Research Paper

Caregiver health-related quality of life 1 year following pediatric gastrostomy tube placement

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ABSTRACT

Introduction: Children undergoing gastrostomy tube placement often have complex medical conditions that can increase caregiver burden and decrease caregiver health-related quality of life. Our goal was to identify changes in health-related quality of life over a 12-month period in the caregivers of these patients.

Methods: We performed a prospective cohort study of pediatric patients undergoing gastrostomy tube placement. Using the PedsQL 2.0 Family Impact Module, we surveyed the caregivers of these patients at baseline (prior to gastrostomy tube placement) and 1 month, 3 months, 6 months, and 12 months following gastrostomy tube placement. We administered the same survey, at baseline only, to a control group composed of caregivers of pediatric patients undergoing elective hernia repair.

Results: We enrolled 130 patients undergoing gastrostomy tube placement and 35 patients undergoing hernia repair. At baseline, these caregivers had significantly lower total health-related quality of life compared to caregivers of children undergoing hernia repair (47.4 ± 16.1 vs 86.0 ± 15.6, P < .001). In the first year after gastrostomy tube placement, caregivers had significant increases in total health-related quality of life (P < .01) and the physical functioning (P < .05), communication (P < .05), worry (P < .05), and daily activities (P < .001) subdomains. A within-subjects analysis comparing scores at baseline and 12 months revealed a significant increase in the total health-related quality of life score over this 1-year period (60.7 ± 18.9 vs 47.4 ± 16.1, P < .01). The total health-related quality of life at 12 months, however, remained significantly lower compared to controls (60.7 ± 18.9 vs 86.0 ± 15.6, P < .001).

Conclusion: Our findings highlight the ongoing caregiver burden associated with children undergoing gastrostomy tube placement and provide evidence of the need for efforts directed at caregiver support post gastrostomy tube placement.

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INTRODUCTION

Children undergoing gastrostomy tube placement are often medically complex beyond the need for enteral access and have concurrent comorbidities, including neuromuscular, cardiovascular, respiratory, and metabolic disorders [1-3]. The medical complexity of these children increases the physical, emotional, and social burden on their caregivers [4]. This increased caregiver burden can lead to decreased caregiver health-related quality of life (HRQoL), impaired productivity, depression, and insomnia [5]. Additionally, decreased caregiver HRQoL can lead to an increase in health care utilization among medically complex infants and children [6-8].

HRQoL is multifaceted and necessitates consideration of multiple individual domains, including physical well-being, mental and emotional well-being, social activities, and relationships [9-11]. Franken et al (2019) reported significant improvements in HRQoL after gastrostomy tube placement but studied the HRQoL of the child undergoing the procedure, rather than the caregiver, and only reported data up until 3 months post gastrostomy tube placement [12]. A subsequent study by Franken et al (2020) found that children undergoing gastrostomy tube placement who have other comorbidities have a lower HRQoL following gastrostomy tube placement than children who do not have comorbidities [13]. Additionally, Pemberton et al (2013) studied HRQoL in caregivers of patients requiring gastrostomy tubes and found that gastrostomy tube placement improves caregiver HRQoL and that the most significant improvement was at 12 months post gastrostomy tube placement; however, no control group was used for comparison [14].

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Although the above studies have evaluated child HRQoL following pediatric gastrostomy tube placement, few have evaluated changes in caregiver HRQoL. Fewer have maintained follow-up for greater than 6 months, and none appear to compare the HRQoL of caregivers of gastrostomy patients to a separate control group. For these reasons, our primary objective was to identify changes over a 12-month period in the HRQoL of caregivers of pediatric patients undergoing gastrostomy tube placement and to assess which subdomains of HRQoL changed over time. We also compared the baseline HRQoL of caregivers of children undergoing gastrostomy tube placement to the baseline HRQoL of caregivers of children undergoing elective hernia repair. We hypothesized that caregivers of patients undergoing gastrostomy tube placement would have a lower baseline HRQoL than caregivers of patients undergoing hernia repairs and that caregiver HRQoL would increase over time following gastrostomy tube placement.

**METHODS**

**Study Design and Participants.** We performed a prospective cohort study of pediatric patients and their caregivers to determine the effect of gastrostomy tube placement on caregiver HRQoL. The study was approved by the IRB at the University of Utah. Patients were recruited from a pediatric general surgery clinic at a tertiary free-standing children’s hospital over a period of 2 years. All patients younger than 18 years undergoing either gastrostomy tube placement or elective hernia repair were eligible for participation in the study. The patients undergoing gastrostomy tube placement served as cases, whereas those undergoing hernia repair served as healthy controls. Patients and their caregivers were recruited for the study during their initial clinic visit and enrolled after providing informed consent for participation. Study participation was voluntary, and patients and their families received no direct compensation for survey completion. All patient data that was collected was stored securely within REDCap.

**Data Collection.** Demographic data for the child and caregiver, as well as information about child comorbidities, was collected in both the gastrointestinal and hernia cohorts. Demographic data included ethnicity, age, education level, etc. The data for comorbidities included cardiovascular, gastrointestinal, craniofacial, and neurological conditions. The specific cardiovascular comorbidities reported included patent ductus arteriosus, patent foramen ovale, ventricular septal defect, atrial septal defect, atrioventricular canal defect, tetralogy of Fallot, transposition of great vessels, valve abnormalities, pulmonary stenosis, hypoplastic left heart, and others. Gastrointestinal comorbidities included intestinal atresia, duodenal stenosis, gastrointestinal malrotation, omphalocele, esophageal atresia with fistula formation, tracheomalacia, and others. Craniofacial comorbidities included cleft lip and palate, ear abnormalities, jaw abnormalities, choanal atresia, and others. Neurological comorbidities primarily included hydrocephalus, macrocephaly, microcephaly, nonepileptic seizures, epilepsy, developmental delay, and lisencephaly.

The PedsQL 2.0 Family Impact Module was used to survey participants [15]. The questions comprising the PedsQL survey assess caregiver HRQoL both as a composite score and across multiple subdomains: physical functioning, emotional functioning, social functioning, cognitive functioning, communication, worry, daily activities, and family relationships. At baseline (prior to surgical intervention), both groups were asked to respond to the PedsQL survey in person, via phone, or via email. Follow-up surveys were sent to patients undergoing gastrostomy tube placement at 1 month, 3 months, 6 months, and 12 months post gastrostomy tube placement. Caregivers of hernia patients were not asked to complete follow-up surveys as they only served as healthy controls at one time point, which was at baseline (prior to surgical intervention).

**Statistical Analyses.** Using RStudio (Version 1.3.959), relative frequencies were calculated for the demographic data, and a \( \chi^2 \) goodness-of-fit test was performed to assess for significant differences between the demographic distributions of cases and controls.

Survey responses were converted to numeric values for analysis using a 5-point Likert scale. Total HRQoL was defined as the sum of the numerical responses within the entire survey divided by the number of questions. The HRQoL for each subdomain was calculated by taking the sum of the numerical scores in each subdomain and dividing by the number of questions in that subdomain. Participants who failed to respond to greater than 1/3 of survey questions or were missing significant amounts of demographic data were excluded from our analyses.

To compare HRQoL scores between case and control groups, we used 2-sample t tests and Wilcoxon rank-sum tests when score distributions were skewed. Our primary outcome of interest was HRQoL at baseline and 12 months post gastrostomy tube placement.

To further evaluate and visualize the changes in HRQoL across the 12-month period, we performed a trend analysis using generalized linear models with random effects. We created a model for each HRQoL subdomain (physical functioning, emotional functioning, social functioning, cognitive functioning, communication, worry, daily activities, and family relationships) and total HRQoL, which were tested independently for significant changes over time from baseline to 12 months.

**RESULTS**

We enrolled 130 patients undergoing gastrostomy tube placement and 35 patients undergoing hernia repair. Of the 130 gastrostomy patients enrolled, 23 (18%) patients were excluded from analysis because of missing data. Of the 35 enrolled hernia patients, 5 (14%) were excluded from analysis because of missing data. Overall, 76 (71%) caregivers of gastrostomy patients had baseline data, 59 (55%) completed the follow-up survey at 1 month, 45 (42%) completed the follow-up survey at 3 months, 37 (35%) completed the follow-up survey at 6 months, and 37 (35%) completed the follow-up survey at 12 months. A total of 25 participants (23%) completed both baseline and 12-month follow-up surveys.

The baseline demographics for the pediatric patients included in the study are shown in Table 1. No significant differences in sex, ethnicity, race, age, gestational age, adoption status, or prenatal care were identified between the gastrostomy tube cohort and hernia repair cohort. However, when compared to patients undergoing hernia repair, patients undergoing gastrostomy tube placement had a significantly higher proportion of cardiovascular comorbidities (31% vs 10%, \( P < .05 \)), gastrointestinal comorbidities (23% vs 0%, \( P < .01 \)), craniofacial comorbidities (25% vs 3%, \( P < .01 \)), and neurological comorbidities (42% vs 3%, \( P < .01 \)).

The demographic information for primary caregivers included in the study is shown in Table 2. Our analysis revealed no significant differences in the relation to the child, primary language, highest level of education, insurance type, employment status, or marital status between caregivers of patients undergoing gastrostomy tube placement and caregivers of patients undergoing hernia repair.

At baseline, caregivers of children undergoing gastrostomy tube placement had significantly lower total HRQoL compared to caregivers of children undergoing hernia repair (47.4 ± 16.1 vs 86.0 ± 15.6, \( P < .001 \)). In all subdomains examined, caregivers of children undergoing gastrostomy tube placement had significantly lower HRQoL compared to caregivers of hernia patients (Table 3). The largest differences in baseline HRQoL between cases and controls were in the daily activities (81.9 ± 27.6 vs 20.3 ± 20.4, \( P < .001 \)) and worry (86.3 ± 14.0 vs 33.0 ± 22.8, \( P < .001 \)) subdomains.

During the first year after gastrostomy tube placement, caregivers had significant improvements in total HRQoL (\( P < .01 \) for trend) and the physical functioning (\( P < .05 \) for trend), communication (\( P < .05 \) for trend), and family relationships (\( P < .05 \) for trend) subdomains. Caregivers of children undergoing gastrostomy tube placement also had significantly lower HRQoL compared to caregivers of children undergoing hernia repair (47.4 ± 16.1 vs 86.0 ± 15.6, \( P < .001 \)). In all subdomains examined, caregivers of children undergoing gastrostomy tube placement had significantly lower HRQoL compared to caregivers of hernia patients (Table 3). The largest differences in baseline HRQoL between cases and controls were in the daily activities (81.9 ± 27.6 vs 20.3 ± 20.4, \( P < .001 \)) and worry (86.3 ± 14.0 vs 33.0 ± 22.8, \( P < .001 \)) subdomains.
DISCUSSION

In this prospective cohort study, we compared baseline HRQoL between caregivers of pediatric gastrostomy tube patients and a control group of caregivers of children undergoing elective hernia repair. In addition, we assessed longitudinal changes in HRQoL among caregivers of pediatric gastrostomy patients over a period of 12 months. We identified significant improvements in total caregiver HRQoL 12 months post gastrostomy tube placement and significant improvements in the physical functioning, communication, worry, and daily activities subdomains relative to baseline. We further determined that although there was a significant improvement in caregiver HRQoL over 12 months, the total HRQoL score at 12 months still remained lower than that of healthy controls.

Our study was unique in many respects. To our knowledge, this study is the first to include caregivers of hernia patients as a control group for caregivers of gastrostomy patients. Additionally, we obtained follow-up data 12 months post gastrostomy tube placement, whereas the majority of HRQoL studies report data only up to 3 or 6 months after surgery. Finally, our study not only assessed the changes in total HRQoL over time but further divided HRQoL into subdomains and assessed the changes within each subdomain.

Franken et al (2019) performed a prospective, longitudinal cohort study assessing the HRQoL of pediatric patients who underwent gastrostomy tube placement at 3 months post gastrostomy tube placement. They reported that the social functioning aspect of child HRQoL significantly improved from baseline to 3 months; however, total child HRQoL did not increase significantly [12]. In the present study, we observed a different pattern among caregivers. Specifically, we report a significant increase in total HRQoL and many HRQoL subdomains 1 year following gastrostomy tube placement; however, the social functioning subdomain did not increase significantly over the 12-month period. Our study extends the work of Franken et al (2019) by our focus on caregivers rather than pediatric patients, the addition of a control group, and tracking of HRQoL 12 months post gastrostomy tube placement.

Using similar methods to the present study, Pemberton et al (2013) performed a prospective repeated measures cohort study to assess the HRQoL of caregivers of pediatric gastrostomy patients at baseline, 2 weeks, 3 months, 6 months, 9 months, and 12 months following gastrostomy tube placement. Caregivers completed 3 different HRQoL measures at each of these time points: Short Form 36v2 (SF-36), Caregiver Strain Index (CSI), and Parent Experience of Childhood Illness (PECI). The authors concluded that gastrostomy tube placement improves the mental health of children’s caregivers, most notably 1 year following gastrostomy tube placement [14]. Although our study found an increase in total caregiver HRQoL, we could not directly assess changes in caregiver mental health because the PedsQL 2.0 Family Impact Module does not have a mental health subdomain. However, closely related subdomains, such as worry, did increase significantly. Additionally, the present study used a control group for comparison. In addition to changes in caregiver HRQoL, we observed a high prevalence of comorbidities among children undergoing gastrostomy tube placement. These findings are consistent with those reported in studies of children with feeding difficulties [16,17] and those reported in studies of children requiring gastrostomy tube placement [13,18].

Table 1
Demographic data for pediatric patients undergoing gastrostomy tube placement versus hernia repair

| Child demographics | G-tube n (%) | Hernia n (%) | P value |
|--------------------|-------------|--------------|---------|
| Sex                |             |              |         |
| Female             | 58 (54%)    | 11 (37%)     | .10     |
| Male               | 49 (46%)    | 19 (63%)     | .10     |
| Ethnicity          |             |              |         |
| Hispanic or Latino | 14 (15%)    | 3 (10%)      | .76     |
| Not Hispanic or Latino | 81 (85%) | 27 (90%)     | .76     |
| Race               |             |              |         |
| Asian              | 1 (1%)      | 0 (0%)       | 1.00    |
| Black or African American | 1 (1%) | 1 (3%)       | .43     |
| Native Hawaiian or Other Pacific Islander | 3 (3%) | 1 (3%)       | 1.00    |
| White              | 89 (95%)    | 28 (93%)     | .68     |
| Age                |             |              |         |
| 12 mo or less      | 58 (55%)    | 10 (34%)     | .06     |
| Greater than 12 mo | 47 (45%)    | 19 (66%)     | .06     |
| Gestational age    |             |              |         |
| Preterm            | 48 (63%)    | 11 (48%)     | .23     |
| Full term          | 28 (37%)    | 12 (52%)     | .23     |
| Adopted            |             |              |         |
| No                 | 93 (92%)    | 30 (100%)    | .19     |
| Yes                | 8 (8%)      | 0 (0%)       | .19     |
| Comorbidities*     |             |              |         |
| Cardiovascular     | 33 (31%)    | 3 (10%)      | .03     |
| Gastrointestinal   | 24 (23%)    | 0 (0%)       | .01     |
| Craniofacial       | 26 (25%)    | 1 (3%)       | .01     |
| Neurological       | 45 (42%)    | 1 (3%)       | .001    |
| Indication for enteral feeding† | | | |
| Failure to thrive  | 25 (27%)    | NA           | NA      |
| GERD               | 6 (6%)      | NA           | NA      |
| Inability to swallow | 50 (53%) | NA           | NA      |
| Other              | 13 (14%)    | NA           | NA      |
| Prenatal care      |             |              |         |
| No                 | 6 (7%)      | 1 (4%)       | .67     |
| Yes                | 76 (93%)    | 27 (96%)     | .67     |

* Some participants had multiple comorbidities.
† Control patients had no indication for enteral feeding as they underwent elective hernia repair only, not G-tube placement.

Table 2
Demographic data for caregivers of patients undergoing gastrostomy tube placement versus hernia repair

| Primary caregiver demographics | G-tube n (%) | Hernia n (%) | P value |
|--------------------------------|--------------|--------------|---------|
| Relation to child              |              |              |         |
| Mother                         | 96 (90%)     | 29 (97%)     | .46     |
| Father                         | 7 (7%)       | 0 (0%)       | .35     |
| Grandparent                    | 3 (3%)       | 0 (0%)       | 1.00    |
| Other                          | 0 (0%)       | 1 (3%)       | .22     |
| Primary language               |              |              |         |
| English                        | 100 (96%)    | 29 (100%)    | .58     |
| Spanish                        | 3 (3%)       | 0 (0%)       | 1.00    |
| Other                          | 1 (1%)       | 0 (0%)       | 1.00    |
| Highest level of education     |              |              |         |
| High school graduate/GED or less | 26 (26%) | 10 (34%)     | .36     |
| Some college or more           | 75 (74%)     | 19 (66%)     | .36     |
| Insurance                      |              |              |         |
| Medicaid/Medicare              | 48 (48%)     | 10 (37%)     | .39     |
| Private                        | 52 (51%)     | 17 (63%)     | .39     |
| Uninsured                      | 1 (1%)       | 0 (0%)       | 1.00    |
| Employment status              |              |              |         |
| Employed                       | 49 (49%)     | 12 (40%)     | .41     |
| Not employed                   | 51 (51%)     | 18 (60%)     | .41     |
| Marital status                 |              |              |         |
| Married or domestic partnership | 90 (88%) | 26 (87%)     | .76     |
| Not married                    | 12 (12%)     | 4 (13%)      | .76     |

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Fig. 1. HRQoL of caregivers of gastrostomy tube patients over a 12-month period. Error bars represent ±1 SD. *P < .05 for trend.

Table 3
Comparison of baseline HRQoL subdomains and baseline total HRQoL between caregivers of patients undergoing gastrostomy tube placement versus hernia repair

| Subdomain                        | Baseline mean (SD) hernia | Baseline mean (SD) G-tube | Mean difference [95% CI] | P value |
|----------------------------------|---------------------------|---------------------------|-------------------------|---------|
| Physical functioning             | 83.2 (19.6)               | 45.8 (21.5)               | 37.4 [26.1, 48.6]       | <.001   |
| Emotional functioning            | 84.3 (18.5)               | 47.8 (19.9)               | 36.5 [26.0, 47.0]       | <.001   |
| Social functioning               | 89.0 (16.7)               | 50.0 (24.3)               | 39.0 [27.4, 50.6]       | <.001   |
| Cognitive functioning            | 80.8 (23.1)               | 58.4 (24.7)               | 22.4 [9.40, 35.5]       | <.05    |
| Communication                    | 92.2 (11.8)               | 46.3 (18.5)               | 45.9 [37.2, 54.5]       | <.001   |
| Worry                            | 86.3 (14.0)               | 33.0 (22.8)               | 53.3 [42.8, 63.9]       | <.001   |
| Daily activities                 | 81.9 (27.6)               | 20.3 (20.4)               | 61.6 [48.6, 74.6]       | <.001   |
| Family relationships             | 92.0 (15.2)               | 67.0 (24.7)               | 25.0 [13.5, 36.5]       | <.001   |
| Total HRQoL                      | 86.0 (15.6)               | 47.4 (16.1)               | 38.6 [30.0, 47.2]       | <.001   |
in caregiver burden secondary to comorbidities may partially explain the significant difference in HRQoL between caregivers of gastrostomy patients and healthy controls. However, the interactions between these variables were not explored in the present study.

The primary limitation in this study was the attrition over time due to loss to follow-up. Although we had a sufficient number of survey responses at 12 months to perform a trend analysis within the gastrostomy tube cohort, it is possible that a bias exists in the caregivers who responded to the study. More specifically, children undergoing gastrostomy tube placement were more likely to have comorbidities given their long-standing relationship with the health care system. This may have resulted in a lower HRQoL among those who completed follow-up surveys. Similarly, it is also possible that caregivers of more medically complex patients that require gastrostomy tube placement are more likely to complete follow-up surveys than caregivers of less medically complex patients who require gastrostomy tube placement given that caregivers of more medically complex patients tend to have more frequent interactions with the health care system. In addition, although the PedsQL 2.0 Family Impact Module spans multiple subdomains, it is an imperfect assessment for HRQoL given its long length, reliance on self-report, and use of questions that do not cover all areas of interest.

In conclusion, we observed a significantly lower HRQoL in caregivers of children undergoing gastrostomy tube placement compared to healthy controls. Although we identified a significant improvement in caregiver HRQoL over time, caregivers of pediatric patients 12 months post gastrostomy tube placement continued to have a lower HRQoL relative to the control group. The largest improvements in HRQoL were in the physical functioning, communication, worry, and daily activities subdomains. These findings highlight the ongoing caregiver burden associated with children undergoing gastrostomy tube placement and provide evidence to suggest that the development of quality improvement efforts directed at caregiver support post gastrostomy tube placement is warranted. Further investigation to identify which specific risk factors are associated with decreased HRQoL in caregivers of patients undergoing gastrostomy tube placement might yield meaningful insights that could serve as the basis of future guidelines for clinicians performing these procedures and caring for this patient population.

Author Contribution

Study conception and design: Karlie O’Brien and Brian Bucher; data acquisition: Karlie O’Brien, Jack Scaife, and Brian Bucher; analysis and interpretation of data: Karlie O’Brien and Brian Bucher; writing: Karlie O’Brien; editing/revising: Karlie O’Brien, Jack Scaife, Stephanie Iantorno, and Brian Bucher.

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Ethics Approval

The study was approved by the IRB at the University of Utah (00091986).

Conflict of Interest

None.

Acknowledgments

None.

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