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A Pilot Study To Assess the Feasibility of Measuring the Prevalence of Slow Colon Transit or Evacuation Disorder in Palliative Care

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Abstract

Context: Constipation is prevalent in palliative care. Whilst numerous factors contribute to this problem, opioid analgesia remains the most quoted aetiology. However, in gastroenterology, constipation is classified as a problem of prolonged transit times of colonic contents, impaired function of the structures of defecation or both. Little work in palliative care has used these assessments.

Aims: The report aims to describe the feasibility of assessing the colon transit times and pelvic floor structures of constipated palliative care patients and to report the results of a pilot study of 10 people who underwent these investigations.

Methods: Colon transit times were measured with a combination of orally administered radio-opaque markers and a single plain radiograph of the abdomen at day 5. Anal manometry plus rectal balloon expulsion was used to assess the pelvic floor. The results of the investigations were used to allocate people to one of four constipation subcategories: 1). slow colonic transit; 2) evacuation disorders; 3) mixed disorder or 4) normal transit.

Results: Two people had slow transit only, 2 people had evacuation disorders only and 5 had both. Only person had neither problem. The investigations were well tolerated and took a small amount of people's time.

Conclusion: These pilot data strongly support the feasibility of undertaking comprehensive assessments of the colon and pelvic floor in palliative care patients with the results, although preliminary, highlighting the complexity of the problem of constipation. The results of this work underpin the need to progress to a much larger study.

Introduction

CONSTIPATION IS A SIGNIFICANT PROBLEM in palliative care and hospice. Observational studies report up to 60% of people at the time of admission to a palliative care unit are prescribed laxatives, with more than half of these receiving two or more laxatives simultaneously.¹ Despite the use of laxatives, many people continue to describe constipation symptoms and dissatisfaction with their symptom management.² The magnitude of the problem in palliative care is highlighted when the number of people prescribed laxatives in hospice/palliative care is compared with the overall population. Even in the 30% of people who experience some degree of functional constipation across their lifespan, only one in six of this group require laxatives.³

Gastroenterologists describe constipation as a physical problem of either the colon or supporting pelvic structures.⁴

Practise guidelines in gastroenterology recommend that these structures be assessed to best define the physical abnormality underlying difficult constipation symptoms. This requires at a minimum, measurement of colon transit time, anorectal manometry and rectal balloon expulsion.⁵ This approach has allowed identification of constipation subcategories including slow transit constipation, disordered defecation and normal transit constipation.⁶ The most important reason to identify the underlying problem is that this then allows the most appropriate interventions for the particular problem to be initiated which for many people, may influence their response to treatment.⁷

Adopting this same premise in hospice/palliative care makes sense given that the same structures of bowel function and defecation must be involved. However, it is likely that these structures become compromised by progressive disease processes and treatments. For example, there are numerous

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factors likely to reduce colon transit times in palliative care. Such factors include medications such as opioids or medications with anticholinergic effects, metabolic factors, reduced activity and reduced oral intake. Furthermore, there are other factors which potentially could affect the pelvic floor including myopathic and neuropathic processes. To date, very little attention has ever been paid to the possibility that changes in the pelvic floor could influence the constipation symptoms experienced by constipated people with palliative care needs. The only way to objectively explore this further is for palliative care/hospice clinicians to adopt the same approaches recommended by gastroenterologists to assess the colon and structures of defecation.

The aim of this pilot study is to describe the feasibility of adopting simple but validated approaches to measuring colon transit times, anal manometry and rectal balloon expulsion in a palliative care population and to report the results of these assessments in 10 participants, drawn from a specialist palliative care service, well enough and able to participate. The results of this pilot will be used to inform a much larger study.

Methods

Study population

This study was conducted in adults with constipation currently under the care of a specialist palliative care service. To be included, people had to be taking regular laxatives prescribed according to Australian clinical guidelines as summarised in table 1,⁸ an intact colon, rectum and anus; prognosis of at least 2 months in the opinion of the treating physician; and willingness to participate in the assessment processes to categorise constipation.

People were excluded if they had a poor performance status (Australian-modified Karnofsky performance status ≤ 40); had participated in a clinical study of a new laxative in the week prior to study entry; short-term constipation due to problems such hypercalcaemia or vinca alkylating agents; local conditions of the peri-anal area and rectum that would contribute to pain on defecation or conditions including faecal impaction, anal fissure, haemorrhoids, anal prolapse or rectocele >2 cm in size; thrombocytopenia of $<50,000$ platelets per microliter or neutropenia of $<2 \times 10^9/L$ or any other condition that would interfere with study procedures or assessments in the opinion of the investigators.

TABLE 1. MANAGEMENT OF CONSTIPATION ACCORDING TO AUSTRALIAN THERAPEUTIC GUIDELINES⁸

Self-reports of passing soft stool:
docusate + sennoside B 100 + 16 mg (=2 tablets) orally, once or twice daily.
If second agent needed
bisacodyl 10 mg (=2 tablets) orally, at night, increasing to a maximum of 10 mg twice daily.
+ / - bisacodyl 10 mg suppository rectally.
Self-reports of passing hard stool:
docusate + sennoside B 100 + 16 mg (=2 tablets) orally, once or twice daily
OR
macrogol 3350 1 to 3 sachets in 500 ml of water orally, taken over 2 hours daily

Study setting

This study was conducted at a regional tertiary palliative care unit with a referral base predominately of people with cancer.

Study investigations

After providing written informed consent, a series of investigations was organised. Colon transit times were measured with a single plain abdominal radiograph to track the progress of orally administered radio-opaque markers. The protocol adopted for this work involves the administration of a single capsule containing twenty four 4.5 mm markers followed by a plain radiograph on the 6th day after ingestion. More than 5 markers visible on a plain abdominal radiograph has been identified as diagnostic of slow colon transit times.⁹

Structures of defecation were assessed with anal manometry and rectal balloon expulsion. Anal manometry was performed at the bedside using a perinometer. This is a simple device that records average anal pressures.¹⁰ The average resting pressure predominantly reflects the internal anal sphincter. Squeeze pressure mostly reflects the external anal sphincter and puborectalis sling. Low or poorly sustained squeeze pressures implies weakness of the pelvic floor. As it is difficult with these simple devices to differentiate between compromised muscle integrity or impaired innervation or both, cough pressure was also collected. Measuring average anal pressure during coughing was undertaken to evaluate whether the rectoanal contractile reflex was intact.¹¹

Rectal balloon expulsion was included in the investigations. This is another test that provides a simple physiologic assessment of simulated defecation. A catheter is inserted into the rectum and the balloon of the catheter is inflated with 50 mls of fluid. Failure to expel the balloon in less than 60 seconds suggests a defecation disorder. Previous work suggests that the balloon expulsion test has a sensitivity of 88% and positive predictive value of 64% for diagnosing pelvic floor dysfunction. Furthermore, the specificity is 89%, with a negative predictive value of 97% for excluding pelvic floor dysfunction. This means that although the failure to expel a balloon strongly suggests disturbed defecation, a normal test does not exclude this possibility. Balloon expulsion should be interpreted along with other anorectal physiologic tests with a diagnosis of defecation disorder requiring at least 2 of the 4 parameters measured being abnormal.^{5,12}

These results were then used to identify if people had objective evidence of constipation diagnostic subcategories namely: 1). Slow colonic transit (slow transit); 2). Pelvic floor dysfunction (evacuation disorder); 3). Mixed disorder; or 4). Normal transit. These approaches were adopted specifically because they are: validated; have minimum patient burdens or risk even in hospice/palliative care patients; and the potential to help subcategorise constipation thereby potentially allowing better targeting of the most appropriate interventions.

Results

Of the 10 people who participated, all had a diagnosis of cancer underlying their referral to palliative care. The median age was 66 years (range 49–82) with just over half the group being men (n=6). All were taking regular laxatives and one half described long term bowel dysfunction. (Table 2) All but

TABLE 2. RESULTS OF 10 PARTICIPANTS

Patient	No of Markers visible on abdominal radiograph at six days (Normal transit <5/24 markers at 6 days)	Perinometer readings (mmH ₂ O)	Balloon expulsion	Interpretation	Self-reported as having a past history of bowel problems	Oral morphine equivalent (mg) (11)
1	0	Resting: Low Squeeze: Low Cough: Low	Unable	Evacuation Disorder	No	50 mg
2	18	Resting: Low Squeeze: Low Cough: Normal	Unable	Mixed	Yes	300 mg
3	17	Resting: Low Squeeze: Normal Cough: Normal	Unable	Mixed	No	440 mg
4	11	Resting: Normal Squeeze: High Cough: Normal	Unable	Mixed	Yes	30 mg
5	7	Resting: Low Squeeze: Low Cough: Low	Unable	Mixed	N/A	75 mg
6	12	Resting: Normal Squeeze: Normal Cough: Normal	Unable	Slow transit	Yes	24 mg
7	24	Resting: Normal Squeeze: Normal Cough: Normal	Unable	Slow transit	Yes	50 mg
8	21	Resting: Low Squeeze: Normal Cough: Normal	Unable	Mixed	N/A	0
9	3	Resting: Low Squeeze: Low Cough: Low	Unable	Evacuation disorder	N/A	75 mg
10	0	Resting: Normal Squeeze: Normal Cough: Normal	Unable	Normal transit	Yes	200 mg

N/A – not available

one was taking opioids with the oral morphine equivalent doses ranging from 24 mg to 440 mg.

Five people had both slow colonic transit and a defecation disorder. (Table 2) A further two people had defecation disorder only suggesting that 7/10 had some degree of pelvic floor dysfunction contributing to their constipation symptoms. Likewise 2 people had slow transit alone suggesting that 7/10 had an element of slow transit contributing to their constipation symptoms. None of the participants found the investigations intolerable. Rather one person noted that the investigations were minimal compared to the distress and discomfort his disturbed bowel problems had caused him over a long period of time.

Discussion

This pilot work strongly supports the need to more closely examine the problem of constipation in palliative care as it is suggested by this pilot that the problems experienced by people are the result of a variety of physical changes most

likely occurring as the result of multiple insults. This work offers a real possibility that in the future, it might be possible to align management of the problem to people's underlying physical disorders, acknowledging that the physical changes are most likely to be the result of numerous risk factors carried by palliative care patients.

Furthermore, the fact that half of the group had both slow transit and disordered defecation strongly supports the need for palliative care to consider just how complex constipation might be and attribute constipation to more than opioids. This observation is supported by two points. Firstly, 70% of the group displayed some degree of defecation difficulties, problems that have received little attention in palliative care. This is despite the fact that muscle weakness is acknowledged as an underlying reason for other problems in palliative care such as breathlessness. The hallmark of cachexia is muscle wasting and the muscles of the pelvic floor are unlikely to be spared. Secondly, slow transit alone was seen in two participants who were taking relatively low doses of opioids whilst the two participants with defecation disorders were taking

higher doses of opioids. This is contrary to what would be expected. Both these observations strongly support the need to continue this work.

At least half of this group described long term problems with constipation. It is not clear if this group self-selected to be involved in this work or if the presence of premonitory problems influences the severity of experiences people have in progressive illness. This is another area that requires further investigation.

The choice of investigations for this pilot work was based on both previous data which describes the use of these investigations whilst at the same considering the tolerability of such investigations in an inherently frail patient population. It is worth noting that there are a variety of different protocols for measuring colon transit times with oral capsules and plain radiographs, most of which require multiple capsule doses and repeat radiographs. However, all of these approaches are hindered by a lack of standardisation of the results. Regardless, the method adopted to progress this work further is accepted in clinical practise. This discussion must also be extended to the balloon expulsion test adopted for this work. So far, whilst recommended in the assessment of chronic constipation, the balloon expulsion test has not yet been standardised. Despite this, the balloon expulsion test is considered best practise when considered along with other tests of the pelvic floor as has been adopted for this work.

The investigations proved to be acceptable to the participants and feasible for a clinical service to perform in a sub-group of people well enough to tolerate them. For such people, the burden of ineffectively treated constipation may be far greater than the inconvenience of three brief and acceptable tests that help clinicians to target effective therapies.

In conclusion, this pilot strongly supports the need for and the feasibility of progressing to a much larger piece of research that will allow a greater exploration of a number of important issues that include: 1). Correlating the objectively documented physical changes with people's subjective experiences; 2) Enabling regression assessments of risk factors for constipation with objectively defined physical sub-groups to define which risk factors are most clinically relevant; 3). Defining the acceptability of the approach in a much larger cohort of palliative care patients; 4). To begin an exploration of whether the management of constipation is improved by identifying the underlying physical subgroup this person falls into.

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Author Disclosure Statement

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