DIGITALCOMMONS @WAYNESTATE

Clinical Research in Practice: The Journal of Team Hippocrates

Volume 6 | Issue 2 Article 12

2020

Transanal irrigation is more beneficial in symptomatic management of neurogenic bowel disease than conservative bowel management

Chi-Lan Tran
Wayne State School of Medicine, gh0289@wayne.edu

Recommended Citation

TRAN C-L. Transanal irrigation is more beneficial in symptomatic management of neurogenic bowel disease than conservative bowel management. Clin. Res. Prac. Oct 16 2020;6(2):eP2276. https://doi.org/10.22237/crp/1593562320

Clinical Research in Practice
The Journal of Team Hippocrates
VOL 6 ISS 2 / eP2276 / OCTOBER 16, 2020
https://doi.org/10.22237/crp/1593562320

Transanal irrigation is more beneficial in symptomatic management of neurogenic bowel disease than conservative bowel management

CHI-LAN TRAN, Wayne State University School of Medicine, gh0289@wayne.edu

ABSTRACT A clinical decision report appraising Christensen P, Bazzocchi G, Coggrave M, et al. A Randomized, Controlled Trial of Transanal Irrigation Versus Conservative Bowel Management in Spinal Cord–Injured Patients. *Gastroenterology.* 2006;131(3):738-747. https://doi.org/10.1053/j.gastro.2006.06.004

Keywords: *constipation, neurogenic bowel disease, transanal irrigation*

Clinical Context

Joshua White (pseudonym) is a 28-year-old African American male with cerebral palsy (CP) characterized by global developmental delay (non-verbal), confinement to a wheelchair, and chronic constipation secondary to neurogenic bowel disease (NBD). He presented to the med-peds clinic with his father, who is his primary caregiver, for hospital follow-up.

Two months prior, Joshua was admitted due to severe colonic distension and abdominal pain. He had been admitted for the same reason multiple times this last year. During the most recent hospital admission, Joshua had not had a bowel movement (BM) in 5 days. Colonoscopy showed sigmoid volvulus and Joshua had bowel decompression performed. He was discharged on a bowel regimen consisting of senna, miralax, lactulose, docusate and milk of magnesia.

Today, Joshua's father noted that his son's BMs have returned to baseline frequency (once every 2 days). However, he stated that the many recent hospital visits due to exacerbations of Joshua's NBD have become taxing on the family. Joshua's father is a single father and balances his time between his day job and tending to his adult son. Additionally, he stated that it is difficult to keep up with his son's multiple medications lately. Joshua's father mentioned that he read online about transanal irrigation (TAI) and asked whether this would be a better treatment option for his son than the current conservative bowel management (CBM) he was on.

Clinical Question

Is transanal irrigation more beneficial in the symptomatic management of neurogenic bowel disease compared to conservative bowel management?

CHI-LAN TRAN *is a medical student at Wayne State University School of Medicine.*

ISSN: 2379-4550
http://digitalcommons.wayne.edu/crp

Clinical Research in Practice
The Journal of Team Hippocrates
VOL 6 ISS 2 / eP2276 / OCTOBER 16, 2020
https://doi.org/10.22237/crp/1593562320

Research Article

Christensen P, Bazzocchi G, Coggrave M, et al. A Randomized, Controlled Trial of Transanal Irrigation Versus Conservative Bowel Management in Spinal Cord–Injured Patients. *Gastroenterology.* 2006;131(3):738-747. https://doi.org/10.1053/j.gastro.2006.06.004.

Related Literature

A search of PubMed was performed using the terms “transanal irrigation” and “neurogenic bowel” in the title or abstract. This search returned forty-three results, eleven of which were deemed relevant to our focus: five review articles[1-5], one meta-analysis[6], and five human clinical trials.[7-11] Of note, two of the clinical trials were conducted by Christensen and his team. We focused on the clinical trials for the purpose of this search.

The paper by Kim et al. is a prospective study of patients in South Korea with NBD secondary to spinal cord injury (SCI).[7] It followed 52 patients treated with TAI over a 6-month period. However, due to low compliance rates with treatment (34%), there was insufficient data to determine whether TAI was beneficial for NBD patients. For this reason, this article was not selected.

The Del Popolo study is a multi-center Italian study following 32 NBD patients treated with Peristeen Anal irrigation for 3 weeks.[8] At the end of the study, there was a significant increase in patient’s quality of life score (P=0.001). However, due to small sample size this paper was not chosen.

The Faaborg study is prospective study that followed 211 patients with NBD from 1994 to 2007 to evaluate the efficacy of TAI as a treatment.[9] Treatment was deemed successful if patients were still on TAI by the end of the study, used TAI until they died or if their symptoms had resolved while using TAI. After a mean follow-up of 19 months, 46% of patients were “successfully treated”. Although this study was long-term and had a larger sample size, its definition for treatment success (eg. staying on treatment until death) was not as robust as other studies and therefore was not chosen.

The Christensen paper (2008) followed 62 patients with NBD who were treated with TAI for 10 weeks.[10] At the end of the study, severity of symptoms was significantly reduced compared to baseline value (Cleveland Clinic Constipation Scoring System [CCCSS]: -3.4; St. Mark’s Fecal Incontinence Grading System [FIGS]: -4.1; Neurogenic Bowel Dysfunction score [NBD]: -4.5; all $P < 0.0001$). This paper had much more robust measurements for determining patient outcome improvement. However, it did not compare outcomes between patients treated with TAI vs CBM, hence it was not selected.

Finally, the Christensen paper (2006) is a prospective, multi-center, randomized, controlled trial (RCT) following 87 patients with NBD secondary to SCI for 10 weeks.[11] Using similar endpoints to the other Christensen study (eg. CCCSS, FIGS and NBD), patients treated with TAI showed improved constipation, fecal incontinence and symptom-related quality of life compared to the CBM group. The study methodology of this paper was superior to previous studies as it had a large sample size, was an RCT, used robust endpoints to define treatment success and offered comparison between TAI vs CBM. The Grade of Recommendation for this body of Literature is B—lower quality studies with consistent findings.

Critical Appraisal

This is a prospective, randomized, controlled multicenter trial that meets Level 1 Evidence using the SORT criteria. The primary outcomes of the study were: 1) CCCSS score (range 0-30, 30 most severe) and 2) FIGS score (range 0-24, 24 most severe) between TAI and CBM groups after 10 weeks of treatment. Secondary end points included: 1) NBD score (range 0-47, 47 most severe) and 2) American Society Colon and Rectal Surgeons Fecal Incontinence score (a graded quality of life score).

The study recruited 87 patients with SCI and neurogenic colorectal dysfunction from 5 spinal cord injury centers across 5 European countries (Sweden, Italy, Germany, England and Denmark). Inclusion criteria consisted of patients 18 and older, at least 3 months out of a SCI and experiencing one or more of the following symptoms: spending 30+ min attempting to defecate each day, 1+ episodes of fecal incontinence a month, symptoms reflecting autonomic dysreflexia, or abdominal discomfort during defecation.

ISSN: 2379-4550
http://digitalcommons.wayne.edu/crp,

Clinical Research in Practice
The Journal of Team Hippocrates
VOL 6 ISS 2 / eP2276 / OCTOBER 16, 2020
https://doi.org/10.22237/crp/1593562320

Some exclusion criteria included: coexisting major unresolved physical problems, pregnancy or lactation, evidence of spinal shock, mental instability, treatment with >5mg/day of prednisolone or implant for sacral nerve stimulation.

Patients were first classified based on the spinal segment damaged. Next, each group was subdivided into complete or incomplete injuries. From there, patients were randomized into one of two treatment options: TAI (n=42) and BCM (n=45). The TAI group used the Peristeen Anal Irrigation system as treatment, while the BCM received best supportive bowel care without irrigation. Blinding was not possible due to the nature of both interventions. Both groups received training by a specialized nurse to ensure sufficient knowledge about their respective procedure.

At inclusion, baseline demographic data was balanced between the 2 groups including: age, sex, SCI etiology and severity of symptoms. However, despite randomization, the mobility status of patients was imbalanced between groups (TAI group was less immobilized).

Baseline values of both primary and secondary endpoints were obtained at inclusion, and repeated after 10 weeks. Patients were also contacted each week during the 10-week trial by an independent observer to complete a questionnaire regarding their symptoms, lifestyle and any adverse effects. Adverse events mainly included urinary tract infections (5.9% TAI, 15.5% CBM).

Throughout the trial, 4 patients were lost to follow-up in the TAI group, while 1 discontinued the experiment, leaving n=37 participants at termination. In the CBM group, 1 patient was lost to follow-up leaving n=44 participants. A total of 93% subjects completed the full trial: 88% in the TAI group and 98% in the CBM group.

Data was analyzed on an intention-to-treat basis. At termination of the study, the mean (SD) scores for the TAI vs CBM groups were: CCCSS: 10.3 (4.4) versus 13.2 (3.4) (P=0.0016), FIGS: 5.0 (4.6) versus 7.3 (4.0) (P= 0.015), NBD: 10.4 (6.8) versus 13.3 (6.4) (P=0.048). The TAI patients reported less severe constipation, fecal incontinence and NBD symptoms compared to CBM patients. TAI patients also reported improved quality of life and reduced time consumption on bowel management procedures.

When assessing limitations, a weakness of this study is the presence of bias. Firstly, since the nature of the 2 treatments would not allow for blinding, performance bias may have been present. Patients receiving TAI may have reported greater improvement of symptoms, knowing they were receiving a more novel treatment. Next, an unequal loss of participants between the TAI and CBM groups may have led to attrition bias, affecting the balance of confounders between the groups. Finally, despite randomization, there was an imbalance in mobility status between treatment groups. Since the CBM group was more immobilized at baseline, this may have affected several endpoints in the study, including quality of life scores. Finally, long-term follow up data is still needed to confirm the results of the study, as it only followed patients for 10 weeks. This includes the emergence of possible adverse effects, long-term safety of the procedures and long-term efficacy of the treatments.

In terms of applying these results to the case of my patient in particular is that the patients in the Christensen paper had NBD secondary to SCI, whereas Mr. White has NBD secondary to CP. However, as there were no papers studying NBD in CP patients, this paper was deemed the most appropriate available. Additionally, the mean age of patients in the CBM and TAI groups were 50.6 and 47.5 respectively. As Joshua is 28 years old, this study may not be entirely applicable.

Clinical Application

Joshua White is a patient with frequent NBD exacerbations secondary to CP. His father was curious whether TAI would be a more effective treatment option for him compared to CBM. The Christensen et al. paper concluded that compared to CBM, TAI improved constipation, fecal incontinence and quality of life in patients with NBD. It also demonstrated that TAI is a relatively safe procedure with mild, transient side effects (i.e. UTIs).

When applying this conclusion to Joshua White, the external validity of the Christensen article is limited, due to the etiology of Joshua's NBD (due to CP) and his age (28). The internal validity of the article, however, is robust, as TAI patients scored better than CBM patients in all endpoints of the study.

When considering the social determinants at play, there are many issues this paper failed to address. Firstly, TAI may not be feasible option in Joshua's case. As Joshua is non-verbal and wheelchair-bound, it is unlikely that he

ISSN: 2379-4550

Clinical Research in Practice
The Journal of Team Hippocrates
VOL 6 ISS 2 / eP2276 / OCTOBER 16, 2020
https://doi.org/10.22237/crp/1593562320

would be able to administer his own irrigations. Considering that Joshua's father works and is his son's only caregiver, he may not always be available to assist Joshua with his irrigations. Next, there is the issue of affordability. The Christensen study was performed in Europe, where insurance policies may differ when it comes to the cost and coverage of TAI. Considering that Joshua is American and his father is the family's sole income provider, CBM may be a better option for our patient at this time as it may be cheaper. However, long-term reduction in health care costs due to better management of NBD with fewer complications may reduce copays for hospitalizations and office visits, so coverage of TAI supplies and copays may need to be considered by Joshua's father over time, as these are often difficult to predict even with insurance.[12] Finally, there is the issue of long-term effectiveness. The family's primary concern was finding a treatment option that would decrease the frequency of Joshua's NBD exacerbations, though, so social work was contacted to make a plan to bridge Joshua from CBM to TAI in a couple of months. Additionally, our physicians looked into scheduling a specialist nurse to visit and train them on TAI and develop a schedule that accommodated Joshua's father's work schedule to give Joshua his irrigations.

New Knowledge Related to Clinical Decision Science

It is crucial when treating a patient to consider their social determinants of care before suggesting a treatment plan. In Joshua's case, although the literature suggests TAI can lead to improvement of symptoms, multiple barriers to accessibility deterred Joshua's physicians from choosing this option immediately. To implement this information in clinical decision making for Joshua, it was decided that he would stay on CBM for the time being, with the goal of starting him on TAI in a couple months. This required contributions from social work, development of an irrigation schedule, and training. While the evidence supported this change in treatment to better support our patient's and his father's goals, the application of this treatment was not as straightforward as something like simply changing one pill prescription for another. Ultimately, it is a physician's duty to work around a patient's socioeconomic constraints and develop a treatment plan that aligns with both scientific guidelines and the individual's situation.

The framework of Clinical Decision Science would highlight how enthusiastic both the doctor and the caregiver are in pursuing a treatment with Grade B Recommendation for quality of evidence. Will the caregiver try it and give up easily or try multiple times if it proves to be difficult? This may depend on how the doctor presents the evidence—an example of the placebo response used in a clinical decision.

References

1. Emmanuel A. Neurogenic bowel dysfunction. *F1000Research.* 2019;8:1800. https://doi.org/10.12688/f1000research.20529.1.
2. Wilson M. A review of transanal irrigation in adults. *British Journal of Nursing.* 2017;26(15):846-856. https://doi.org/10.12968/bjon.2017.26.15.846.
3. Gor RA, Katorski JR, Elliott SP. Medical and surgical management of neurogenic bowel. *Current Opinion in Urology.* 2016;26(4):369-375. https://doi.org/10.1097/mou.0000000000000299.
4. Christensen P, Krogh K. Transanal irrigation for disordered defecation: A systematic review. *Scandinavian Journal of Gastroenterology*. 2010;45(5):517-527. https://doi.org/10.3109/00365520903583855.
5. Emmanuel A. Review of the efficacy and safety of transanal irrigation for neurogenic bowel dysfunction. *Spinal Cord.* 2010;48(9):664-673. https://doi.org/10.1038/sc.2010.5.
6. Coggrave M, Norton C, Cody JD. Management of faecal incontinence and constipation in adults with central neurological diseases. *Cochrane Database Syst Rev.* 2014;(1):CD002115. https://doi.org/10.1002/14651858.cd002115.pub5.
7. Kim HR, Lee BS, Lee JE, Shin HI. Application of transanal irrigation for patients with spinal cord injury in South Korea: a 6-month follow-up study. *Spinal Cord.* 2013;51(5):389-394. https://doi.org/10.1038/sc.2012.171
8. Del Popolo G, Mosiello G, Pilati C, et al. Treatment of neurogenic bowel dysfunction using transanal irrigation: a multicenter Italian study. *Spinal Cord*. 2008;46(7):517-522. https://doi.org/10.1038/sj.sc.3102167.
9. Faaborg PM, Christensen P, Kvitsau B, Buntzen S, Laurberg S, Krogh K. Long-term outcome and safety of transanal colonic irrigation for neurogenic bowel dysfunction. *Spinal Cord*. 2008;47(7):545-549. https://doi.org/10.1038/sc.2008.159.
10. Christensen P, Bazzocchi G, Coggrave M, et al. Outcome Of Transanal Irrigation For Bowel Dysfunction 1N Patients With Spinal Cord Injury. *The Journal of Spinal Cord Medicine*. 2008;31(5):560-567. https://doi.org/10.1080/10790268.2008.11754571.

ISSN: 2379-4550
http://digitalcommons.wayne.edu/crp,

Clinical Research in Practice
The Journal of Team Hippocrates
VOL 6 ISS 2 / eP2276 / OCTOBER 16, 2020
https://doi.org/10.22237/crp/1593562320

11. Christensen P, Bazzocchi G, Coggrave M, et al. A Randomized, Controlled Trial of Transanal Irrigation Versus Conservative Bowel Management in Spinal Cord–Injured Patients. *Gastroenterology*. 2006;131(3):738-747. https://doi.org/10.1053/j.gastro.2006.06.004
12. Emmanuel A, Kumar G, Christensen P, Mealing S, Størling ZM, Andersen F, and Kirshblum S. Long-Term Cost-Effectiveness of Transanal Irrigation in Patients with Neurogenic Bowel Dysfunction. *PLoS One*. 2016;11(8):e0159394. https://doi.org/10.1371/journal.pone.0159394

ISSN: 2379-4550
http://digitalcommons.wayne.edu/crp