Research protocol-H09-01329 "Sennosides PEG study"

A RANDOMIZED DOUBLE-BLIND, DOUBLE-DUMMY, 2-TREATMENT, 2-PERIOD, CROSS-OVER COMPARISON OF SENNOSIDES AND POLYETHYLENE GLYCOL FOR CONSTIPATION IN OUTPATIENTS WITH CANCER

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Introduction

Among hospitalized patients with cancer, 70-100% of patients have been shown to have constipation[1-5]. As reported by Sykes[6], the prevalence of constipation is greater than 60 % in terminally ill cancer patients not receiving opioids, with the likelihood of constipation rising to at least 87 % when an opioid is used.

Constipation is a common problem which can generate considerable levels of suffering for patients, both from physical symptoms and psychological preoccupations that can arise[7,8]. There are many definitions of constipation in existence, with a general reference to infrequent, difficult or incomplete bowel evacuation; the stools can range from small, hard or "rock-like", to a large soft mass[9,7,10,8]. Cimprach[11] suggests that using a single parameter such as frequency of stool to assess constipation is too simplistic and that it is also important to include assessment of size, consistency and comfort of passage. According to Sykes[8], individuals vary in the weight they give to the different components making up their definition of constipation when assessing their own bowel function[12]. They may introduce factors such as flatulence, bloating or sense of incomplete evacuation. It must also be remembered that the process of defecation is person-specific so that individualised assessment and care is essential. Maestri-Banks and Burns define constipation as 'reduced frequency of bowel movements than is normal for the individual concerned, which may lead to pain and discomfort'. The basis of this definition is variation from an individual's known bowel habits and an associated difficulty with defecation. There are some problems associated with this in that patients may compare constipation with what they perceive to be normal rather than their own usual bowel habits[13].

Constipation can cause a variety of discomforts, e.g., abdominal pain, distension, anorexia, nausea, general malaise and overflow leakage in faecal impaction. Other symptoms such as headaches, halitosis and confusion have also been reported[7]. Patients with a terminal illness may also find that they experience feelings of restlessness and even experience delirium[14].

In addition, there are significant psychological and social consequences linked to constipation which may contribute to a reduction in an individual's quality of life. Constipation affects carers as well as patients. Carers may be unaware that the distressing symptoms exhibited are the result of constipation, or may experience embarrassment at becoming directly involved in such an intimate, personal issue, and in what is often considered 'dirty work'[15]. Patients may be reluctant to ask for assistance because of embarrassment.

Help and care for patients with constipation can consume considerable time and resources for health professionals. A UK-based study[16] found that 80% of community nurses could spend up to half a day each week treating constipation. Withell reported that 5.5%of calls to an out-of-hours district nursing service including non palliative care patients were directly related to constipation[17]. This figure may be an underrepresentation of the situation, as constipation was also identified during planned visits and other unplanned calls. These estimates are likely to be higher in palliative care settings where the patient population is at significantly higher risk of developing constipation

The causes of constipation may be classified into three categories:

1. Lifestyle-related or “primary” constipation - associated with low fibre diet; poor fluid intake and inactivity which bring about a reduction in abdominal muscle activity and stimulation[8]. A slowing of cognitive and physical activity in depression (irrespective of the constipating side effects of antidepressants) can contribute to primary constipation. Furthermore, a lack of privacy or environmental factors, or both, such as having to use a bedpan or a commode can also inhibit bowel function and predispose to constipation in already debilitated patients. Prevention and management of primary constipation usually includes increasing fluid and fibre intake; encouragement of physical activities and measures to improve privacy and positioning.

2. Disease-related or “secondary” constipation - arises from a pathologic condition and includes a variety of disease processes. Sykes[6] has described concurrent diseases attributable to constipation as: anal fissure; anterior mucosal prolapse; colitis; diabetes; diverticular disease; hypercalcaemia; haemorrhoids; hernia; hypokalaemia; hypothyroidism and rectocele.

3. Drug-induced constipation - there is a wide range of drugs that have constipation as a side effect. These include: opioids, anticholinergic drugs such as antiparkinsonian drugs; tricyclic antidepressants; antipsychotics; anticonvulsants, iron and calcium supplements, and antacids (calcium and aluminium compounds).

A small number of studies have investigated the relative effects of various types of laxative in the management of constipation, some in a palliative care setting. These laxatives include sennosides[18] and polyethylene glycol[19]. However, there have been no quality randomised comparative studies in cancer-related constipation, and collectively there is no available data to suggest that one treatment is superior to another. It has also been shown that laxatives for terminally ill patients are often ineffective, with many patients taking laxatives still complaining of constipation [20].

Sennosides and Polyethylene glycol (PEG) are laxatives which have been approved for the treatment of patients suffering from constipation. Both are available widely without prescription. There is no consensus on the ’best’ management of constipation in palliative care and wide variation in practice between palliative care settings.

Sennosides derivatives act mainly in the large intestine, directly stimulating the myenteric plexus and increasing water and electrolyte secretion, thus stimulating peristaltic activity. Their action extends over 6-12 hr. Side effects are described as abdominal pain, nausea, vomiting, and diarrhea. There is very limited evidence (but much clinical consensus) that sennosides are as effective as lactulose in the management of opioid-induced constipation,[21] but lactulose has an unpleasant ‘sickly-sweet’ taste, and generates intestinal gas leading to bloating, and sometimes explosive diarrhea.

(PEG) is a large polymer with substantial osmotic activity[21]. PEG is chemically inert and cannot be metabolized by colonic bacteria, thus ingested PEG is delivered unchanged to the colon. In the gastrointestinal tract PEG exerts its substantial osmotic activity, leading to modification of stool consistency and increased faecal bulk[22]. For some time, high dose PEG with electrolytes has been used widely in lavage solutions for gut cleansing before colonoscopy or bowel surgery. These solutions have been shown to be safe and effective. Electrolytes are added to the PEG solution to prevent their loss through the faeces due to the large volume of the lavage. However, this gives the lavage solution an unpleasant salty taste[23]. Recently, polyethylene glycol has been shown to provide short and long term benefit in patients with idiopathic constipation and faecal impaction[19, 24, 25-29]. Puxty[30] first used a balanced electrolyte solution containing polyethylene glycol (Golytely) to treat faecal impaction caused by constipation in the elderly. Since then, more studies have been carried out. PEG-based laxatives appear to be a promising treatment for chronic constipation and are increasingly being used as first line treatment.

PEG has become commonly used by cancer patients in the ambulatory setting, and the physicians at the Pain and Symptom Management clinics at the BCCA centres have now accumulated a wealth of very positive clinical experience with its use in cancer patients with opioid-induced constipation. We would like to be able to advise patients on the best choice of laxative to the best of our ability, and study of PEG for this patient group has become an urgent requirement. PEG has never been formally studied in palliative care patients and has never been compared to sennosides. The development of effective, evidence-based laxative guidelines for cancer patients requires us to address the deficiency of evidence on the various treatments available.

Aim: To compare the effectiveness and tolerability of polyethylene glycol vs. sennosides in treatment and prevention of opioid-induced constipation in outpatients with cancer.

Methods:

Setting:

Pain and Symptom Management/Palliative Care clinics at the BC Cancer Agency (BCCA) centres in Vancouver, Victoria, Fraser Valley, Kelowna and Abbotsford.

Study population:

Adult outpatients referred to the BCCA Pain and Symptom Management/Palliative Care Clinics with cancer and opioid-induced constipation.

Inclusion criteria:

1. Adult patient (18 years and above) with diagnosis of cancer.
2. Patient requires treatment or prevention of constipation.
3. Patient is able to communicate effectively with staff.
4. Expected prognosis more than 12 weeks.
5. On or starting opioid therapy.

Exclusion criteria:

1. Patient unable to take oral medication.
2. Allergy or previous intolerance to PEG or sennosides.
3. Lactose intolerant.
4. Contraindication to PEG or sennosides.
5. Known or suspected bowel obstruction or ileus.
6. Colostomy or ileostomy.
7. Inflammatory bowel disease.
8. Hospitalisation expected within the study period.
9. Inability to complete the patient diary in English.

Outcomes:

The study will include a primary outcome, several secondary outcomes and exploratory outcomes.

For each subject participating in the study, the primary outcome will be derived at the end of each study period based on the revised Victoria Bowel Performance Scale (BPS) [see appendix], which has been validated by the scale's authors and has been introduced by the BC Bowel Care Initiative to a variety of palliative care settings [31.32]. Specifically, for each of the two study periods, subjects will record their daily BPS score for days 1 through 21 of that period. The possible values of this daily score can range from –4 to +4. A daily BPS score between –1 and +1 (inclusive) will be interpreted to mean that the patient had a normal bowel movement on that day, with a score of 0 being considered ideal. In each of the two 21-day study periods the primary outcome will be defined as the number of days out of the last 18 days in that period when the subject had a BPS of -1, Goal, or +1. The primary outcome will thus be measured on a quantitative scale.

For each subject in the study, the secondary outcomes will be defined as follows:

1. The time - in days - to an ideal BPS score of G (patient's goal) at the end of Period I (when the patient was allocated to the first treatment in the sequence).

2. The treatment preference of that subject at the end of the study, recorded on a categorical (nominal) scale, whose possible values will be "Treatment A", "Treatment B" and "Neither Treatment". (The treatment allocation will be disclosed to the subject by their pharmacist at the end of the subject's participation in the study.)

3. Rectal measures and incidence of cramps, as measures of failure or "overshoot" of the laxative protocol.

In addition to the primary and secondary outcomes mentioned above, a number of exploratory outcomes will be recorded for each subject:

- Baseline characteristics (age, gender, primary cancer);
- Palliative Performance Status (PPS);
- Presence of history of irritable bowel syndrome (IBS);
- Use of opioids and any drugs which could contribute to constipation (e.g., anti-Parkinsonian drugs);
- Use of antidepressants;
- Use of antipsychotics,
- Use of anticonvulsants;
- Use of iron, calcium supplements and antacids;
- Bowel habit during the 4 weeks before enrolment in the study, described in terms of frequency of bowel movements, ease of passage, and stool consistency (the components of the BPS scale);
- Patient's goal bowel habit.

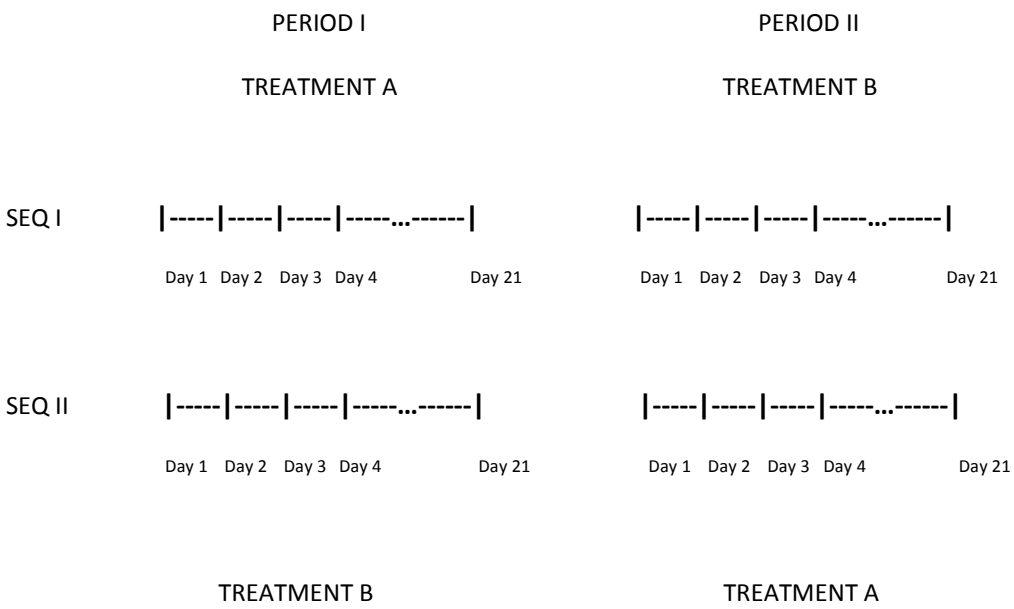
Study design:

A randomized, double blind, double-dummy, 2-treatment, 2-period, cross-over design will be employed in this study. A brief description of the design is provided below along with reasons for this particular choice of design.

The subjects recruited in the study will be randomly allocated to one of two sequences of treatments - AB and BA, where A denotes the polyethylene glycol plus placebo capsules and B denotes the sennosides plus placebo powder. An equal number of subjects will be allocated to each sequence of treatments.

The subjects allocated to the first sequence of treatments, AB, will spend the first three weeks of the study (i.e., Period I) on treatment A and then switch to treatment B for the last three weeks of the study (i.e., during Period II). The subjects allocated to the second sequence of treatments, BA, will spend the first three weeks of the study on treatment B and then switch to treatment A for the last three weeks. For each treatment sequence, the first 3 days of Period I will function as a wash-out period from any prior laxative

consumption, while the first 3 days of Period II will function as a wash-out period between the study treatments. A diagrammatic representation of the study design is provided below.



Both the subjects and the investigators involved in this study will be blinded to the assignment of subjects to a treatment sequence until study completion and data freeze. This will avoid situations where knowledge of the treatment assignment will affect subjects' responses or the investigators' assessment of the treatment effects.

The purpose of the crossover design is so that each subject acts as his/her own control, so the expected variety of patient demographic factors will not bias one study treatment over another. This will enable the study to include a more heterogeneous group of subjects (with different cancers, different stages of disease etc.) than would otherwise be needed to ensure that both treatment groups were comparable, thereby facilitating recruitment and decreasing sample size requirements. It will also provide benefit to subjects, as they will have an opportunity to try two different laxatives, and can use their experience during the study to guide their subsequent choice of laxative.

Statistical Methods:

The primary outcome will be treated as a binomial outcome, expressed as the number of successful trials out of a pre-defined number of trials n = 18. Given this, the primary outcome will be analysed via a generalized mixed effects model[37]. The model will include: (i) fixed effects for treatment, treatment period and their interaction, (ii) fixed effects for the baseline characteristics and (iii) a random patient effect. Including the latter effect in the model will help capture the within-patient correlation among the values of the primary outcome collected in Period I and Period II for the same patient. If the data provide no evidence in favour of a significant interaction between treatment and treatment period, the interaction between these two variables will be dropped from the model. In the reduced model, the effect of treatment will be constant across periods and will be expressed as an odds ratio, which will compare typical patients in the two treatment groups in terms of their odds of having a normal bowel movement on a day, assuming these patients share the same baseline characteristics. However, if the data provide evidence in favour of a significant interaction between treatment and treatment period, separate odds ratios will be reported for describing the effect of treatment in each period.

The time to an ideal BPS score at the end of Period I will be analyzed using median regression (also known as 0.5th quantile regression) [38]. This time will be evaluated from day 4 onward, since the first 3 days in Period I are considered to be part of the washout period. The median regression model will include a variable which keeps track of the treatment assigned to each patient in Period I and will also include baseline characteristics. The model will

aim to compare the median times to an ideal BPS score in Period I for patients assigned to Treatment A and Treatment B who share the same baseline characteristics.

The end of study treatment preference outcome will be analysed using multinomial logistic regression[39] with treatment sequence, treatment effect and baseline characteristics as potential explanatory factors. For each patient, the treatment effect will be computed in relation to the primary outcome and expressed as the difference between Period II and Period I in the number of days out of the last 18 of each of these periods when the patient had a BPS of -1, Goal or 1. The model will examine the relationship between each of these factors and patient preference for Treatment A, Treatment B or neither. Any reasons for treatment preference provided by the patients will be noted and described.

The secondary outcome referring to rectal measures is intended to document whether or not patients used a suppository, enema or other such aid on each of the study days in order to facilitate a successful bowel movement on that day. As such, the rectal measures outcome will be assessed separately in each study period and expressed as the number of days out of the last 18 in that period when the patient used a suppository, enema or other such aid to facilitate a successful bowel movement. Since the rectal outcome is similar in nature to the primary outcome, it will be treated as a binomial outcome and analyzed via a generalized mixed effects model similar to the one proposed for the primary outcome.

The secondary outcome referring to incidence of cramps will also be assessed separately in each of the study periods I and II and expressed as the number of days out of the last 18 in that period when the patient experienced cramps. The outcome will be treated as a binomial outcome and analyzed using a generalized mixed effects model similar to the ones proposed for the primary outcome and for the secondary outcome concerning rectal measures.
The above statistical analyses will be supplemented by appropriate descriptive statistics and graphical displays, which will be applicable to all outcomes considered in the study (including the exploratory ones) and to the baseline characteristics.

All statistical analyses will be conducted using the open-source statistical software package R[40].

Limitations:

The relatively small sample size of 64 patients precludes us from including a larger number of patient characteristics in our statistical models. In particular, if the final number of patients enrolled in the study is not adequate to support the inclusion of the baseline characteristics in the proposed statistical models, we will have to report treatment effects without adjustment for baseline characteristics.
In the event that some patients may have missing data values on any of their outcome or explanatory variables, the proposed modeling procedures may need to be adapted to account for the missing data.

Study drugs:

Polyethylene glycol (PEG) as powder to be mixed with juice by the patient, and sennosides as powder packed into capsules.

Treatment protocol:

Subjects will be started on polyethylene glycol or sennosides, plus the dummy alternate treatment, for 3 weeks, and then switched to the other treatment and dummy for another 3 weeks. Subjects will be instructed to titrate the dose to effect, and provided with a modified version of the BCCA Bowel Protocol[33] to assist them.

Randomization and allocation concealment:

- To be generated by statistician using a computerized random number generator.
- The randomization schedule will be given to the pharmacist who will dispense PEG + dummy capsules or sennosides capsules + dummy powder. At the 3-week visit (the end of the first treatment period) they will be dispensed the alternate treatment and placebo for the second period. The pharmacist will not disclose which of these treatments is active to either the patient or the study team until the end of the subject's participation.
- Subjects will be allocated consecutive study numbers by the pharmacy.
- The study drugs will be sealed in sequentially numbered identical containers according to allocation sequence.

Blinding process:

PEG is a tasteless powder and will be mixed with juice. The dummy powder (lactose) will be indistinguishable from the active product. The sennosides powder and dummy powder (lactose) will be placed in identical capsules and will be indistinguishable.

Data collection:

Data will be collected by a clinic physician or nurse at each of the baseline and 2 follow up visits. Data will include the baseline characteristics of the participants (age, gender, primary cancer), Palliative Performance Status (PPS), presence of history of irritable bowel syndrome (IBS), use of opioids and any drugs which could contribute to constipation, e.g. anti-Parkinsonian drugs; antidepressants; antipsychotics; anticonvulsants, iron, calcium supplements and antacids. The bowel habit during the 4 weeks before enrolment in the study will be described in terms of frequency of bowel movements, ease of passage, and stool consistency (the components of the BPS scale), and the patient's goal bowel habit identified. Subjects will complete a daily bowel movement diary for the duration of the study and be asked about their satisfaction with their bowel management. At the end of the subject's participation in the study their treatment allocation will be disclosed by the pharmacy, and their laxative preference will be documented.

Sample Size:

In what follows, we provide the calculation needed to determine the total sample size n required to ensure that a minimum difference in treatment effects of 2 days with normal bowel movements out of 18 is identified with 80% power at the 5% significance level when the within-subject standard deviation is assumed to be 3.54 days. Here, the within-subject standard deviation quantifies the expected variation among repeated measurements of the primary outcome variable on the same subject.

Our sample size calculation assumes that the wash-out period of 3 days between the two treatments is large enough to ensure that there is no carry over effect and no period effect. In addition, this calculation assumes the normality of the primary outcome data collected on each patient. However, this calculation relies heavily on the fact that the error distribution for a mean value is likely to be nearly normal, whatever the distribution of the individual values might be. The method described is therefore adequate for the purpose of planning the trial[34, 35].

To derive the sample size n, we use the formula provided by Hills and Armitage, 1979[34], but corrected as in Machin et al., 1997[36]:

$$n = \frac{\left(z_{\alpha/2} + z_{\beta}\right)^2 \cdot 2\sigma_w^2}{\Delta^2} + \frac{1}{2} z_{\alpha/2}^2$$

where $z_{\alpha/2}$ and z_{β} are critical values from a standard normal distribution, σ_w is the within-subject standard deviation and Δ is the minimum difference between the effects of the treatments A and B that we would like to detect with power $1-\beta$ at the significance level α. In the above, the formula correction refers to the addition of $\frac{1}{2} z_{\alpha/2}^2$ when determining the total sample size n for the purpose of improving the normal approximation underlying this determination.

According to the sample size formula provided above, the calculation of the total number of subjects to be included in the study relies on the specification of the quantities $z_{\alpha/2}$, z_{β}, Δ and σ_w.

When we set the significance level α to 0.05 (5%) and the power level $1-\beta$ to 0.80 (80%), we get $z_{\alpha/2} = 1.96$ and $z_{\beta} = 0.84$. Also, we take $\Delta = 2$.

The within-subject standard deviation σ_w can be calculated as $\frac{1}{\sqrt{2}}\sigma_d$, where σ_d represents the standard deviation of the change in the value of the primary outcome variable within the same patient. We identify a sensible value for σ_d by postulating a range r_d of plausible values for the change in the value of the primary outcome within the same patient and dividing this range by 4:

$$\sigma_d = \frac{r_d}{4}.$$

In this study, we anticipate that $r_d = 20$ (i.e., the change in the value of the primary outcome variable within the same patient is anticipated to range between –10 and +10; recall that the value of the primary outcome variable itself can range between 0 and 18). This yields $\sigma_d = \frac{r_d}{4} = \frac{20}{4} = 5$ and $\sigma_w = \frac{1}{\sqrt{2}}\sigma_d = \frac{1}{\sqrt{2}}5 = 3.54.$

Substituting the values $z_{\alpha/2} = 1.96$, $z_{\beta} = 0.84$, $\Delta = 2$ and $\sigma_w = 3.5$ in the above formula for the sample size yields:

$$n = \frac{\left(1.96 + 0.84\right)^2 \cdot 2 \cdot 3.54^2}{2^2} + \frac{1}{2}\left(1.96\right)^2 = 49.1.$$

This study will continue to enroll subjects until there are 40 evaluable subjects who have completed both treatment arms of the study. In summary, the total number of subjects to be included in this study is going to be based on achieving the end goal of 40 subjects completing both treatment arms. Half of these subjects will be randomly allocated to the sequence of treatments AB and the other half will be allocated to the sequence of treatments BA.

Duration of study and follow up:

The study will continue for 6 weeks. Subjects will be assessed in person at baseline, at 3 weeks and 6 weeks as outpatients. Each subject will be given a diary to record daily bowel performance and will be contacted periodically by phone to facilitate compliance with the study protocol.

Ethical considerations:

Ethical approval will be obtained from the BCCA ethics committee. The consent form will be signed by the patient or approved alternate. The consent form will be written in a clear, simple English language and translated for those not speaking English. The consent form will explain the reason for the study, what is supposed to be tested, why the subject has been selected, what exactly is required for participants, potential benefits and risks (side effects), right to decline or withdraw, who to contact if concerns. A copy of the consent form will be given to the patient.

Subjects will be able to think about participation for as long as they need. The maximum permissible period without defecation will be 3 days unless this is normal for an individual subject, after which an enema and or mechanical bowel evacuation will be prescribed. After the study the subjects will be advised of their treatment order and can choose their subsequent laxative based on their experience. Data will be kept in a password-protected computer system with access limited to the professional staff involved in research, with all identifying information removed.

Potential harms to patients:

As the dummy powder for both treatment periods will be lactose, subjects who are lactose intolerant will be excluded. If a subject was unaware that they were lactose intolerant it is possible that they could react adversely to the dummy. To avoid this, all subjects will be asked if they drink milk before recruitment. The quantity of lactose that subjects will consume as placebo will vary depending on how much laxative they require in each study period. Fifteen grams of lactose powder per day (step 2 on the protocol; expected to be the most commonly chosen level) would be approximately equivalent to 300ml of milk. The dose of lactose in the dummy senna capsules is much less.

As with use of any laxative, over-use could cause diarrhoea. Subjects will be instructed in the bowel protocol to stop their laxatives if diarrhoea occurs, and then to resume use at a lower dose.

Funding:

The study will be funded by private donations directed for Palliative Care research to the VCC Palliative Care Fund, held by the BC Cancer Foundation. Statistical support to analyse the data will be available through the Division of Palliative Care from the Department of Family Practice, as the study team includes a resident in the Division of Palliative Care and the Division purchases such support from the Department of Family Practice.

Budget:

Drug costs, including labour and supplies are:

PEG	$1140
Placebo PEG	$1140
Sennosides	$2955
Placebo sennosides	$2280

Total product costs: $7715
The PEG is to be donated by Pendopharm: the manufacturers of Lax-a-Day. The majority of the drug cost is for repackaging by Macdonalds Prescriptions, Vancouver.
$1312.50 has been spent on consultation for statistical advice due to lack of availability of BCCA or UBC statistician to assist with changes to address REB provisos. Data analysis is expected to be provided by UBC at no cost to the study.

Total interim study budget is therefore $9027.50

Pharmacy dispensing costs will be billed to the VCC Palliative Care Fund.

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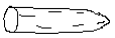
Appendix

Victoria Bowel Performance Scale (*revised)* (*r*BPS)

Downing, Hawley, Barwich, Black. BPS revised scale 2009. [© Victoria Hospice Society].

- 4	-3	- 2	- 1	BPS Score G	+ 1	+ 2	+ 3	+ 4
Constipation						Diarrhea		
Impacted or Obstructed ± small leakage 	Formed Hard with pellets 	Formed Hard 	Formed Solid 	**Characteristic** Formed Semi-solid 	Formed Soft 	Unformed Loose or paste-like 	Unformed Liquid ± mucus 	Unformed Liquid ± mucus 
No Stool produced after Goal plus 3 days	Goal plus 3 or more days delay	Goal plus 1-2 days delay	Pt's Goal frequency occurs	**Pattern** **Pt's Goal** for frequency	Pt's Goal frequency occurs	Goal or more frequent than goal	More frequent than goal	More frequent than goal
Unable to defecate despite maximal effort or straining	Major effort or straining required to defecate	Moderate effort or straining required to defecate	Minimal or no effort required to defecate	**Control** Minimal or no effort to defecate	Minimal or no effort required to control urgency	Mod. effort required to control urgency	Very difficult to control urgency & may be explosive	Incontinent or explosive - unable to control or unaware

1. **BPS is a 9-point scale. It is a** single score**, based on the overall** 'best vertical fit' **among the above three parameters [characteristics, pattern, & control] and is recorded for example as: BPS +1, BPS -3 or BPS G.**
2. **Look vertically down each BPS level to become familiar with how the three parameters of** characteristics, pattern & control **change in gradation from constipation to diarrhea.**
3. **For the bowel pattern, it is the patient's** goal **that is the determining factor. The goal is recorded in the centre section, marked with the patient's desired goal for how often they would prefer to have a bowel movement. Based on their goal, then the** actual frequency **is either within that goal, delayed beyond the goal, or more frequent than the goal. If the goal is met, the score is** BPS G**.**
4. **Patients may use different words than above to describe their bowel activity. One must use clinical judgment in deciding which boxes are most appropriate.**
5. **For patients with ostomies or short bowel syndrome,** all 3 parameters **should be assessed according to closeness to the patient's desired** goal**. In potential confounding cases, determination of the most appropriate BPS score is made using the following methods:**
6. **Two vertically similar parameters generally outweigh the third;**
7. **Single priority weighting among parameters is Characteristics > Pattern > Control**
8. **When recording BPS in hospital or facility patient charts where charting is required every shift or daily, a** BPS 'X' **is used to indicate no bowel assessment was done in that timeframe. Otherwise, the actual BPS number is recorded.** Do not write "0" **as it is misleading; the correct recording would be** BPS X**.**
9. **The BPS cannot be applied when there is no expected functioning bowel, as may occur with patients on TPN, or if imminently dying with no oral intake. If this is the case, the correct recording is** BPS N/A.