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Peristeen integrated transanal irrigation system successfully treats faecal incontinence in children

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Abstract *Objective:* Faecal incontinence secondary to myelomeningocele, Hirschsprung disease, and anorectal anomalies remains a significant and common problem. We aimed to report our 5-year experience with the Peristeen trans-anal irrigation system (TAIS) to manage such children.

Patients and method: This study was a combination of a retrospective case note review and assessment using a validated quality of life questionnaire (QOL) to determine pre- and post-TAIS bowel function and continence. QOL scores and functional outcomes before and during TAIS use were compared using Wilcoxon matched pairs test ($p < 0.05$ significant).

Results: Twenty-four children (median age 6 years) were managed with the TAIS 2006–2011 to treat faecal incontinence. Three did not tolerate the system. Median QOL scores in 20 out of 21 patients using TAIS demonstrated significant improvement in bowel management and continence. Two discontinued use due to failure to improve continence; one underwent the Malone antegrade continence enema (MACE) procedure and one returned to oral/rectal medications. Nineteen of 24 patients (79%) continue to use TAIS.

Conclusions: The Peristeen TAIS is an effective, safe, non-operative alternative to MACE in children with faecal incontinence, if initial compliance can be achieved.

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Introduction

Faecal incontinence and constipation associated with myelomeningocele, anorectal malformation, and Hirschsprung disease are common, debilitating, and difficult to treat [1–3]. In the quest to achieve continence, oral and rectal medications have limited value in children with these conditions. The Malone Antegrade Continence Enema (MACE) has been used for over two decades, with measurable improvements in bowel function and quality of life. MACE requires surgery with an associated complication rate, particularly stomal stenosis [4–8]. There is often reluctance to commit to a surgical stoma in younger children (4–7 years), in whom compliance is unpredictable.

The Peristeen trans-anal irrigation system (TAIS) (Coloplast, Denmark) instils water or irrigation solution via a disposable balloon catheter to the colon and rectum. The instillate, along with the contents of the descending colon, sigmoid, and rectum, is then evacuated in a controlled manner [9]. We selected this system over simple rectal or conus irrigation because of the element of controlled evacuation that the system manufacturer claimed to provide. Our centre began offering this management regimen 5 years ago to families with children suffering from constipation and faecal incontinence who were responding poorly to medication. The carers (and child, if competent) are taught by a specialist nurse how to use the system. The volume and frequency of the instillations are decided on a case by case basis.

Small series of children using TAIS have been published and demonstrated improved continence but the impact on quality of life was not assessed [10,11]. We aimed to assess any change in bowel function and quality of life of the patients and their carers following introduction of TAIS, as well as overall compliance and complications.

Patients and methods

Since its introduction to our centre in 2006, we have offered the Peristeen TAIS to all patients with faecal incontinence who we would previously have considered for MACE. All patients/carers to whom TAIS was offered, agreed to trial its use. We retrospectively reviewed the case notes of all children who used TAIS over the next 5 years.

We also conducted an interview with each patient's primary carer using the validated Fecal Incontinence/Constipation Quality Of Life (FICQOL) questionnaire [12]. The questionnaire collected information on what bowel care regimen was in use and who administered it. Functional outcomes including stool frequency, frequency of incontinence, proportion of motions in toilet and necessity for pads to control incontinence of stool (distinct from necessity for urinary incontinence) were also obtained. The questionnaire also contained 19 scaled questions designed to measure the impact of the child's incontinence on their lives and the lives of their carer's. Analysis of the answers produced a numerical score which has been validated as an accurate indicator of QOL. As the patients had all started TAIS at different times, the duration of use at the time of interview varied from 2 months to 4 years. Interview

sessions were conducted during scheduled clinic visits, or by telephone if more convenient. During each interview the carer was asked to fill out the questionnaire twice: firstly to describe their child's incontinence before using TAIS, and secondly to describe it while using TAIS. QOL scores and functional outcomes before and during TAIS use were compared using Wilcoxon matched pairs test and $p \leq 0.05$ was considered significant.

Patients who had used the system for 2 months or less were not assessed for change in QOL, but were included in the study and functional outcomes were recorded.

Results

Twenty-four patients (13 male) were instructed in the use of TAIS. The goal in these patients (aged 4 years and over) was to achieve faecal continence.

Median age at commencement was 6 years (range 4–16 years). Primary diagnosis was neuropathic bowel (secondary to myelomeningocele and sacral agenesis) in 15, anorectal malformation in five (1 with additional spinal anomaly), and Hirschsprung disease in four. Eight of the children with neuropathy had reduced mobility, requiring either a wheelchair or walking aids.

Prior to starting TAIS, 4 of 24 (17%) children used oral medications only, 3 of 24 (13%) used rectal medication (suppositories and/or enemas) only, and 15 of 24 (63%) used both. Two (8%) children were reported as not using any regular medication; these children had used oral and rectal medications previously but had abandoned them due to poor results. Twenty-two of 24 children were regularly using pads.

Following the introduction of TAIS, Following the introduction of TAIS, median duration of follow-up was 1 year (range 2 months–4 years).

Three of 24 (13%) patients abandoned the system almost immediately: one child experienced a burst balloon on his second use of the catheter and was fearful of using it again, another complained of abdominal colic, and the third found the use of a transanal irrigation system embarrassing.

Twenty-one patients used the system for longer than 2 months, and 20 responded to the questionnaire (95% response rate). Median frequency of use was once every 2 days and median volume of instillate was 300 mL. The instillate was tap water in all cases, with additional phosphate in two. Two patients discontinued use due to failure of the washouts to improve continence, one patient subsequently underwent MACE, and one returned to combined oral and rectal medications. Nineteen of 24 patients (79%) continue to use TAIS at the time of writing. There were no adverse effects associated with the use of tap water.

Bowel function improved significantly in the 20 patients who completed the questionnaire (Table 1). The rate of absolute continence (i.e. no soiling reported at all) in the 21 patients who used TAIS for more than 2 months was 0 of 21 (0%) prior to commencement and 6 of 21 (28%) at the time of most recent follow-up.

Of the 19 patients still using TAIS, 1 of 19 (12%) was free of pads before starting the regimen. After starting TAIS, 5 of 19 (26%) children still used pads for fear of faecal and/or urinary incontinence, 5 of 19 (26%) children continued using

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