WHICH BOWEL PREPARATION WORKS BEST?
A RANDOMISED CONTROL TRIAL

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Lack of prospective, adequately powered trials to identify if any one intervention can result in a consistently empty rectum (McNair, 2014).

Published literature compares a laxative to no intervention

No published studies comparing two different types of laxatives.

Variety of different laxatives used throughout Australia

Central West Cancer Care Centre (CWCCC) – Movicol + low gas diet
Probiotics

- The use of probiotics has been shown to reduce gas and bloating in IBS. (WHO, 2002)
- The homeostasis of gut microorganisms can be disturbed during radiation therapy to the GIT.
- Probiotic use during radiation may reduce intestinal inflammation (Timko, 2010)
- One study conducted using probiotics during prostate radiotherapy. Results showed a trend towards reduction in gas levels (Ki etal 2013).
Study design

- Single blinded randomised control trial compared two laxatives
  - Osmotic laxative (Movicol)
  - Bulking laxative (Metamucil) + probiotic
  - Both groups followed a standard low gas diet
- Study aims
  - To determine if a bulking laxative combined with a probiotic is more effective than an osmotic laxative at reducing rectal gas during radiation treatment
Objectives

- To determine if there is a difference in rectal gas between the two treatment arms
- To determine if there is a difference in treatment related toxicity between the two treatment arms
- To assess compliance to the low gas diet, laxatives and probiotic regimen
- Ethics was approved by the Greater Western Human Research Ethics Committee, project number HREC/15/GWAHS/120.
Inclusion criteria: Adult patients 50 years of age or older undergoing external beam radiotherapy (EBRT) to the intact prostate, using fiducial markers for position verification.

Exclusion criteria: Severe constipation, abdominal disease, history of extensive abdominal surgery, patients using digoxin or salicylates. Individuals whose primary language was other than English.

Study was conducted between June – December 2016
Data collection and analysis

- Rectal gas measured on a scale of 1-5 (1 no gas present – 5 gas occupying 100% of the rectum) (McNair, 2011)

- Self reported 3 day food and bowel habit diaries were completed at 4 time points.
  - Fibre and fluid intakes were calculated using Food Works Software.
  - Stool frequency and consistency were recorded using the Bristol Stool Chart 7 point scale
  - Compliance to laxataive, probiotic use and diet measured
• Patients were analysed according to the intention to treat principle.
• A priori effect size calculation was limited by the absence of published studies, previous studies compared use of a laxative to no intervention.
• Sample size for this study was calculated setting power at 80%, alpha (p-value) at 0.05. Ten patients per arm, would be sufficient to detect an effect size of 0.38 (small to medium effect size).
Results

- 29 patients screened and 17 consented to participate
  - 9 were recruited into the osmotic laxative arm
  - 8 into the Bulking laxative + probiotic arm
- 433 Cone Beam Computed Tomography (CBCT) scans were analysed
  - 180 scans analysed from the osmotic laxative arm
  - 253 scans analysed from the bulking laxative + probiotic arm
  - The difference between the number of scans per group trended towards significance (p=0.054)
Mean age of participants 74 yrs (±5)
35% (n=6) travelled for treatment
41% (n=7) lived away from home while receiving treatment
Compliance with laxative use
  – 86% (65/76 recordings) bulking laxative
  – 88% (94/107 recordings) osmotic laxative group.
Compliance with probiotic use
  – 68% (65/96 recordings)
Results

- 3 participants reported consuming gas forming foods, eggs (n=2), coffee intake greater than four cups per day (n=2), curry (n=1) and cruciferous vegetables (n=1)
- Fibre intakes were higher in the bulking laxative group 27.3g (± 6.9) compared to 19.8g (± 6.5) in the osmotic laxative group (p=0.036)
- Participants in the osmotic laxative group reported looser stools (Bristol Stool Type 5) on commencing the laxative (p=0.018)
- 1 patient from each group experienced diarrhoea in week 7 of tx
Participants in the bulking laxative group had a statistically significant higher proportion of scans which received a gas rating of three or above (43% versus 22% respectively, p<0.001)

Figure 1. Percentage of scans per treatment group based on rectal gas rating.
The odds of a higher (poorer) gas rating were increased for the bulking/probiotic group (OR = 3.20, 95% CI 1.77–5.78, p<0.001).

Average fibre intake was significantly higher in the bulking laxative group but not a contributing factor to the higher rectal gas levels (OR 1.001, 95% CI 0.92 – 1.09, p= 0.036).
Results

- The median (IQR) proportion of scans rated as gas fails was higher in the bulking laxative group 2.9% (11%) compared to the osmotic laxative group 1.5% (9%) (p=0.284).
- There was no differences between the groups in the median (IQR) number of rectum fails; bulking laxative group (IQR) 0.1% (5%), osmotic laxative group 0% (5%) (p=0.835)

Figure 2. Number of gas and rectum fails per participant.
This is the first study to compare common laxatives used in the Australian setting.

Osmotic laxative is more effective than a bulking laxative + a probiotic at achieving low rectal gas levels during treatment.

Higher fibre intakes not a contributing factor to increased gas levels.

The effect of an osmotic laxative drawing water into the bowel made stools looser resulting in an early and consistent bowel evacuation before treatment.

Use of the bulking laxative to stimulate peristalsis through increasing stool bulk is not effective at consistently emptying bowels before treatment.
Further Research

- Use of an objective measure to determine rectal volume
- Further explore the role of probiotics in this setting
- Determine the impact of stress on bowel habits due to travel and accommodation changes
- Determine the effect of long term use of Movicol on gut microbiota and the role that probiotics may play
- Increase understanding of the physiology behind gut functioning taking into consideration gut microbiota and how this influences rectal fullness and rectal gas levels
Thank You

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References

- Timko J. Probiotics as prevention of radiation–induced diarrhoea Journal of Radiotherapy in Practice 2010:9; 201–208