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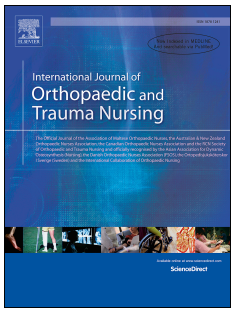

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Bowel management post major joint arthroplasty: a randomised controlled trial to test two pre-admission bowel regimens

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BACKGROUND

In 2009 a clinical audit based on the Practical Application of Clinical Evidence System (PACES) from the Joanna Briggs Institute (JBI) was undertaken at a large private hospital in Perth, Western Australia. The JBI is the world's largest provider of evidence-based guidelines for nurses and allied health professionals and based at the University of Adelaide, South Australia. The audit confirmed that opportunities for improvement existed in orthopaedic bowel management.

In response, the Murdoch Bowel Protocol® (MBP) (Figure 1) was developed using evidence-based guidelines from the JBI (2008), the World Gastroenterology Organisation (2007) and a 2005 systematic review (Ramkumar & Rao, 2005). The MBP is based on the titrated administration of an inert, non-absorbable, iso-osmotic solution of macrogol 3350 (polyethylene glycol) with electrolytes (sodium chloride, sodium bicarbonate and potassium chloride) and sold over the counter under various trade names including Macrogol, LaxaCon, Movicol, Lax-Sachets, Macrovic and Molaxol. The aperient is supplied as a powder which is mixed with water and the dose titrated to achieve a Bristol Stool Chart type 3-4 which reflects a soft, easily passed stool.

After successful implementation of the MBP across orthopaedic and neurosurgical wards at the study hospital, it was robustly evaluated in a cluster randomised controlled trial (RCT) across seven private hospitals in Victoria and Western Australia in 2011. The study confirmed both clinically and highly statistically significant results and saw uptake of the MBP in hospitals both nationally and internationally (Ross-Adjie, Monterosso, & Bulsara, 2014).

In recent years fast track surgical regimens (also known as enhanced recovery after surgery [ERAS]) were introduced with the aim of faster functional recovery and reduced post-operative length of stay (LOS) (Husted, Holm, & Jacobsen, 2008; van den Eeden, de Turck, & van den Eeden, 2017). Over the last two decades, orthopaedic technique standardisation and evidence-based fast track principles in combination with revised organisational factors

have seen a reduction in length of stay after major joint replacement without compromising patient safety (den Hartog, Mathijssen, & Vehmeijer, 2013; van den Eeden et al., 2017). Whilst ERAS guidelines are widely used in Western countries, their use is not universal with slow or incomplete uptake likely due to "the requirement for multidisciplinary collaboration and organisational factors that delay change" (Tan, Hunt, & Gwini, 2018). In addition, one of the original architects of ERAS guidelines recently reported that "in most of the surgical world, enhanced recovery principles remain either foreign or unimplemented" (Kehlet & Joshi, 2017, p. 2154).

Since 2011, length of stay at the study site has reduced from an average of seven to three days for a total knee replacement and from eight to three days for a total hip replacement (Ross-Adjie, 2018). This significant reduction in length of stay after major joint arthroplasty (MJA) and anecdotal reports of an increase in post-operative constipation in this cohort provided the justification for revision of the MBP.

One of the pillars of enhanced recovery is the minimal or non-use of opioid analgesia (den Hartog et al., 2013; Husted et al., 2008; van den Eeden et al., 2017). Opioid analgesia is a well-documented cause of post-operative constipation (Ross-Adjie et al., 2014) and while reduced opioid use may decrease the incidence of constipation in this cohort (Vendittoli et al., 2019), the most recent ERAS society guidelines on total hip and knee replacement do not make any recommendations around bowel management (Wainwright et al., 2020).

STUDY AIMS

Primary research question:

- which of two dosage regimens of macrogol commenced pre-operatively is most effective in facilitating a return to normal bowel function at one-week post MJA compared to the control group?

Secondary research question:

- is the pre-operative commencement of macrogol acceptable and feasible for patients.

STUDY DESIGN

A randomised controlled trial (RCT) of 91 patients undergoing MJA was conducted.

Inclusion criteria

- aged >18 years;
- booked to undergo MJA (total hip or total knee replacement);
- able to read and understand English; and
- able to provide informed consent to participate in the study.

Exclusion criteria

- unable to read and understand English;
- pregnant or breastfeeding;
- unable to give informed consent;
- history of ulcerative colitis, Crohn's disease, intestinal obstruction or perforation, toxic megacolon;
- known allergy to macrogol

METHOD

Sample and Setting

The study was undertaken on two 30-bed orthopaedic wards at a 520 bed private, tertiary teaching hospital in Perth, Western Australia. The hospital is a major centre for orthopaedic surgery and research with almost 2000 MJA procedures performed in 2019. Patient recruitment for the RCT was undertaken between December 2017 and April 2019.

A sample size calculation conducted by an independent biostatistician found a minimum of 29 experimental subjects and 29 control subjects were required to be able to reject the null hypothesis that the population means of the experimental and control groups are equal, with 80% probability (power). The Type I error probability associated with this test of the null hypothesis is 0.05. In total 91 patients were recruited: 31 into regimen 1; and 30 into both regimen 2 and the control group. While 14 months is an extended period to recruit 91

patients, 111 patients were actually recruited with 20 calling prior to surgery to decline participation for a variety of reasons detailed in Figure 2.

Intervention

When designing this study, much thought was given to the timing of the macrogol intervention. Prior success using the Murdoch Bowel Protocol® meant the researchers were reluctant to alter the inpatient macrogol regime leaving the pre-operative period the only opportunity to amend the protocol. Product information for macrogol states that the onset of action is usually 1-2 days (Movicol®, n.d., para, 6) hence the decision to test two pre-operative regimes against a control group:

Regimen 1: participants commenced macrogol one sachet in the morning for two days prior to hospital admission for MJA;

Regimen 2: participants commenced macrogol two sachets (one morning and one evening) on the day prior to hospital admission for MJA;

Control: no pre-operative bowel management.

Eligible MJA patients were identified by the surgeon's receptionist at their pre-surgery consultation and given a Patient Information and Consent Form (PICF) to read whilst waiting. Patients were able to discuss the proposed study with their surgeon and given time to have any questions answered prior to providing written consent if they agreed to participate. All patients who agreed to participate in the study received a copy of the PICF for their records and were given a sequentially numbered study envelope containing details of their allocated regimen at this appointment. Figure 2 shows the study flowchart for this study.

INSERT FIGURE 2 HERE

Patient randomisation into each regimen occurred via an online random number generator with the first 30 numbers allocated to regimen one; the second 31 numbers into regimen two; and the final 30 numbers allocated to the control group. Study envelopes contained two

sachets of macrogol (if randomised to an intervention group) and instructions for administration. Patients allocated to the control group received an envelope advising them that no specific bowel intervention was required prior to their surgery.

Due to the often extended period of time between consenting to surgery and the date of surgery itself, all patients were telephoned by a registered nurse (employed as a research assistant for this study) several days prior to their surgery and reminded to open their study envelope and follow the instructions. A master list with the patient name and their study envelope number was securely stored to enable study staff to identify which patients were included in the study and their group allocation. Ward nursing staff were blinded to which regimen each patient had been randomised to as macrogol commenced prior to hospital admission for those randomised to an intervention group. Once admitted to hospital, all participants continued to be administered macrogol titrated to achieve Bristol Stool Chart type 3 or 4 (considered normal). This in-hospital regimen follows the current Murdoch Bowel Protocol® and forms part of routine post-operative practice at the study hospital.

All participants were contacted by the study research assistant approximately one week after hospital discharge. Using a data collection tool, they were asked to provide information about whether they had followed their regimen instructions; their experience of starting macrogol pre-operatively and whether they had returned to normal bowel function at the time of the follow-up phone call.

Ethical Considerations

Ethical approval for this study was gained from the hospital's Human Research Ethics Committee. To preserve participant privacy, a coded master sheet was kept to enable participant identification and only staff directly associated with this study had access to this

master sheet. The data was stored on a password protected computer within a locked office at the study site which has high levels of electronic and physical security.

The study was funded by an AUD $4995 Research Incentive Grant. Macrogol sachets used in the study were provided free of charge by Norgine Pty Limited, a pharmaceutical company based in Sydney, Australia.

Data Analysis

Data was analysed on an intention-to-treat basis using IBM SPPS V24. The study population was described using descriptive statistics with parametric tests used for normally distributed data and non-parametric tests used for non-normally distributed data. Results were considered statistically significant at the 0.05 level.

RESULTS

The RCT participants (N = 91) ranged in age from 45 to 87 years (M 66.98; SD 9.40), with 51% females (n = 46) and 50% males (n = 45) recruited. Table 1 compares baseline variables by group and shows no statistically significant difference confirming all cases were drawn from the same sample population.

INSERT TABLE 1 HERE

Pre-operative results

Of the 91 study participants, 24% (n = 22) reported taking aperients on a regular basis at home prior to surgery. The most commonly taken aperients were macrogol, then psyllium, coloxyl and senna, fruit or fruit juices, senna, magnesium tablets or powder with bisacodyl tablets taken by only one participant. Three participants (14%) reported taking more than one aperient.

Of the 61 participants in one of the two intervention groups, 90% (n = 55) reported taking the macrogol before their surgery as per the regimen instructions. Of those who did not take macrogol as instructed, there were seven comments from six participants: three said they were concerned about getting diarrhoea so chose not to take it; two misread the instructions and whilst they did take the macrogol it was at the wrong time; one took the first sachet of macrogol but reported it caused diarrhoea so did not take the second sachet; and one participant experienced nausea and abdominal cramping after taking the first sachet so opted not to take the second sachet.

In-hospital results

A baseline Bristol Stool Chart (BSC) number was recorded for 84% of study participants (n = 76) with BSC number ranging from 1-6 (M 3.7; SD .878). Length of stay for total hip arthroplasty ranged from 2-8 days (M 3.28; SD 1.20) while LOS for total knee arthroplasty ranged from 1-6 days (M 3.29; SD 1.03) with an independent samples t-test finding no significant difference in length of stay between the groups (p = .863).

Whilst analgesia prescribed in hospital was recorded, it was not analysed for effect as it was often not given and doses varied between prescribers and patients meaning the results would not have been generalisable.

Post-discharge results

A Chi square analysis indicated no significant differences between intervention regimens and whether the participant had returned to normal bowel function one-week post discharge (p = .470). Seventy-seven percent of regimen one participants had returned to normal bowel function one-week post discharge; 83% of regimen two participants had returned to normal bowel function one-week post discharge; and 70% of control participants had returned to normal bowel function one-week post discharge.

Of the 22 patients who took aperients regularly prior to hospital admission, 19 (86%) reported taking aperients in the week after discharge. Only 32% of regimen one participants reported taking aperients in the week after discharge compared to 57% in regimen two and 60% in the control group (p = .060).

DISCUSSION

Pre-hospital results confirmed that of the aperients regularly taken by study participants, macrogol was most commonly used. Macrogol was well tolerated by the majority of intervention patients although only three of the five patients who usually took macrogol were allocated to an intervention group. Of the reasons cited for not taking the macrogol as instructed, only one participant reported diarrhoea after taking the first sachet of the aperient yet this is a reason commonly cited for avoiding it.

While 31participants were recruited into regimen 1 and 30 patients into regimen 2, each it was not until completion of the study when all participants had been followed up that we became aware that three participants had not taken the macrogol as directed. As statistical analysis was undertaken on an intention-to-treat basis, their data was still analysed and results included.

A baseline Bristol Stool Chart (BSC) number was recorded in only 84% of participants (n = 76) although a mean score of 3.7 indicates normal stool consistency. While the authors acknowledge that a baseline BSC should be recorded for all patients, as our participants recorded a mean baseline BSC of 3.7, we feel confident that had a BSC been recorded for all patients, it would remain between 3-4 i.e. a normal stool. Of note, while 50% (n = 15) of control participants reported having opened their bowels by day two post-operatively, 71% (n = 22) of patients in regimen 1 and 70% (n = 21) of patients regimen 2 had done so. By day 4 however, there was little difference between groups.

While there was no statistically significant difference between regimens and control on return to normal bowel function one-week post discharge, the result is considered clinically significant. Seventy-seven percent of participants randomised to regimen one had returned to normal bowel function at one-week post discharge; 83% of participants allocated to regimen two had returned to normal bowel function at one week post discharge and 70% of participants randomised to the control group had returned to normal bowel function at one week post discharge. Despite not reaching statistical significance, the opinion of senior orthopaedic nurses and managers, and orthopaedic surgeons operating at the hospital was that the difference was clinically significant. Ross-Adjie and colleagues (2014) found that days four to seven post-operatively were when most bowel habit change occurred between control and intervention groups hence the reason 'return to normal' was assessed at one week post discharge.

Post-operative analgesia prescribed to patients was collected as part of this study, however an in-depth analysis of use was not undertaken as while most patients were prescribed multiple types of analgesia, prescription did not equal administration. In total, 13 different analgesics were prescribed to our study cohort, with the most commonly administered analgesics being paracetamol (96.7%), buprenorphine patch (82.4%) and celecoxib (80.0%). Prescribing of analgesia is largely undertaken by anaesthetists at the study hospital and the large number of analgesics prescribed likely reflects prescriber preference. The combination of simple analgesia (paracetamol), a non-steroidal anti-inflammatory and judicious use of opiates is consistent with published best practice guidelines for multi-modal analgesia after MJA (O'Donnell & Dolan, 2018; Soffin & YaDeau, 2016) and the most up-to-date ERAS guidelines (Wainwright et al., 2020).

One participant who originally consented to participate in the study requested withdrawal due to a perceived adverse reaction to the first sachet of macrogol and was subsequently admitted to another hospital for investigation of suspected pulmonary embolus. While this episode was

reported to the hospitals ethics committee as a possible 'adverse event' in was not considered related to macrogol administration.

Limitations and Strengths

Whilst the study was conducted at a single private hospital, this site is a major provider of orthopaedic surgery conducting almost 2000 MJA surgeries in 2019. Patients were consented by one of three orthopaedic surgeons however they had no involvement in the study design, randomisation, implementation, outcome or reporting. Follow-up phone calls were not made exactly one week after discharge for all patients as some patients were discharged over the weekend. Were this the case, the follow up call was made as close as possible to one week after discharge.

The researchers acknowledge that while analgesia was recorded on the data collection sheet, its effect was not analysed due to the significant variation in administration. Some patients refused all but simple analgesia (paracetamol) while others received regular doses of paracetamol, a NSAID and buprenorphine patch. It is also acknowledged that the regular use of aperients prior to surgery reported by 24% of study participants was a confounding factor. While multivariate regression would generally be used to adjust for this confounding variable, the relatively small numbers in each group would likely call any results into question. Remembering to commence aperients prior to admission may prove problematic as it is dependent on the patient remembering to purchase the aperient and take it as directed.

The limitations to this study were balanced by considerable strengths. A randomised controlled trial, considered the gold standard to measure the effectiveness of a new intervention, was undertaken (Hariton & Locascio, 2018). In addition, the study was adequately powered with the sample size determined by an independent biostatistician. As the study intervention occurred prior to hospitalisation, nursing staff remained blinded to which

group participants had been randomly allocated to ensuring no in-hospital bias. Once in hospital, all patients received bowel management as per the current MBP.

In addition, the study was funded by a highly competitive university grant which are only awarded to studies which meet the high benchmark for significant rigor and scientific merit.

CONCLUSION AND RECOMMENDATIONS

Commencing macrogol prior to hospital admission for MJA has shown statistically and clinically significant outcomes. A higher proportion of intervention patients returned to normal bowel function one week after discharge and had a lower requirement for aperients in the week following discharge compared to the control group. Commencing aperients prior to surgery was found to be acceptable to the majority of patients with the perception that macrogol may lead to diarrhoea not substantiated.

Whilst there was no statistically significant difference between intervention regimens and the proportion of patients who had returned to normal bowel function one week after hospital discharge, there was a statistically significant reduction in the need for aperients post discharge for those randomised to regimen one. In view of this, we recommended that MJA patients self-administer macrogol one sachet in the morning on the two days prior to admission for MJA. Education around the importance of initiating aperients pre-operatively to help avoid post-operative constipation should be communicated to all MJA patients (in whom macrogol is not contraindicated) when other important pre-operative information is conveyed.

Whilst this study was adequately powered, replication using a larger sample size would be advantageous to confirm these results. Macrogol is an inexpensive ‘over-the-counter’ aperient in Australia with a wholesale cost of 23 cents per sachet. The authors acknowledge

that macrogol may be significantly more expensive in other countries and this may be a disincentive to administering it, or for patients to purchase it themselves (if required).

Reduced length of stay, minimal use of opioids, regional anaesthetic, and peripheral nerve blocks for suitable patients will likely see a reduction in those who experience severe bowel dysfunction after MJA. Whilst death as a result of severe constipation is uncommon, it is not rare (Sumida et al., 2019) and nurses need to remain vigilant to the risk of severe post-operative constipation and the significant risks it poses to MJA patients. Further qualitative research around the reasons patients choose to take (or not take) aperients would be of interest to orthopaedic nurses and help guide further aperient prescribing.

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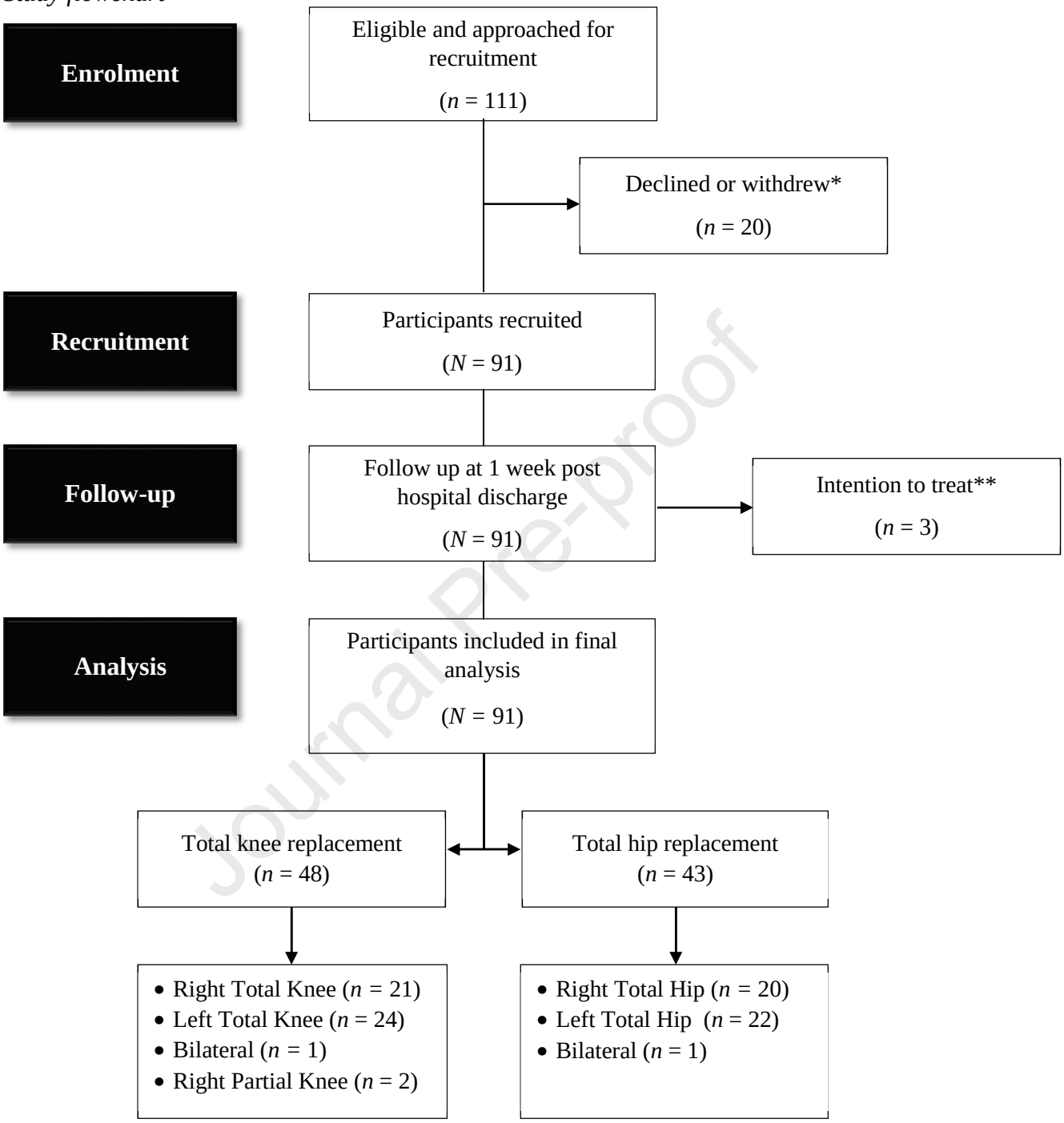
Table 1
Comparison of baseline variables by group

Variable	Control	Regimen 1	Regimen 2	
	n = 30	*n* = 31	*n* = 30	*p*
Age[+]	66.93 (9.69)	67.32 (8.88)	66.67 (9.92)	*.961*
Gender*				
Male	15 (50)	15 (48)	15 (50)	*.992*
Female	15 (50)	16 (52)	15 (50)	
Operation*				
THR	16 (53)	15 (48)	12 (40)	*.561*
TKR	14 (47)	16 (52)	18 (60)	
Length of stay[+]	3.17 (0.75)	3.52 (1.44)	3.17 (1.02)	*.440*
Baseline BSC[+]	3.67 (.96)	3.71 (.74)	3.83 (.95)	*.799*

Note. [+] *M* (*SD*), * *n* (%)

Figure 2.

Study flowchart



*Reasons cited with withdrawal: No reason given (*n* = 1); concerned macrogol would cause diarrhoea (*n* =3); history of inflammatory bowel disease, ulcerative colitis or Crohn's disease (*n* = 3); surgery cancelled or brought forward and RA not notified (*n* = 7); requested withdrawal due to other bowel related medical condition (*n* = 3); RA on leave at time of surgery and follow-up (*n* = 1); recruited in error – not for joint replacement (*n* = 1); requested withdrawal due to perceived adverse reaction to first sachet of macrogol (*n* = 1)

**Intention to treat: participants who did not take macrogol sachets as directed (*n*=2) took only one sachet; (*n*=1) took one sachet the night before surgery, and the second sachet the morning of surgery.

Murdoch Bowel Protocol© for use in total hip and total knee replacement patients only

DAYS 2 AND 3

BNO OR TYPE 1 OR 2 (CONSTIPATION)
- High fibre diet & increased fluids
- Encourage mobilisation as able
- Consider reducing constipation causing medications e.g. opioids
- Commence Macrogol (e.g. Movicol®, LaxaCon®) one sachet BD

TYPE 3 OR 4 (NORMAL STOOL)
- Diet, fluids and mobilisation as above
- Commence Macrogol one sachet daily

TYPE 5, 6 OR 7 (LOOSE STOOL OR DIARRHOEA)
- Diet, fluids and mobilisation as above

DAYS 4 AND 5

BNO OR TYPE 1 OR 2 (CONSTIPATION)
- Diet, fluids and mobilisation as per day 2
- Continue Macrogol one sachet BD
- Administer Microlax® enema

TYPE 3 OR 4 (NORMAL STOOL)
- Diet, fluids and mobilisation as above
- Continue Macrogol one sachet daily

TYPE 5, 6 OR 7 (LOOSE STOOL OR DIARRHOEA)
- Diet, fluids and mobilisation as above
- Cease Macrogol

DAYS 6 AND 7

BNO OR TYPE 1 OR 2 (CONSTIPATION)
- Diet, fluids and mobilisation as above
- Continue Macrogol one sachet BD
- Refer to Continence Nurse or other senior clinician for assessment

TYPE 3 OR 4 (NORMAL STOOL)
- Diet, fluids and mobilisation as above
- Continue Macrogol one sachet daily

TYPE 5 OR 6 (LOOSE STOOL)
- Diet, fluids and mobilisation as above
- Cease Macrogol

TYPE 7 (DIARRHOEA)
- Cease Macrogol
- Consult with continence nurse or other senior clinician to exclude impaction with overflow

Days 8, 9 AND 10

BNO OR TYPE 1 OR 2 (CONSTIPATION)
- Diet, fluids and mobilisation as per day 2
- Refer to Continence Nurse or other senior clinician for thorough bowel assessment

TYPE 3 OR 4 (NORMAL STOOL)
- Diet, fluids & mobilisation as above
- Cease Macrogol

TYPE 5, 6 OR 7 (LOOSE STOOL OR DIARRHOEA)
- Diet, fluids and mobilisation as above
- Cease Macrogol
- Refer to continence nurse or other senior clinician prior to discharge if necessary

BRISTOL STOOL CHART

TYPE 1
Separate hard lumps, like nuts (hard to pass)

TYPE 2
Sausage-shaped but lumpy

TYPE 3
Like a sausage but with cracks on the surface

TYPE 4
Like a sausage or snake, smooth and soft

TYPE 5
Soft blobs with clear-cut edges

TYPE 6
Fluffy pieces with ragged edges, a mushy stool

TYPE 7
Watery, no solid pieces. Entirely liquid

If patient has had past bowel surgery please contact the patient's treating doctor prior to commencing any laxatives

St John of God Health Care

Conflict of interest statement

None of the study authors have any financial or personal relationships with people or organisations that could inappropriately influence the results of this study. While macrogol sachets were provided free of charge from Norgine pharmaceuticals, Norgine were not involved with the design or outcome of any part of this study.

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Statement of ethical approval

The study was reviewed and approved by the St John of God Human Research Ethics Committee on 8 November 2017 (approval number 1288).