.000				0.0001				0.424	
Very good	28	6.04	0.19		0.772	93.14	11.69		0.305	82.31	22.94		0.060
Good	47	6.40	0.65		0.709	90.04	8.35		0.931	83.45	13.56		0.217
Fair/Poor/Very poor	40	7.18	1.39			79.28	14.07			80.10	17.15		
Tetralogy of Fallot Sample													
Parent perceived rognosis after Surgery				0.010				0.000				0.000	
Very good	67	6.45	1.53		0.212	92.40	16.87		0.333	87.24	13.76		0.783
Good	51	6.73	1.04		0.531	88.00	8.05		1.757	76.43	13.86		0.584
Fair	5	8.40	4.34			77.00	3.67			63.33	28.52		
Presence of any symptoms				0.001				0.018				0.003	
Yes	103	6.51	1.39		0.423	90.59	14.60		0.325	83.89	14.28		0.768
No	20	7.30	2.23			86.65	8.99			70.94	19.07		
General growth & development				0.000				0.000				0.000	
Very good	40	6.20	0.56		0.177	94.55	16.19		0.188	88.10	12.49		0.335
Good	48	6.33	0.91		0.664	92.17	7.71		0.912	84.20	10.71		0.813
Fair/Poor/Very poor	35	7.57	2.48			81.66	14.36			71.26	19.78		

Known group validity: n≥100 per group very good; n=50-99 per group adequate; n=30-49 per group doubtful; n<30 per group inadequate. Cohen's D effect size thresholds 0.2–0.49, 0.5–0.79 and >0.8 denote small, medium and large effect size, respectively. PedsQL: Paediatric Quality of Life Inventory, SD standard deviation. Comparison between prognosis and general growth groups were between very good vs good, good vs poor.

Table 4 Convergence between EQ-TIPS and PedsQL in Omphalocele sample

Total	Movement	Play	Pain	Social Interaction	Communication	Eating	LSS	EQ VAS
PF (1m-4y)	-0.1431	-0.2222*	-0.1951*	-0.2010*	-0.0961	-0.2011*	-0.3027*	0.2149*
PS (1m-24m)	-0.0662	-0.0662	-0.3139*	-0.1441	-0.0341	-0.2483	-0.3825*	0.3707*
EF (1m-4y)	-0.1012	-0.1631	-0.1597	-0.0844	-0.0481	-0.0928	-0.1739	0.1467
SF (1m-4y)	-0.16	-0.2210*	-0.1301	-0.1447	-0.0959	-0.2181*	-0.2645*	0.2031*
CF (1m-24m)	0.16	0.16	-0.3128*	-0.1991	-0.2521*	-0.2349	-0.3260*	0.1581
School (2-4y)	-0.3155*	-0.4274*	-0.2808	-0.0853	-0.2206	-0.3393*	-0.4642*	0.4546*
Total (1m-4y)	-0.1428	-0.2253*	-0.2688*	-0.1909*	-0.1116	-0.1787	-0.3178*	0.2983*

Correlations of 0.1–0.29 were considered weak (shaded pink), 0.3–0.49 moderate (shaded orange), and ≥ 0.5 strong (shaded green).

PF: physical functioning; PS: physical symptoms; EF: emotional functioning; SF: social-functioning ; CF: cognitive-functioning; School: School functioning.

Item level correlations are reported in Appendix Tables S1-S3.

Table 5 Convergence between EQ-TIPS and PedsQL in Tetralogy of Fallot sample

Total	Movement	Play	Pain	Social Interaction	Communication	Eating	LSS	EQ VAS
PF (1m-4y)	-0.2773*	-0.3303*	-0.1576	-0.2946*	-0.3013*	-0.2816*	-0.3952*	0.4296*
PS (1m-24m)	-0.3030*	-0.1699	-0.2126	-0.0857	-0.1784	-0.2567*	-0.3555*	0.3495*
EF (1m-4y)	-0.2117*	-0.1514	-0.3154*	-0.2178*	-0.1593	-0.1876*	-0.2589*	0.4073*
SF (1m-4y)	-0.1413	-0.1907*	-0.2599*	-0.2758*	-0.2292*	-0.1446	-0.2246*	0.3716*
CF (1m-24m)	-0.3420*	-0.2122*	-0.0898	-0.2575*	-0.3164*	-0.2389*	-0.3737*	0.4540*
School (2-4y)	1.0000*	-0.3221*	0.1265	-0.0331	0.1598	-0.237	-0.0274	0.5866*
Total (1m-4y)	-0.2783*	-0.2768*	-0.2003*	-0.3192*	-0.2715*	-0.2623*	-0.3598*	0.4914*

Correlations of 0.1–0.29 were considered weak (shaded pink), 0.3–0.49 moderate (shaded orange), and ≥ 0.5 strong (shaded green)

PF: physical functioning; PS: physical symptoms; EF: emotional functioning; SF: social-functioning ; CF: cognitive-functioning; School: School functioning.

Item level correlations are reported in Appendix Tables S4-S5

Figures

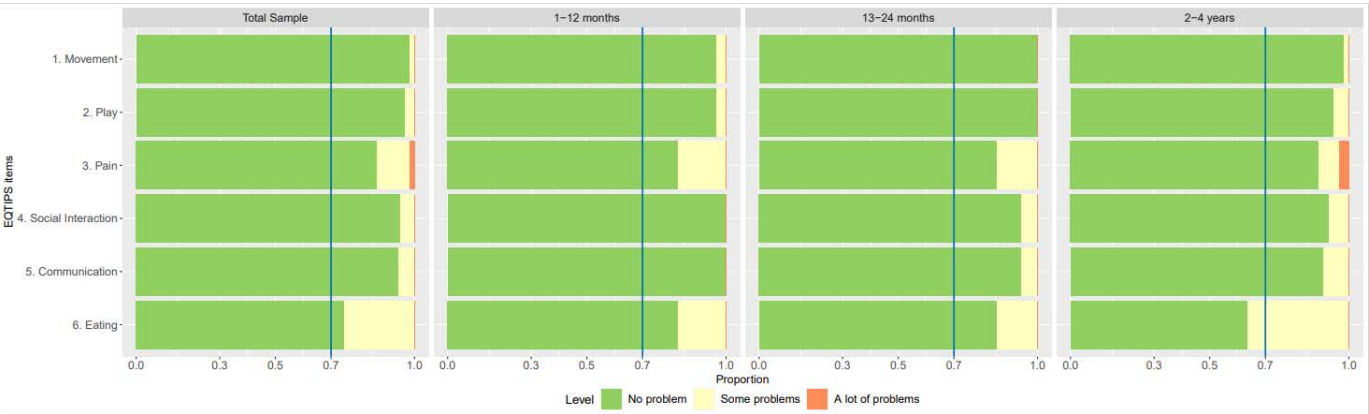


Fig 1a Distribution of EQ-TIPS responses in children affected by Omphalocele

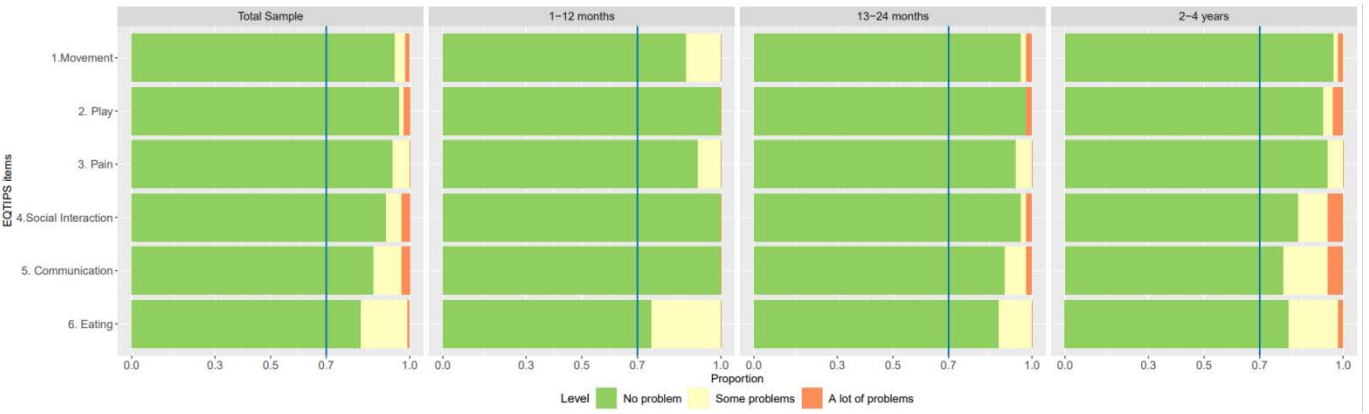


Fig 1b Distribution of EQ-TIPS responses in children affected by Tetralogy of Fallot

Appendix

Table S1 Convergence between EQ-TIPS items and PedsQL items in Omphalocele sample (1-12 months)

	movement	play	pain	social interaction	communication	eating
Physical functioning						
1. Low energy level	0.1605	0.1605	-0.0648	1.0000*	1.0000*	-0.2917
2. Difficulty participating in active play	0.1303	0.1303	-0.3366	1.0000*	1.0000*	-0.2735
3. Having hurts or aches	0.1397	0.1397	-0.2912	1.0000*	1.0000*	-0.4401*
4. Feeling tired	-0.249	-0.249	-0.6034*	1.0000*	1.0000*	-0.3239
5. Being lethargic	-0.2413	-0.2413	-0.3897*	1.0000*	1.0000*	-0.1948
6. Resting a lot	0.1596	0.1596	-0.2126	1.0000*	1.0000*	-0.2126
Physical symptoms						
1. Having gas	-0.2917	-0.2917	-0.1927	1.0000*	1.0000*	-0.0257
2. Spitting up after eating	-0.0502	-0.0502	-0.1215	1.0000*	1.0000*	-0.2552
3. Difficulty breathing	0.161	0.161	0.2341	1.0000*	1.0000*	-0.156
4. Being sick to his/her stomach	-0.1751	-0.1751	-0.4243*	1.0000*	1.0000*	-0.2788
5. Difficulty swallowing	0.1397	0.1397	-0.0948	1.0000*	1.0000*	-0.4672*
6. Being constipated	-0.1376	-0.1376	-0.3334	1.0000*	1.0000*	-0.0424
7. Having a rash	-0.1266	-0.1266	-0.3925*	1.0000*	1.0000*	-0.0307
8. Having diarrhea	-0.3335*	-0.3335*	-0.4396*	1.0000*	1.0000*	-0.0194
9. Wheezing	0.1608	0.1608	0.1624	1.0000*	1.0000*	-0.2208
10. Vomiting	0.2145	0.2145	-0.1406	1.0000*	1.0000*	-0.0428
Emotional functioning						
1. Feeling afraid or scared	-0.1453	-0.1453	-0.4546*	1.0000*	1.0000*	-0.0704
2. Feeling angry	0.2552	0.2552	-0.3339	1.0000*	1.0000*	-0.2411
3. Crying or fussing when left alone	0.1729	0.1729	-0.3543	1.0000*	1.0000*	-0.0387
4. Difficulty soothing himself/herself when upset	0.2795	0.2795	-0.2893	1.0000*	1.0000*	-0.16
5. Difficulty falling asleep	-0.1374	-0.1374	-0.4117*	1.0000*	1.0000*	-0.109
6. Crying or fussing while being cuddled	0.0634	0.0634	-0.3132	1.0000*	1.0000*	-0.2211
7. Feeling sad	0.2387	0.2387	-0.2739	1.0000*	1.0000*	-0.3774*
8. Difficulty being soothed when picked up or held	-0.1774	-0.1774	-0.4299*	1.0000*	1.0000*	-0.2211
9. Difficulty sleeping mostly through the night	0.1808	0.1808	-0.244	1.0000*	1.0000*	-0.244
10. Crying a lot	-0.1493	-0.1493	-0.5065*	1.0000*	1.0000*	-0.0482
11. Feeling cranky	0.252	0.252	-0.3175	1.0000*	1.0000*	-0.0305
12. Difficulty taking naps during the day	-0.1239	-0.1239	-0.2042	1.0000*	1.0000*	-0.2763
Social functioning						
1. Not smiling at others	-0.118	-0.118	-0.3747	1.0000*	1.0000*	-0.3747
2. Not laughing when tickled	-0.2725	-0.2725	-0.2509	1.0000*	1.0000*	-0.4555*
3. Not making eye contact with a caregiver	0.1199	0.1199	-0.1597	1.0000*	1.0000*	-0.5590*
4. Not laughing when cuddled	-0.2859	-0.2859	-0.2704	1.0000*	1.0000*	-0.4815*
Cognitive functioning						
1. Not imitating caregivers' actions	0.1831	0.1831	-0.1268	1.0000*	1.0000*	-0.2345
2. Not imitating caregivers' facial expressions	0.2042	0.2042	-0.2969	1.0000*	1.0000*	-0.2041
3. Not imitating caregivers' sounds	0.1951	0.1951	-0.2836	1.0000*	1.0000*	-0.1953
4. Not able to fix his/her attention on objects	0.1812	0.1812	-0.3638	1.0000*	1.0000*	-0.2822

Grey shaded areas indicate pairs hypothesized to be at least moderately correlated. Correlations of 0.1–0.29 were considered weak (red), 0.3–0.49 moderate (yellow), and ≥ 0.5 strong (green).

Table S2 Convergence between EQ-TIPS items and PedsQL items in Omphalocele sample (13-24 months)

	movement	play	pain	social interaction	communication	eating
Physical functioning						
1. Low energy level	1.0000*	1.0000*	-0.0957	-0.2229	0.0647	-0.0096
2. Difficulty participating in active play	1.0000*	1.0000*	-0.14	-0.2254	0.0075	0.015
3. Having hurts or aches	1.0000*	1.0000*	-0.2149	-0.0431	-0.165	-0.2961
4. Feeling tired	1.0000*	1.0000*	-0.0895	-0.1912	0.0991	0.1414
5. Being lethargic	1.0000*	1.0000*	-0.053	-0.1448	0.0507	0.1494
6. Resting a lot	1.0000*	1.0000*	-0.1351	-0.145	0.0507	0.0724
7. Feeling too tired to play	1.0000*	1.0000*	-0.0384	-0.1298	0.0649	0.2207
8. Difficulty walking	1.0000*	1.0000*	0.0256	-0.3542	-0.0308	0.1794
9. Difficulty running a short distance without falling	1.0000*	1.0000*	0.254	-0.1762	0.0294	0.1808
Physical symptoms						
1. Having gas	1.0000*	1.0000*	-0.2412	-0.145	-0.145	-0.2123
2. Spitting up after eating	1.0000*	1.0000*	-0.0745	-0.1679	0.0979	-0.2234
3. Difficulty breathing	1.0000*	1.0000*	-0.0801	-0.0642	-0.0642	0.2939
4. Being sick to his/her stomach	1.0000*	1.0000*	-0.3920*	-0.1122	-0.1122	-0.1913
5. Difficulty swallowing	1.0000*	1.0000*	-0.0336	-0.1297	0.0648	-0.4171*
6. Being constipated	1.0000*	1.0000*	-0.3346	-0.1257	-0.2514	-0.1208
7. Having a rash	1.0000*	1.0000*	0.0786	0.0486	-0.2085	-0.0046
8. Having diarrhea	1.0000*	1.0000*	-0.1196	-0.1869	0.1006	-0.2009
9. Wheezing	1.0000*	1.0000*	0.0097	-0.2399	-0.0509	0.1596
10. Vomiting	1.0000*	1.0000*	-0.2413	-0.2092	0.0418	-0.2831
Emotional functioning						
1. Feeling afraid or scared	1.0000*	1.0000*	-0.2412	-0.2828	-0.145	0.0338
2. Feeling angry	1.0000*	1.0000*	-0.197	0.0623	0.0623	-0.197
3. Crying or fussing when left alone	1.0000*	1.0000*	0.1755	0.2851	0.1354	-0.2704
4. Difficulty soothing himself/herself when upset	1.0000*	1.0000*	-0.2065	0.0705	-0.0917	-0.2581
5. Difficulty falling asleep	1.0000*	1.0000*	-0.3617*	-0.0286	-0.1859	-0.257
6. Crying or fussing while being cuddled	1.0000*	1.0000*	-0.3242	-0.1146	0.0716	0.2003
7. Feeling sad	1.0000*	1.0000*	-0.0422	0.0422	0.1831	0.1453
8. Difficulty being soothed when picked up or held	1.0000*	1.0000*	-0.1661	-0.1321	0.0807	0.2589
9. Difficulty sleeping mostly through the night	1.0000*	1.0000*	-0.3527*	0.0581	0.0581	0.0821
10. Crying a lot	1.0000*	1.0000*	-0.3098	0.0834	-0.0625	-0.3098
11. Feeling cranky	1.0000*	1.0000*	-0.1722	0.1259	-0.035	-0.1722
12. Difficulty taking naps during the day	1.0000*	1.0000*	-0.2452	-0.241	0.1205	0.1698
Social functioning						
1. Not smiling at others	1.0000*	1.0000*	-0.0384	-0.2524	0.0649	0.0096
2. Not laughing when tickled	1.0000*	1.0000*	-0.1334	-0.0308	-0.0308	0.1949
3. Not making eye contact with a caregiver	1.0000*	1.0000*	-0.2548	-0.3663	-0.0999	0.0997
4. Not laughing when cuddled	1.0000*	1.0000*	-0.1666	-0.2428	-0.0152	0.202
5. Being uncomfortable around other children	1.0000*	1.0000*	-0.1881	-0.145	0.0507	0.0724
Cognitive functioning						

1. Not imitating caregivers' actions	1.0000*	1.0000*	-0.293	-0.2788	-0.0734	0.2539
2. Not imitating caregivers' facial expressions	1.0000*	1.0000*	-0.4633*	-0.206	-0.3268	0.0142
3. Not imitating caregivers' sounds	1.0000*	1.0000*	-0.4257*	-0.2985	-0.2985	-0.1088
4. Not able to fix his/her attention on objects	1.0000*	1.0000*	-0.2496	-0.191	-0.0212	0.1554
5. Not imitating caregivers' speech	1.0000*	1.0000*	-0.291	-0.3174	-0.4021*	-0.1361
6. Difficulty pointing to his/her body parts when asked	1.0000*	1.0000*	-0.1819	0.0222	-0.0886	-0.1819
7. Difficulty naming familiar objects	1.0000*	1.0000*	-0.2643	-0.2696	-0.3476	-0.3163
8. Difficulty repeating words	1.0000*	1.0000*	-0.2631	-0.2824	-0.3812*	-0.1879
9. Difficulty keeping his/her attention on things	1.0000*	1.0000*	-0.061	-0.2678	-0.2678	-0.2533

Grey shaded areas indicate pairs hypothesized to be at least moderately correlated. Correlations of 0.1–0.29 were considered weak (red), 0.3–0.49 moderate (yellow), and ≥ 0.5 strong (green).

Table S3 Convergence between EQ-TIPS items and PedsQL items in Omphalocele sample (2–4 years)

	movement	play	pain	social interaction	communication	eating
Physical functioning						
walking	-0.26	-0.3722*	-0.02	-0.07	-0.23	-0.4888*
running	-0.3501*	-0.4419*	-0.02	-0.12	-0.24	-0.5873*
active play or exercise	-0.3185*	-0.4408*	-0.17	-0.4918*	-0.19	-0.4270*
lifting something heavy	-0.2700*	-0.4142*	0.05	-0.05	0.00	-0.3894*
bathing	-0.3690*	-0.5519*	-0.09	-0.15	-0.10	-0.4279*
helping to pick up toys	-0.30	-0.4702*	-0.05	-0.10	-0.05	-0.3589*
hurts or aches	-0.3863*	-0.5522*	-0.07	-0.16	-0.34	-0.4409*
low energy level	-0.25	-0.4144*	-0.05	-0.30	-0.22	-0.3730*
Emotional functioning						
afraid or scared	-0.22	-0.3568*	0.24	0.01	-0.11	-0.23
sad or blue	-0.2656*	-0.3797*	0.02	-0.4105*	-0.17	-0.21
angry	-0.2382*	-0.3405*	0.05	-0.22	-0.13	-0.3174*
trouble sleeping	-0.2482*	-0.28	0.09	-0.02	-0.15	-0.26
worrying	-0.3011*	-0.4305*	0.01	-0.08	-0.23	-0.21
Social functioning						
playing with other children	-0.2633*	-0.3763*	-0.13	-0.4932*	-0.13	-0.21
other kids not wanting to play with them	-0.2782*	-0.3976*	-0.15	-0.4431*	-0.20	-0.28
teased by other children	-0.2769*	-0.3959*	-0.24	-0.4384*	-0.20	-0.26
not able to do things that other children can do	-0.3271*	-0.4676*	-0.21	-0.11	-0.26	-0.28
keeping up when playing with other children	-0.3641*	-0.5039*	-0.03	-0.13	-0.26	-0.3146*
School functioning						
same school activities as peers	-0.3641*	-0.5039*	-0.03	-0.13	-0.29	-0.3332*
missing school because of not feeling well	-0.3368*	-0.4559*	-0.19	-0.11	-0.25	-0.3189*
missing school to go to doctor	-0.3371*	-0.4613*	-0.19	-0.11	-0.25	-0.3320*

Grey shaded areas indicate pairs hypothesized to be at least moderately correlated. Correlations of 0.1–0.29 were considered weak (red), 0.3–0.49 moderate (yellow), and ≥ 0.5 strong (green).

Table S4 Convergence between EQ-TIPS items and PedsQL items in Tetralogy of Fallot sample (1-12 months)

	movement	play	pain	social interaction	communication	eating
Physical functioning						
1. Low energy level	-0.259	1.0000*	0.2181	1.0000*	1.0000*	-0.0992
2. Difficulty participating in active play	-0.3342	1.0000*	0.2203	1.0000*	1.0000*	0.0401
3. Having hurts or aches	-0.385	1.0000*	-0.3674*	1.0000*	1.0000*	-0.4287
4. Feeling tired	-0.2419	1.0000*	-0.0588	1.0000*	1.0000*	0.0392
5. Being lethargic	-0.2691	1.0000*	-0.1855	1.0000*	1.0000*	-0.1649
6. Resting a lot	-0.0152	1.0000*	-0.2093	1.0000*	1.0000*	-0.0105
Physical symptoms						
1. Having gas	-0.4195	1.0000*	-0.212	1.0000*	1.0000*	-0.4915*
2. Spitting up after eating	-0.3949	1.0000*	-0.3694*	1.0000*	1.0000*	-0.3985
3. Difficulty breathing	-0.0795	1.0000*	0.1754	1.0000*	1.0000*	-0.0219
4. Being sick to his/her stomach	-0.4940*	1.0000*	0.2203	1.0000*	1.0000*	-0.4606*
5. Difficulty swallowing	-0.0628	1.0000*	0.1732	1.0000*	1.0000*	0
6. Being constipated	-0.2668	1.0000*	-0.2323	1.0000*	1.0000*	-0.3968
7. Having a rash	-0.2078	1.0000*	0.2455	1.0000*	1.0000*	-0.0921
8. Having diarrhea	-0.4015	1.0000*	-0.0395	1.0000*	1.0000*	-0.0593
9. Wheezing	-0.2906	1.0000*	-0.0601	1.0000*	1.0000*	-0.2904
10. Vomiting	-0.0723	1.0000*	-0.3191	1.0000*	1.0000*	-0.5783*
Emotional functioning						
1. Feeling afraid or scared	-0.0288	1.0000*	-0.1788	1.0000*	1.0000*	-0.1887
2. Feeling angry	-0.3741	1.0000*	-0.1388	1.0000*	1.0000*	-0.0992
3. Crying or fussing when left alone	-0.3613	1.0000*	-0.249	1.0000*	1.0000*	-0.2682
4. Difficulty soothing himself/herself when upset	-0.1985	1.0000*	-0.2149	1.0000*	1.0000*	0.0293
5. Difficulty falling asleep	-0.3478	1.0000*	-0.1534	1.0000*	1.0000*	-0.2397
6. Crying or fussing while being cuddled	-0.0705	1.0000*	-0.0194	1.0000*	1.0000*	0.1264
7. Feeling sad	-0.0288	1.0000*	-0.0198	1.0000*	1.0000*	-0.1487
8. Difficulty being soothed when picked up or held	-0.3667	1.0000*	0.2722	1.0000*	1.0000*	0.1264
9. Difficulty sleeping mostly through the night	-0.3083	1.0000*	-0.2125	1.0000*	1.0000*	-0.2318
10. Crying a lot	-0.2797	1.0000*	-0.1928	1.0000*	1.0000*	-0.2409
11. Feeling cranky	-0.347	1.0000*	-0.1722	1.0000*	1.0000*	-0.2009
12. Difficulty taking naps during the day	-0.4887*	1.0000*	-0.154	1.0000*	1.0000*	-0.2791
Social functioning						
1. Not smiling at others	-0.1885	1.0000*	0.1732	1.0000*	1.0000*	-0.3031
2. Not laughing when tickled	-0.1934	1.0000*	0.1555	1.0000*	1.0000*	-0.1111
3. Not making eye contact with a caregiver	-0.2109	1.0000*	0.1565	1.0000*	1.0000*	-0.3578
4. Not laughing when cuddled	-0.2109	1.0000*	0.1565	1.0000*	1.0000*	-0.1342
Cognitive functioning						
1. Not imitating caregivers' actions	-0.5465*	1.0000*	-0.2775	1.0000*	1.0000*	-0.3073
2. Not imitating caregivers' facial expressions	-0.5504*	1.0000*	-0.1198	1.0000*	1.0000*	-0.2596
3. Not imitating caregivers' sounds	-0.5317*	1.0000*	0.2179	1.0000*	1.0000*	-0.0495
4. Not able to fix his/her attention on objects	-0.1496	1.0000*	0.3104	1.0000*	1.0000*	0.0229

Grey shaded areas indicate pairs hypothesized to be at least moderately correlated. Correlations of 0.1–0.29 were considered weak (red), 0.3–0.49 moderate (yellow), and ≥ 0.5 strong (green).

Table S5 Convergence between EQ-TIPS items and PedsQL items in Tetralogy of Fallot sample (13-24 months)

	movement	play	pain	social interaction	communication	eating
Physical functioning						
1. Low energy level	-0.1407	-0.2897*	-0.1847	-0.1407	-0.4052*	-0.1732
2. Difficulty participating in active play	-0.1555	-0.3024*	-0.2292	-0.1555	-0.4201*	-0.093
3. Having hurts or aches	-0.1361	-0.2888*	-0.205	-0.1361	-0.3393*	-0.1828
4. Feeling tired	-0.1286	-0.2813*	-0.1658	-0.1286	-0.3358*	-0.1929
5. Being lethargic	-0.1188	-0.2772*	-0.1634	-0.1188	-0.3308*	-0.1365
6. Resting a lot	-0.3346*	-0.2342*	-0.3339*	-0.0753	-0.1901	-0.2276
7. Feeling too tired to play	-0.1115	-0.2627*	-0.1751	-0.1115	-0.3359*	-0.1427
8. Difficulty walking	-0.3745*	-0.2762*	-0.3800*	-0.1247	-0.3521*	-0.3446*
9. Difficulty running a short distance without falling	-0.1237	-0.2739*	-0.1379	-0.3514*	-0.5369*	-0.3049*
Physical symptoms						
1. Having gas	-0.0197	-0.174	-0.115	-0.0197	-0.2562	-0.0273
2. Spitting up after eating	-0.0796	-0.2407*	0.0193	-0.0796	-0.1537	0.0283
3. Difficulty breathing	-0.3391*	-0.1812	-0.2777	-0.0644	-0.083	-0.1977
4. Being sick to his/her stomach	-0.0927	-0.2450*	0	-0.0927	-0.0674	-0.1056
5. Difficulty swallowing	-0.1591	-0.3034*	-0.0745	-0.1591	-0.1297	-0.1089
6. Being constipated	-0.141	-0.0264	-0.3076*	-0.141	-0.3312*	-0.1817
7. Having a rash	0.0203	-0.0931	0.0194	0.0203	-0.1319	0.0826
8. Having diarrhea	-0.1367	-0.021	-0.3067*	-0.1367	-0.3275*	-0.0973
9. Wheezing	-0.0034	-0.1173	-0.2273	-0.0034	-0.1816	0.053
10. Vomiting	-0.3157*	-0.2210*	-0.1889	-0.0759	-0.0456	-0.1285
Emotional functioning						
1. Feeling afraid or scared	-0.0693	0.0317	-0.2334	-0.0693	-0.2253	-0.2002
2. Feeling angry	-0.1466	0.0369	-0.3637*	-0.058	-0.2031	-0.159
3. Crying or fussing when left alone	0.0664	-0.0827	-0.0701	-0.1182	-0.3157*	0.1269
4. Difficulty soothing himself/herself when upset	-0.0906	0.0209	-0.2674	-0.0906	-0.3111*	-0.173
5. Difficulty falling asleep	0.1026	-0.0158	-0.0186	-0.1367	-0.1858	0.0498
6. Crying or fussing while being cuddled	-0.1757	-0.0424	-0.2689	-0.1757	-0.3243*	-0.144
7. Feeling sad	-0.2164	-0.0477	-0.3903*	0.0765	-0.2273	-0.0137
8. Difficulty being soothed when picked up or held	0.0766	-0.0477	-0.1501	0.0766	-0.1622	0.1645
9. Difficulty sleeping mostly through the night	0.0161	-0.11	0.0162	0.0161	0.0828	0.0829
10. Crying a lot	-0.0839	0.0263	-0.2604	0.1443	-0.1069	-0.0249
11. Feeling cranky	-0.1262	0.0733	-0.3550*	-0.0236	-0.2215	-0.1895
12. Difficulty taking naps during the day	0.0582	-0.0699	0.0507	0.0582	0.0753	0.044
Social functioning						
1. Not smiling at others	-0.3598*	-0.2798*	-0.1986	-0.1279	-0.2009	-0.1722
2. Not laughing when tickled	-0.1351	-0.2866*	-0.031	-0.1351	-0.2432	-0.0554
3. Not making eye contact with a caregiver	-0.1565	-0.3043*	-0.0146	-0.1565	-0.2611	-0.0615
4. Not laughing when cuddled	-0.1395	-0.2846*	0.0036	-0.1395	-0.2263	-0.0365
5. Being uncomfortable around other children	-0.1407	-0.2897*	0.0244	-0.1407	-0.2431	-0.0204
Cognitive functioning						
1. Not imitating caregivers' actions	-0.117	-0.2731*	0.0099	-0.3511*	-0.3820*	-0.2497

2. Not imitating caregivers' facial expressions	-0.3364*	-0.2676*	-0.1642	-0.3364*	-0.3543*	-0.3576*
3. Not imitating caregivers' sounds	-0.3696*	-0.2640*	-0.1905	-0.3356*	-0.2954*	-0.3760*
4. Not able to fix his/her attention on objects	-0.1031	-0.2622*	0.0258	-0.1031	-0.1545	-0.1294
5. Not imitating caregivers' speech	-0.3211*	-0.2645*	-0.14	-0.3211*	-0.3255*	-0.3255*
6. Difficulty pointing to his/her body parts when asked	-0.1028	-0.2616*	0.0321	-0.3279*	-0.3733*	-0.2583
7. Difficulty naming familiar objects	-0.0949	-0.2506*	0.0353	-0.3160*	-0.3576*	-0.2464
8. Difficulty repeating words	-0.0901	-0.2480*	-0.1335	-0.3053*	-0.4822*	-0.1812
9. Difficulty keeping his/her attention on things	-0.3199*	-0.2603*	-0.1347	-0.3199*	-0.2573	-0.3708*

Grey shaded areas indicate pairs hypothesized to be at least moderately correlated. Correlations of 0.1–0.29 were considered weak (red), 0.3–0.49 moderate (yellow), and ≥ 0.5 strong (green).

Table S6 Convergence between EQ-TIPS items and PedsQL items in Tetralogy of Fallot sample (2-4 years)

	movement	play	pain	social interaction	communication	eating
Physical functioning						
walking	1.0000*	-0.3048*	-0.3048*	-0.1217	-0.0974	-0.3083
running	1.0000*	-0.2906*	-0.1292	-0.1857	-0.1083	-0.3249
active play or exercise	1.0000*	-0.2989*	0.1439	-0.1114	-0.0106	-0.2918
lifting something heavy	1.0000*	-0.2761*	-0.1062	0.0458	0.1425	-0.285
bathing	1.0000*	-0.3293*	-0.1931	-0.0408	0.1687	-0.2122
helping to pick up toys	1.0000*	-0.3103	0.0944	0.1358	0.2263	-0.2133
hurts or aches	1.0000*	-0.2184	0.1379	-0.314	-0.011	-0.1818
low energy level	1.0000*	-0.1068	-0.2564	-0.1536	0.128	-0.2714
Emotional functioning						
afraid or scared	1.0000*	0	-0.2074	-0.1491	0.1988	-0.20
sad or blue	1.0000*	-0.106	-0.2863*	-0.0762	0.2083	-0.15
angry	1.0000*	-0.0839	-0.2516	-0.0527	0.221	-0.32
trouble sleeping	1.0000*	-0.2933*	-0.2933*	-0.1135	0.1189	-0.29
worrying	1.0000*	-0.1292	-0.2906*	-0.3017	0.0309	-0.19
Social functioning						
playing with other children	1.0000*	-0.2055	0.137	-0.3939*	-0.0656	0
other kids not wanting to play with them	1.0000*	-0.2055	0.137	-0.0492	0.1641	0
teased by other children	1.0000*	-0.2968	0.1032	-0.14	0.06	0.0556
not able to do things that other children can do	1.0000*	-0.2346	0.129	-0.34	-0.21	-0.2754
keeping up when playing with other children	1.0000*	-0.1909	0.1459	-0.3793*	-0.2044	-0.043
School functioning						
same school activities as peers	1.0000*	-0.3246	0.0947	-0.1653	0.0259	-0.3759
missing school because of not feeling well	1.0000*	-0.2597	0.1113	-0.1067	0.0889	-0.0889
missing school to go to doctor	1.0000*	-0.3326*	0.1109	0.1594	0.2656	-0.1594

Grey shaded areas indicate pairs hypothesized to be at least moderately correlated. Correlations of 0.1–0.29 were considered weak (red), 0.3–0.49 moderate (yellow), and ≥ 0.5 strong (green).

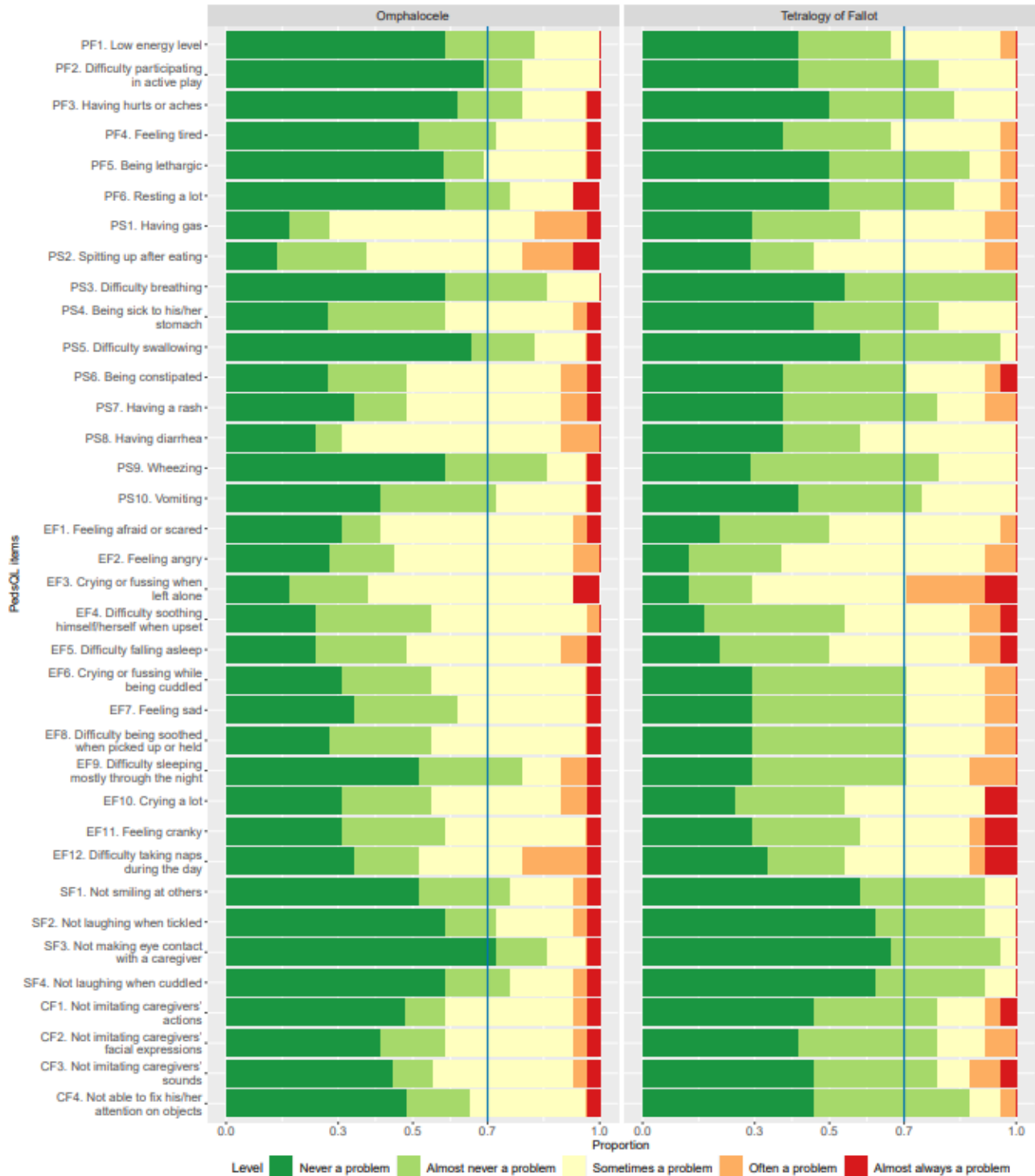


Figure S1 Response Distribution of PedsQL items in children aged 1-12 months

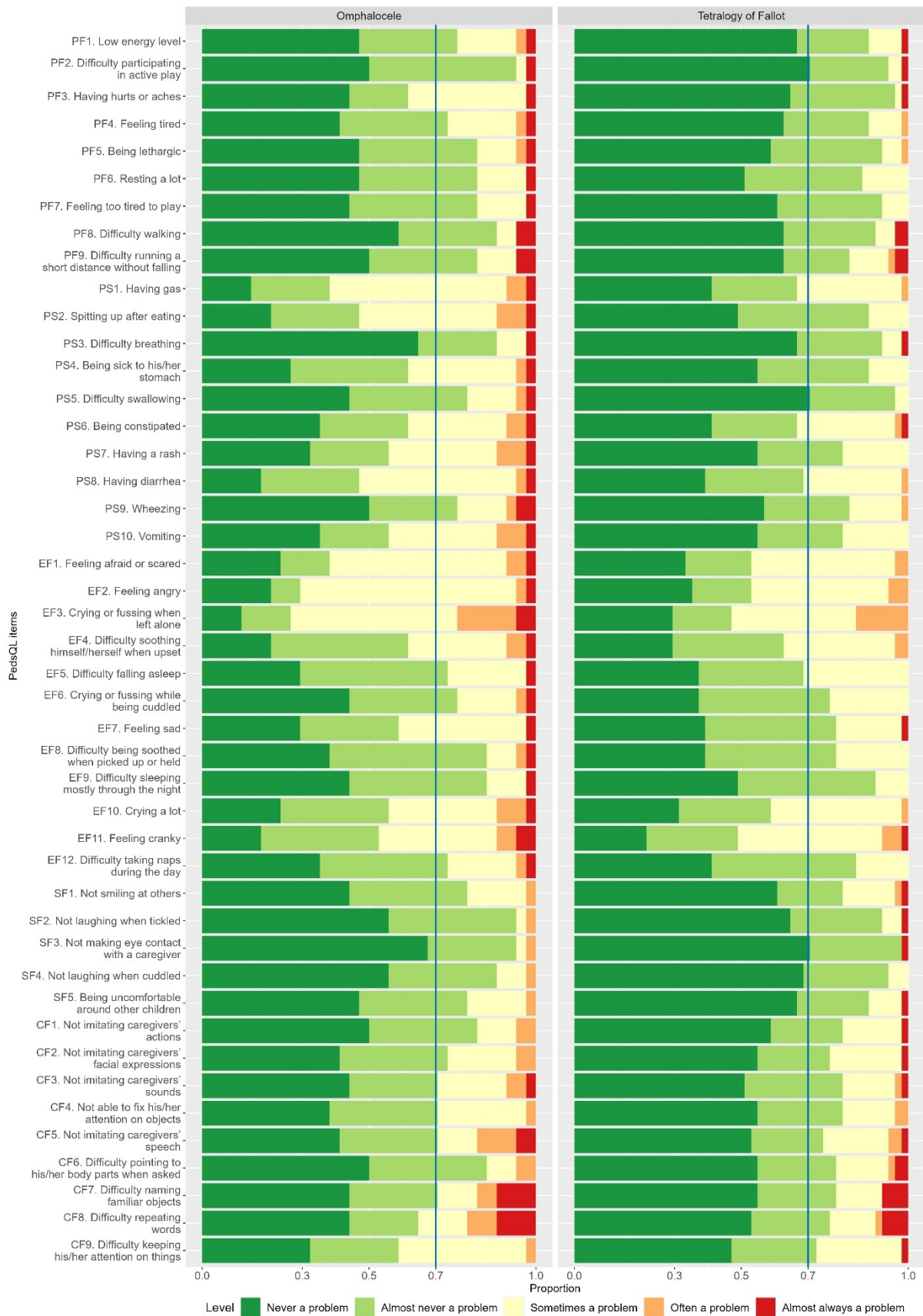


Figure S2 Response Distribution of PedsQL items in children aged 13-24 months



Figure S3 Response Distribution of PedsQL items in children aged 2-4 years