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Objective measurement of quality of life changes after ACE Malone using the FICQOL survey

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KEYWORDS

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Abstract Purpose: There is little objective data demonstrating improved quality of life after a Malone antegrade continence enema (ACE) despite the dramatic subjective improvements seen by physicians and caretakers.

Methods: We utilized the FICQOL survey, a reliable and valid instrument for measuring the impact of fecal incontinence and constipation on quality of life (FICQOL) of caregivers and children with spina bifida. Between 2002 and 2009, 23 families were evaluated prospectively before and after an ACE procedure. Items on the survey were compared with Wilcoxon rank sum or signed rank test.

Results: After an ACE Malone the mean number of bowel movements (BM) per day decreased along with a decrease in number of accidents per week from 3.9 to 0.3. There was no change in the time committed to bowel care. The percentage of patients taking oral laxatives decreased from 44% to 6%. Both parent and child were less often prevented from leaving the house and the caretakers' bother, anxiety and depression due to bowel care decreased. Although factors regarding the child's social issues and parent's employment improved, the changes were not statistically significant.

Conclusions: Among patients with spina bifida and fecal incontinence who underwent the ACE procedure at our institution, a significant improvement in fecal incontinence and QOL scores was observed using a validated instrument, FICQOL. Without changing the amount of time necessary for bowel care, the ACE procedure decreases the families' worries and anxieties and allows them to leave home with the confidence that their child will not have leakage of stool.

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Introduction

Longitudinal studies following patients with spina bifida (SB) from birth to adulthood show that these patients

experience chronic neuropathic bowel, bladder symptoms and issues related to mobility [1]. There is significant impact of this chronic disease on the patient's family [2]. Of patients with SB, 34% of those 16–25 years old report

Abbreviations: BM, bowel movement; FICQOL, fecal incontinence constipation on quality of life; QOL, quality of life.

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bowel incontinence and 77% perceive that bowel incontinence has a negative impact on their lives [3]. Krogh et al found that two-thirds of patients with myelomeningocele who were 6 years of age or older and had fecal incontinence report that incontinence significantly influenced social activities and QOL [4].

Non-surgical bowel care programs generally include oral agents such as laxatives, stool softeners, fiber and/or a rectal component such as digital stimulation, manual evacuation or enema. The bowel care regimen can be significantly simplified with the surgical placement of access for antegrade enemas. Malone et al combined the principles of ACE and the Mitrofanoff non-refluxing catheterizable channel to develop the "ACE Malone" procedure in 1990 [5]. Administration of a large volume of fluid through the appendix allows complete colonic evacuation and fecal continence. Since the initial description of the ACE procedure there have been several advancements that have simplified the technique and reduced stoma complications [6–10]. The laparoscopic technique used by our group has been described previously [11,12].

The subjective evidence that an ACE improves quality of life for children with neuropathic constipation and/or encopresis is overwhelming. Notable comments from families include: "best thing since sliced bread," "life changing," "wonderful" and "I wish we had done this earlier." On the other hand, there is little literature demonstrating objective changes in quality of life [13–16] and only one using a reliable and validated questionnaire that evaluated behavior and emotional problems and self esteem [17]. The lack of QoL data has been due to a lack of an instrument that objectively measures QoL parameters specific to bowel function. In 2008, we presented the Fecal Incontinence and Constipation Quality of Life (FICQOL) questionnaire, a valid and reliable instrument for measuring quality of life changes in families of children suffering from constipation and stool incontinence due to spina bifida [18]. Our goal was to utilize this instrument to determine and measure QOL changes afforded by surgery. By so doing, we hoped to better understand the changes these children would experience and the impact upon the family's social and personal interactions. We also sought to determine which families would benefit most and least from surgery. Ultimately, we believe this information will help us counsel families, facilitate their decision making and set appropriate expectations.

Materials and methods

The Fecal Incontinence and Constipation Quality of Life (FICQOL) survey, a 51-item questionnaire was developed to evaluate patients with SB in regard to bowel function and measure the magnitude of change in QOL after medical or surgical treatment. It focuses on the aspects of daily life in which bowel incontinence and bowel care have a significant impact. FICQOL survey includes 4 items describing demographic parameters (age, gender, diagnosis and race) and 47 describing fecal incontinence and QOL. The 47 items were separated into 7 QOL groupings including; bowel program (16 items), dietary management (6), symptoms (4), travel and socialization (5), family relationships (4), caregiver support and emotional impact (8), and financial impact (4). Of these

items 26 were considered functional, while 21 measured bother. The FICQOL survey, available for investigational and clinical use, is being used by other investigators. http://www.ucdmc.ucdavis.edu/urology/specialties/pediatric_urology/.

Between 12/2002 and 1/2009, 23 families were evaluated prospectively with the FICQOL survey. Families of children, who had an ACE procedure and completed the survey prior to surgery and at a minimum of 6 months after surgery, were included. The ACE procedure was done laparoscopically in 65% of the patients with the remaining undergoing open ACE with concomitant bladder surgery.

The survey was completed by the primary caregiver. The majority of the surveys were administered in clinic but some were completed at home and mailed back. The rate of return of surveys before surgery was 100%, while 5 out of 23 families did not complete the survey after surgery.

Statistical analysis was performed on the survey items before and after surgery with pair matched (18 patients) (Wilcoxon signed rank test). An additional pair matched *sub-analysis* was performed excluding *survey items* where improvement was not possible (i.e. a Likert score of zero prior to surgery). Data was analyzed using STATA 11 SE (StataCorp, College Station, TX). Statistical significance was defined at $P < 0.05$.

Results

All 23 families were analyzed in unmatched fashion comparing 23 pre- and 18 post-surgery QOL surveys. There were minimal differences in results when compared to the paired analysis. We will describe only the paired analysis results using the 18 families that completed the survey pre- and post-surgery (10 boys, 8 girls). The median age at the time of surgery was 11 years and the majority of patients are Caucasian (72%). The results presented below, unless stated, were the standard paired analysis without excluding patient items.

Bowel program (Fig. 1)

There was a significant improvement in sensation and percentage of bowel movements into the toilet from 45% to 97%, $P < 0.01$. The number of bowel movements per day and need for diaper changes decreased. The number of accidents improved from 3.9 to 0.3 per week ($P < 0.01$). The need for oral and rectal medications as part of the bowel regimen decreased. However the total time for bowel care did not change and remained approximately 45 min.

Dietary management and constipation

Overall there was no significant impact on diet with no change in food sensitivity or need for diet modification. However, there was a significant decrease in abdominal pain from constipation (Fig. 2). The percentage of patients taking oral laxatives decreased from 44% to 6%.

Travel and socialization (Fig. 3)

Pair matched analysis showed a trend toward parent and child being less likely to be prevented from leaving the

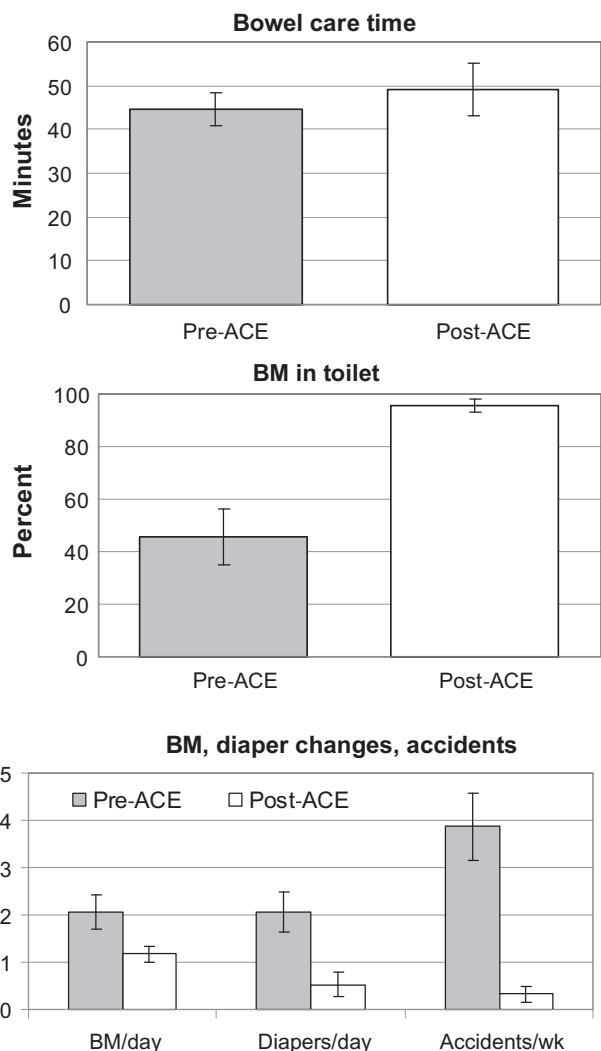


Figure 1 Charts illustrate representative objective changes after ACE Malone with no significant difference in time needed for bowel care, almost all BMs in toilet and corresponding decrease in incontinent episodes per week ($P < 0.05$ for all except bowel care time).

house due to bowel care. Additional pair analysis excluding patient items that could not show improvement (Likert score zero pre-ACE), demonstrated a significant reduction in bowel care preventing the child and caretaker from leaving home and decreased anxiety related to leaving home. This sub-analysis is illustrated in Fig. 3.

Family relationships

ACE did not have significant impact on relationships with siblings, other children or the caregiver’s relationship with his/her partner. This was not a problem area for the families prior to surgery.

Caregiver support and emotional impact (Fig. 4)

There was a significant improvement in caretaker anxiety, depression, worry of smell of stool incontinence and bother

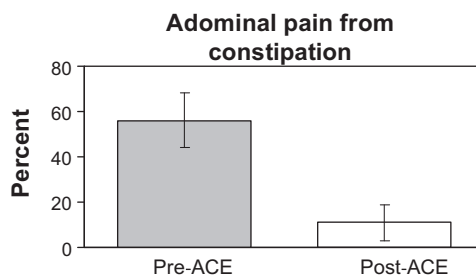


Figure 2 Chart illustrates the significant decrease in percentage of children reporting abdominal pain from constipation after the ACE Malone ($P < 0.05$).

related to bowel care problems. The child’s worry of smell of stool incontinence was also alleviated. The improvements were more dramatic when the sub-analysis was employed by excluding patient items that could not show improvement. This sub-analysis is illustrated in Fig. 4.

Financial impact

Surgery did not have a significant impact on caregiver employment status, affect on work or household activities.

Discussion

Spina bifida has a significant impact on the patient’s and family members’ QOL [1,19,20]. Fecal incontinence is a socially awkward problem that affects at least one-third of patients with SB [21]. Advances in surgical treatment for neurogenic bowel, such as the antegrade continence enema, allows children to stop using diapers and be more like their peers [22]. Studies show improved self-esteem following the antegrade continence enema procedure. There is an excellent surgical success rate and non-validated questionnaire studies show improvements in measured QoL factors [13–16].

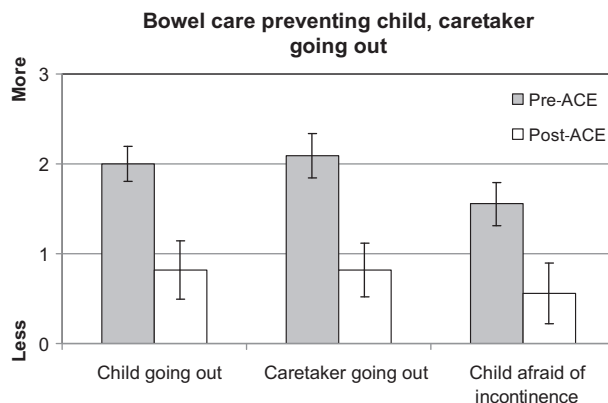


Figure 3 Chart illustrates representative changes of socialization QoL parameters after an ACE Malone with decreased bother or anxiety of leaving the house. All questions were on a Likert scale and all differences were statistically significant ($P < 0.05$).

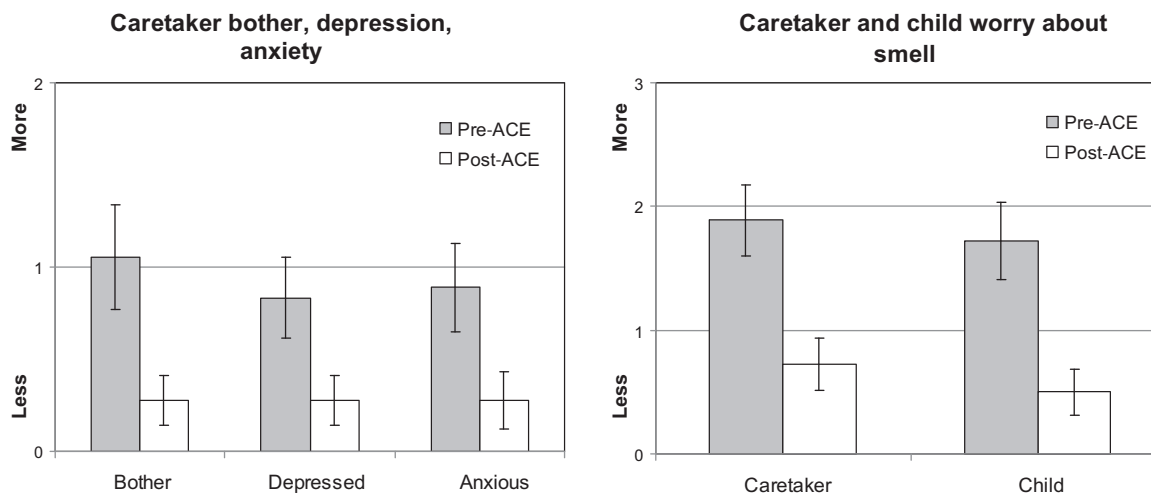


Figure 4 Charts illustrate representative caregiver support and emotional impact QoL changes. All questions were on a Likert scale and all differences were statistically significant ($P < 0.05$).

Aksnes et al evaluated 20 children before and after surgery. Mental health, psychosocial functioning and self-esteem were assessed by standardized questionnaires. Significant improvements in independence, feeling of security and self-esteem were reported [17]. Shankar et al evaluated a cohort of 40 children after surgery retrospectively. Twenty-eight achieved continence. Only 50% of wheelchair bound patients with spinal dysraphism were continent. Their QoL scores were significantly lower than ambulatory patients based upon a non-standardized questionnaire. Incontinent patients had a significantly lower anorectal squeeze pressure by manometry. Continent and incontinent patients showed no difference in colonic transit time measured by radio-opaque beads.¹⁵

The FICQOL instrument allows the measurement of the impact of fecal incontinence on the QoL in the SB population. The ACE procedure results in significant improvement in continence with decreased number of bowel movements, need of diapers and accidents. Overall the bowel management is simple, more reliable with less need of oral or rectal medications resulting in almost all bowel movements into the toilet. The regular and complete bowel movements have many social and psychological benefits including parent and child being less likely to be prevented from leaving the house due to bowel care, decreased anxiety and caregiver depression. However, improved bowel care did not have a significant impact on patient diet, family relationships or caregiver employment.

The prospective study was limited by the number of patients, somewhat inherent in this uncommon procedure, and the non-participation of 5 families after surgery. The follow up was short for some patients. Yet, all the patients continued to use the ACE and enjoy the freedom from stool incontinence. A characteristic of the FICQOL survey and the families, which affected the results, is the disparity between patient comments and the small improvements seen on the Likert scale for certain questions. Families describe the ACE procedure as "life changing" and comment "I wish we had done this earlier" yet the average improvement in QoL scores is less than 1 point. While the severity scale goes up to 3 or 4, the average of the pre-

procedure scores was less than 2. This provides little room for improvement even for a "life changing procedure." Patients and families were found to be well adjusted to the constipation and encopresis prior to surgery.

We attempted to overcome this *phenomenon* by performing an additional sub-analysis on the Likert portion of the survey by excluding items that were scored zero pre-procedure, since improvement was impossible. The travel and socialization was the only QOL grouping that changed from statistically insignificant to significant after this modification. Thus by excluding 7 families that had no bother (scored zero) in this category, eleven families were included who reported pre-op bother with travel and child socialization. These patients and families that were anxious about and prevented from leaving the house due to bowel care were more likely to show improvement after the procedure. Other item groupings did show greater change with this additional analysis but did not reach significance.

Our most unexpected finding was the lack of change in the time devoted to bowel care. Prior to these results, we had been counseling families that bowel care with the ACE would require more time than their current medical management. Surprisingly, families were committing as much time to the diaper changes, rectal enemas and cleaning up stool incontinence before surgery as the time required for the ACE enema. Of the 45 min spent with the antegrade enema, only 10 min requires parent participation. For most children, the remaining toilet time is spent doing homework or playing video games.

Conclusions

Among patients with spina bifida and fecal incontinence who underwent the ACE procedure at our institution, a significant improvement in fecal incontinence and QoL scores was observed using a validated instrument, FICQOL. Without changing the amount of time necessary for bowel care, the ACE procedure decreases the families' worries and anxieties and allows them to leave home with the confidence that their child will not have leakage of stool.

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