

Introduction

As the Excellence in Continence Care guidance from the NHS notes, constipation and faecal incontinence cause avoidable consumption of healthcare resources, as well as being associated with severe distress to affected patients – both physical and mental.

Relieving those symptoms can be transformatory for sufferers, whether they have a functional gut disorder, neurogenic bowel dysfunction or suffer from a childhood condition.

Transanal irrigation is a technique that is increasingly used in these patient groups, with several studies documenting efficacy over standard bowel care. Patients' comments include: "Using irrigation has changed my daily life"; "I was more or less housebound previously. Now I have my social life back".

The National Institute for Health and Care Excellence (NICE) has objectively evaluated the beneficial contribution of transanal irrigation – specifically when implemented through Coloplast's Peristeen system – and published its recommendations in NICE guidance MTG36.

This brief document summarises some of the key points from MTG36 and offers other evidential points around the benefits and cost-effectiveness of implementing transanal irrigation with Peristeen.

"Many hospitals have now created, or are developing, dedicated bowel management pathways based on NICE guidance, and are already experiencing the resulting improved patient outcomes. This document is aimed at all clinicians, specialist care professionals, general practitioners and commissioners to help understand the rationale and positioning of this therapy that can have a profoundly positive effect on people's health, quality of life, dignity and requirement for healthcare."

Professor Anton Emmanuel, Neurogastroenterology, University College London Hospital and National Hospital for Neurology & Neurosurgery

The MTG36 guidance on transanal irrigation is a landmark for the evidence base for good - and more widespread - practice in this important area of bowel management. It validates the work we have been doing for some years in building a service here at Kings. There is a really significant and often unrecognised burden here, for the quality of life of patients, but also the effects on avoidable A&E attendances and length of stay in hospital. Knowing from our work that the effect of these therapies for patients can be life-transforming, I would encourage all Trusts to review their local data in light of this documentation and other key guidance on incontinence and constipation management.

Dr Bu'Hussain Hayee FRCP PhD, Clinical Lead for Gastroenterology, King's College Hospital NHS Foundation Trust, and Reader in Gastroenterology, King's College London

"It is important that clear guidance documentation is available in the cause of promoting every aspect of good bladder and bowel health. For too long, patients have not been sufficiently supported in managing this taboo subject, but this is changing. The increasing awareness of transformatory clinical practice and patient experiences, along with the rising tide of good practice guidance, is to be welcomed. The result should be that patients have access and choice to ensure the therapies they receive are the most appropriate and tailored to each individual's needs."

Angie Rantell, Lead Nurse Urogynaecology / Nurse Cystoscopist, Kings College Hospital NHS Foundation Trust

"I've lived with a high-level spinal cord injury for over 20 years and was accustomed to alternate night visits from DNs to assist with bowel and bladder care. From 2010 I wanted more flexibility in my life at a time when their service was growing increasingly stretched and under resourced. With growing uncertainty as to when they would turn up, if at all, I was at greater risk of complications occurring. Delegating healthcare tasks to my PAs has given me more time to live the lifestyle I always envisaged; contributing back to society; freely socialising with friends and family. The irrigation system I've switched to has improved my health with better results, less pain and more energy. I now have the time to do what I want, when I want, rather than waiting hours upon hours for nurses to get to me whenever they could. I've dropped from nearly 200 visits a year to 6, so nurses have more time to spend with other patients and it saves the NHS money too. It's a win-win all round in my opinion."

Rob Moriarty, Patient

The Peristeen system gives me security, assistance & quality of life in clearing my bowel on a daily basis. Self-worth, dignity and respect are high on the agenda for people with faecal incontinence. A great deal of patients suffer with depression, anxiety and isolation. Every person needs a good quality of life. Peristeen allows us who want to work part/full time, pay our bills, socialise and be part of the wider community. Are we not worthy of this?

Tara Willson, Patient

Questions & Answers

Question

Answer

1 What is Transanal Irrigation (TAI)?

Transanal Irrigation is a constipation and faecal incontinence therapy that is clinically effective. As NICE MTG36 observes, "The case for adopting Peristeen for transanal irrigation in people with bowel dysfunction is supported by the evidence."

The Guidance continues, "If bowel continence cannot be achieved by medication, changes to diet and physiotherapy and long-term management, strategies such as transanal irrigation should be considered."

Transanal irrigation is distinct from an enema, colonic irrigation or flush. There are a variety of low-volume and/or variable flow flush products on the market, which do not provide a constant regulated pressure to avoid over pressurisation of the bowel.

The Peristeen balloon catheter transanal irrigation product involves pumping water under constant pressure into the colon, stimulating a reflex bowel contraction and voiding of colonic content¹.

This significantly reduces the daily inconvenience and anxiety of frequent, urgent and uncontrolled bowel motions².

What impact does transanal irrigation (TAI) have for patients?

Transanal irrigation can transform people's lives.

NICE MTG36 notes that "Peristeen can reduce the severity of constipation and incontinence, improve quality of life and promote dignity and independence."

The clinical and patient experts included in the evidence review explained that "for people with bowel dysfunction, even small improvements in these patient-reported outcome measures can translate into significant quality-of-life benefits and could mean the difference between adequate bowel control and incontinence. The committee concluded that the evidence with which it had been presented may underestimate the quality-of-life benefits of Peristeen."

The review reported "highly positive comments from parents and carers, who stated that transanal irrigation had significantly improved their child's quality of life."

Overall, the patient experts emphasised that "using Peristeen has vastly improved their lives, allowing them a degree of functional independence (such as going on holiday and maintaining a permanent job) that was not possible with the standard bowel care they had previously received."

Question

(TAI) have on the NHS?

3

What impact does transanal irrigation

Answer

The benefits of transanal irrigation are currently under-represented in the NHS, according to MTG36. It advises that more attention should be paid to TAI in the NHS, noting, "There is a need for improved awareness of transanal irrigation in the NHS as a treatment option for bowel dysfunction."

In terms of the scale of the issues that transanal irrigation helps to treat, NHS evidence records that one in every ten adults is affected by faecal incontinence. Untracked side effects may amplify the true cost of bowel problems: for instance, 38% of patients experience depression. As for the cost of constipation, the impact is significant. Further NHS evidence shows that constipation unplanned A&E visits cost the NHS £794 million³ in a single year (equivalent to an average £3.8 million per CCG per year).

Systemic benefits cited in the evidence considered in the NICE Guidance reveals a 40%+ drop⁴ in hospitalisation rates, a 60%+ drop⁵ in GP visits and a 35% reduction⁶ in the need for stoma surgeries.

As far as clinical efficacy is concerned, the evidence considered by the NICE external assessment centre (EAC) reports a 22-30% reduction in adverse symptoms (faecal incontinence or constipation), an 80%+ reduction in faecal incontinence incidents, and a 55% therapy continuation rate fafter 40 months. In addition, urinary tract infections have been seen to more than halve in these same studies in Importantly for commissioners, NICE MTG36 is clear that the use of Peristeen is at least cost-neutral, and may deliver a saving, while delivering important patient outcomes. It says specifically that, "It is likely that Peristeen provides additional clinical benefits without costing more than standard bowel care."

4 What is the evidence of effectiveness for transanal irrigation (TAI)?

The evidence for Peristeen assessed by the external assessment centre (EAC), "comprised 13 studies in adults and 11 studies in children, plus 2 studies and 1 audit that were included specifically to provide information on adverse events."

At **Aintree University Hospital**, following the successful use of Peristeen and increased referrals to the service, general practitioners who are responsible for ongoing prescription of the systems are becoming aware of the costs. Aintree have found that explaining the benefits to GPs of the systems and the potential for cost savings through reduced appointments and ongoing costs of someone who has had a stoma created has helped overcome these apprehensions.

5 Who reviews and/or implements MTG36, what resources do we need to commit, and which patient populations are appropriate? As with all NICE recommendations, "Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it¹¹."

NICE MTG36 offers pathways¹² for the implementation of faecal incontinence management and constipation management on the Guidance website, at www.nice.org.uk/guidance/mtg36

There are several patient populations who are appropriate.

General bowel management. **Manchester University NHS Foundation Trust** provides a nurse led bowel clinic. This clinic provides care for

Question Answer

patients with a variety of bowel complaints, including chronic constipation and faecal incontinence in line with relevant evidence based guidance including the NICE guideline on faecal incontinence. The clinic has implemented MTG36. The team were keen to use Peristeen because it is a UK prescribed medical device with published evidence with a RCT to support its use. Patients said the Peristeen system was easier to use, it has a small air filled balloon to hold the catheter in place, a pump to insert the water and had a much softer flexible catheter. Use of Peristeen has resulted in major reductions in other therapies, and use of a medications. Patients talk of "getting their life back."

Functional bowel disorders. **Aintree University Hospital's** dedicated healthy bowel clinic offers care for people with functional bowel problems. In 2009 the team adopted Peristeen within a bowel care pathway to treat 3 main functional disorders; slow-transit constipation, faecal incontinence and obstructed defecation syndrome. A pilot pathway was established. Treatment includes transanal irrigation. So far, the new pathway has saved 231 bed days and cut costs by an estimated £92,400. Any objections from general practitioners about the cost of this therapy are reassured by Aintree with an explanation of the benefits and the potential cost savings. Patient comments include: "It has changed my life. I was more or less housebound previously. Now I have my social life back".

6 What level of support is needed to ensure success of transanal irrigation?

Transanal irrigation with Peristeen requires a trained professional to introduce and instruct the patient and their carer(s).

NICE MTG36 notes that, "People using Peristeen should have training from a specialist healthcare professional." The committee heard that most people will have 1 face-to-face appointment to learn how to use Peristeen, and then have further follow-up support in the community (usually over the phone). The experts noted that it takes most people a few months to get used to Peristeen. Even once someone is confident with using the device, they still need access to a professional support system (such as easily accessible contact details of a specialist nurse) to provide advice as needed." It should be noted that a collaborative approach between healthcare provider and supplier is likely to be the most successful.

Not all device providers offer this level of support, so it is imperative that clinicians and care professionals – not to mention CCGs – consider the total package of product and support that will be available to patients. Best practice services provide patient assessment, on-site or in-home training, proactive tele-support in the initial phase of use, and ongoing tele-support over time.

NICE MTG36 concludes that, "The device is most effective when offered with specialist training and structured patient support." Moreover, it is the overall cost package considered by NICE, the Guidance adding, "It is likely that using Peristeen in people with bowel dysfunction does not cost any more than standard care."

Question

guidance?

7 What policy compliance responsibilities are associated with the NICE MTG36

Answer

NICE MTG36 should be viewed in the context of broader guidance, particularly Excellence in Continence Care¹³ and Safer Bowel Care Safety Notice. This guidance is designed to assist commissioning discussions for those developing high quality community continence services. It states that, "The National Audit of Continence Care has found that many services were not providing services in line with NICE guidance..." Therefore, particular attention should be devoted to setting up protocols for early assessment, effective resourcing, population needs analysis, containment therapies, proactive patient presentation, and effective ongoing care delivery.

The guidance notes the interrelationship between faecal incontinence and urinary tract infections (UTIs), and also notes that, "Pathways of care should be commissioned that ensure early assessment, effective management of incontinence, along with other bladder and bowel problems such as constipation and urinary tract infections and their impact on social, physical and mental well-being and existing comorbidities."

To this end – improved bowel management may be viewed as contributing to the overall reduction in UTIs. As the Excellence in Continence Care guidance highlights, "Gram negative septicaemia is most commonly caused by UTIs and is considered to some extent to be preventable through good quality continence and medical care. NHS Improvement have mandated that all NHS Trusts have a strategy to reduce incidence by 10% in 2017 and by 50% in 2020."

8 Are other transanal irrigation devices available in the NHS?

Peristeen is the first and (to date) the only bowel management device to receive NICE Guidance. Moreover, Peristeen is the only device in the NICE pathways for Constipation, Faecal Incontinence and Children.

Nevertheless, other transanal irrigation products do exist. Not all are balloon devices like Peristeen, nor is any other offering the same level of extensive evidence as Peristeen which has been evaluated by the EAC and forms the basis of the NICE guidance MTG36.

Transanal irrigation with Peristeen results in an average of two days for new faeces to reach the rectum, helping users to remain continent between regular irrigations.

Overall, the NICE Guidance took a holistic approach observing that, "The clinical and patient experts explained that Peristeen should be offered as part of a supportive bowel care programme. People using Peristeen should have training from a specialist healthcare professional."

Footnotes

- 1. NHS England (2018), Excellence in Continence Care. Practical guidance for commissioners, and leaders... Available from: www.england.nhs.uk/wp-content/uploads/2018/07/excellence-in-continence-care.pdf
- 2. ibid
- NHS (2018), NHS HES data report. Available from digital.nhs.uk/data-and-information/data-tools-andservices/data-services/hospitalepisode-statistics
- Passananti V, Wilton A, Preziosi G, Storrie J.B and Emmanuel A (2016), Long-term efficacy and safety of transanal irrigation in multiple sclerosis. Neurogastroenterol Motil. Sep;28(9):1349-55.
- 5. Emmanuel A, et al. (2016), Long-Term Cost-Effectiveness of Transanal Irrigation in Patients with Neurogenic Bowel Dysfunction. PLoS ONE 11(8): e0159394. doi:10.1371/journal.pone.0159394.
- 6 ibio
- 7. Christensen P, et al. (2006), A randomized, controlled trial of transanal irrigation versus conservative bowel management in spinal cord-injured patients. Gastroenterology 131:738-747.
- 8. Passananti V, Wilton A, Preziosi G, Storrie J.B and Emmanuel A (2016), Long-term efficacy and safety of transanal irrigation in multiple sclerosis. Neurogastroenterol Motil, Sep;28(9):1349-55. *mean of 40 months follow-up.
- 9. ibid
- 10. ibid
- 11. NHS England (2018), TITLE Available from pathways.nice.org.uk/pathways/patient-experience-in-adult-nhs-services#content=view-info-catego-ry%3Aview-about-menu-responsibilities
- 12. See also, NHS England (2007), NICE CG49 Faecal incontinence in adults. Available from www.nice.org.uk/guidance/cg49
- 13. NHS England (2018), Excellence in Continence Care. Practical guidance for commissioners, and leaders. Available from: www.england.nhs.uk/wp-content/uploads/2018/07/excellence-in-continence-care.pdf

The NICE MTG 36 Guidance, Peristeen transanal irrigation system for managing bowel dysfunction, may be accessed at www.nice.org.uk/guidance/mtg36

