PROTOCOL NUMBER: N/A

TITLE: Effect of prunes on gastrointestinal function after gynecological surgery: A randomized controlled trial

STUDY ARMS: Standard care (Docusate alone) vs. Standard care plus prunes

PRINCIPAL INVESTIGATOR(S):

Name: Begüm Özel, MD
Address: 1200 N State St IRD 502
Los Angeles, CA 90033
Telephone: 323-442-9589
Fax: 323-442-8974

CO-INVESTIGATOR(S):

Melody Rasouli; Christina Dancz, MD Victor Velasco, MD

Sponsor: Investigator initiated

PARTICIPANTS/Locations: LAC+USC Medical Center

AMENDMENTS/REVISIONS: 9.3.2017

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1.0 BACKGROUND AND HYPOTHESES

1.1 Background:

Postoperative constipation is among the most common complaints among women after gynecologic surgery[1]. In the early postoperative period a temporary delay in gastrointestinal motility can be expected secondary to manual manipulation of bowel and medications including anesthesia and opiates. Postoperative constipation is a significant problem as return of bowel function is the most common reason for delayed hospital discharge after abdominal surgery[2]. Without intervention, the average time to bowel movement after benign gynecologic and urogynecologic surgery is 4 days +/ - 1.5 days[3,4]. Delayed time to first bowel movement after surgery is often associated with patient discomfort and contributes to a delay in postoperative recovery.

The exact pathophysiology of delayed return of bowel function is unknown. Bayliss and Starling described the presence of inhibitory spinal reflexes acting on the bowel in 1899, which were later identified to be sympathetic inhibitory pathways in the autonomic nervous system[5,6]. Sympathetic inhibition involves prevention of acetylcholine release from excitatory fibers in the myenteric plexus. The enteric nervous system has also been implicated as Holzer and Lippe suggested the role of Substance P, a neurotransmitter associated with pain. Bult et al. proposed that nitric oxide is the major inhibitory nonadrenergic noncholinergic neurotransmitter in the enteric nervous system[7,8]. Hormones and neuropeptides such as vasoactive intestinal peptides, inflammation mediated by macrophages and neutrophils, general anesthesia and opioid narcotics may also contribute to the pathophysiology of delayed return to bowel function after surgery[10-12].

1.2 Previous Studies:

The standard at our institution for post-operative bowel regimen is the use of docusate sodium twice daily. Docusate lowers the surface tension of stool, facilitating the passage of water into the stool[13].There have been two studies looking at post-operative bowel regimens after anorectal and pelvic reconstruction surgeries which demonstrated a reduction in time to first bowel movement with the use of docusate sodium plus an additional therapy (senna or polyethylene glycol 3350, fiber wafers and bisacodyl suppositories) compared to docusate sodium alone[3,4].

Prunes (dried plums, Prunus domestica) has been studied for treating constipation among those with chronic constipation[15-17]. The exact mechanism by which prunes relieve constipation is not fully understood, but its efficacy is attributed to the high fiber content and the presence of chlorogenic and neochlorogenic acids which pass undigested into the colon[18,19]. Prunes can be a safe and inexpensive addition to the bowel regimen of women undergoing benign gynecologic surgery. However, no study has yet evaluated the efficacy of adding prunes to the bowel regimen after gynecologic surgery. We hypothesize that prunes will enhance the return of intestinal function as measured by time to first bowel movement.

1.3 Significance

Better management of constipation and its associated discomfort addresses a major postoperative complaint among patients, and has the potential for significant savings for healthcare systems. Postoperative constipation is associated with longer hospital stays and contributes, in part, to the $1 billion spent annually in the United States on treatment of postoperative nausea, vomiting and constipation[20-22]. With an increased awareness of cost-conscious healthcare delivery, postoperative constipation management is an opportunity to reduce costs through an initiative that directly improves patient care.

2.0 OBJECTIVES AND PURPOSE

2.1 To determine the time to first bowel movement after benign gynecological surgery in women treated with prunes and docusate compared to those treated with docusate alone.

2.2 To determine pain associated with first bowel movement (scale 1-10), stool consistency using Bristol stool form scale, the need for additional laxatives, compliance and patient satisfaction.

3.0 STUDY DESIGN

3.1 This is a prospective, randomized control trial.

3.2 Identification of Subjects:
All potential participants will be identified in the Gynecology or UroGynecology clinic at Los Angeles County-University of Southern California (LAC+USC) Medical Center. On average, between 8-10 patients undergo benign gynecologic surgery with overnight stay per week.

3.3 Recruitment of Participants:
Each eligible participant will be approached in person by one of the study investigators and invited to participate in the study. The informed consent will be reviewed in detail with a physician and the potential participant will be given time to ask questions. The potential participant will be allowed to take a copy of the consent home to review and discuss with family or friends.

3.4 Evaluation Pre-Intervention:

Clinical information will be collected.

3.5 Intervention:

1. Participants that undergo benign gynecologic surgery without intraoperative complications that are admitted overnight will be randomized to one of two groups.

2. Participants in the treatment arm will receive a 12 oz package of prunes on the morning of postoperative day 1.

3. All participants will receive the standard 100 g docusate sodium twice daily. Participants in the treatment arm will be instructed to consume 4 oz prunes (12 prunes) daily.

4. Additional laxatives will not be routinely given. There will be additional laxative medications (Milk of Magnesia) available for participants as needed, and it will be recorded that additional laxatives were needed.

3.6 Evaluation Post-Intervention:

1. All participants will record the date and time of, consistency of and pain associated with their first bowel movement, and answer whether they experienced secondary outcomes as described later.

2. Participants in the treatment arm will also log the number of prunes consumed each day.

2. Participants will be given a stamped and addressed envelope to return the data collection sheets in. Participants will receive a call from an investigator masked to the treatment allocation on postoperative day 3 inquiring about whether the participant has mailed the data collection sheets back. Those who do not answer will be called again the next day.

3. During the phone call, if the participant indicates any postoperative concerns, she will be instructed to contact the on call physician at the LAC+USC Ob/Gyn Triage.

4.0 DRUG INFORMATION

4.1 Pitted California prunes are made without preservatives or added ingredients.

4.2 Prunes will be independently purchased through in store or online retailers based on availability.

4.3 Prunes are not associated with known toxicities. They can be stored at room temperature (15°C to 30 °C).

5.0 SELECTION AND WITHDRAWAL OF SUBJECTIONS

5.1 Inclusion Criteria:

1. Female patients seen in the Gynecology or Urogynecology clinics at LAC+USC Medical Center who are planned for surgery requiring at least 24 hour stay
2. Age 18 or greater
3. Able to give informed consent
4. No contraindications to docusate or prune consumption

5.2 Exclusion Criteria

1. Unable to give informed consent
2. Unwilling to follow protocol
3. Active malignancy

4. Emergency surgery
5. Diabetes mellitus
6. Inflammatory bowel disease, gastroparesis, or other bowel disorder
7. History of bowel resection or presence of colostomy
8. Dependence on regular laxative use prior to surgery
9. Baseline frequency of bowel movements less than weekly
10. Intraoperative enterotomy or any bowel surgery performed at the time of surgery
11. Patient unable to initiate oral intake on post op day 1 for any reason
12. Allergy to docusate or prunes

5.3 Withdrawal Criteria

1. Participant request

6.0 STRATIFICATION/DESCRIPTIVE FACTORS/RANDOMIZATION SCHEME

6.1 Stratification factors. N/A

6.2 Descriptive factors. Age, height, weight, self-described race and ethnicity, menopausal status, baseline frequency of bowel movements, laxative use, fiber use, medications used, and baseline stool consistency.

6.3 Randomization plan:

On morning of post-operative day 1, participants who do not meet exclusion criteria will be randomized to the treatment or control group at a 1:1 ratio. Randomization blocks of 6 will be applied in this study to ensure balanced treatment assignments throughout the recruitment period. The randomization assignment list will be generated by the study statisticians, Victoria Cortessis, Ph.D

Participants will be standardly administered 100 g of docusate twice daily for three days per existing routine post-operative care. In addition, we will administer a total of 12 oz of prunes to the study group which are pitted and preservative free. The prunes will be provided to the participant in a sealed package. The study group be instructed to eat 4 oz of prunes daily. The control group will be advised to avoid prune products for 3 days. Each group will be given a diary to note their prune and/or docusate consumption and details of their first bowel movement.

7.2 Drug studies:

AGENT	DOSE	ROUTE	DAYS	NOTES
Prunes	4 oz/day	PO	3	Participant to eat any time during the day

7.3 Criteria for removal from treatment:

7.31 Unable to tolerate eating prunes.

7.32 A participant may always be removed from treatment whenever she wishes.

7.33 Bowel complications including ileus, obstruction, delayed recognition of bowel injury.

7.34 NPO status recommended by supervising physician.

8.0 ASSESSMENT OF EFFICACY AND SAFETY

8.1 Side effects/Toxicities to be monitored.

8.11 Prunes have a favorable safety profile, but mild, transitory gastrointestinal cramping, flatulence, pains, or diarrhea may occur.

8.12 No long-term toxicities to monitor after completion of therapy.

8.2 No formal dosage change will take place based on toxicity as associated with prunes. However, participants will be instructed that they may reduce their prune consumption or discontinue prune consumption if they experience side effects.

8.3 Adverse Event Reporting:

8.31 Patient will be advised to tell study physician if she feels that she has been injured because of taking part in this study.

8.32 The PI will appropriately report all adverse events to the IRB.

8.4 Data Monitoring Committee: All injuries believed by the treating medical doctor to be due to participation in this study will be reviewed by the Data Monitoring Committee of USC.

9.0 CLINICAL AND LABORATORY EVALUATIONS AND STUDY CALENDAR

Parameter	Pre-Treatment	Postoperative day 1	Postoperative day 3*	Postoperative day 5*
Targeted history	X			
Operative history		X		
Postoperative Data Collection Sheet to be Mailed-In			X	X

* If unable to reach patient by the telephone on postoperative day 3, another attempt will be made on postoperative day 5.

10.0 CRITERIA FOR EVALUATION AND ENDPOINT DEFINITIONS

The outcome status of all eligible patients will be reported. All eligible patients who begin treatment will be included in the analysis.

Primary endpoints: Time to first bowel movement (in hours)

Secondary endpoints:

1. Stool consistency of the first bowel movement as classified by the Bristol Stool Scale (The stool types are categorical variables, and we will evaluate the differences in the frequencies of the responses by treatment status with a chi-square test)
2. Pain with bowel movement measured (Likert scale, and assessed using t-test or non-parametric methods as appropriate)
3. Satisfaction with bowel regimen (Likert scale, and assessed using t-test or non-parametric methods as appropriate)
4. Satisfaction with surgery overall (Likert scale, and assessed using t-test or non-parametric methods as appropriate)
5. Requirements for laxative (yes or no, assessed as categorical variables and evaluated by chi-square test)
6. Compliance with docusate (percentage of medications consumed, and assessed using t-test or non-parametric methods as appropriate)
7. Compliance with prunes (percentage of prunes consumed, and assessed using t-test or non-parametric methods as appropriate)

8. Adverse events of extreme bloating or flatulence (yes or no, assessed as categorical variables and evaluated by chi-square test)

Compliance with prune consumption will be defined as reported successful consumption of 2/3 of the assigned prunes.

11.0 SPECIAL INSTRUCTIONS:

N/A

12.0 DATA COLLECTION AND MONITORING

12.1 Data sheets will be kept locked in the Urogynecology Clinic (A3A129) of the clinic tower until transcription into a REDcap database. The data will be subsequently transcribed into REDcap database. Data will be monitored via REDcap.
After transcription into REDCap, the data collection sheets will be kept in a locked cabinet in a locked room (IRD 224) in the IRD building until data analysis is completed, after which they will be destroyed.

Protected Health Information will be kept on the initial contact information sheet, and all additional sheets will be coded. The codes will be kept in a master database on REDCap. Access to identifying information is necessary to link the follow up visit to the initial data collection.

13.0 STATISTICAL CONSIDERATIONS

The sample size of 63 participants per treatment group was calculated to detect a clinically significant mean difference in time to first bowel movement of 12 hours using a two-sample t-test with a standard deviation of 23.7 at 80% power and two-sided significance level of p=0.05. The sample size was inflated to 70 participants per group to account for an estimated 10% attrition rate.

Summaries of participant characteristics will be described by treatment arm. Participant characteristics will be presented as means and standard deviations for continuous variables and counts and percentages for categorical variables. Comparisons of baseline characteristics will be assessed using two-sample t-tests or the non-parametric corollary for continuous variables and chi-square test for categorical variables. The primary outcome, a comparison of the time to first bowel movement between the treatment and control groups, will be assessed using two-sample t-tests. The secondary outcome, pain at first BM, will also be evaluated using two sample t-tests.

14.0 REGISTRATION GUIDELINE

14.1 Forms and records needed for registration will include: Informed Consent, Patient's Bill of Rights, and HIPAA form.

14.2 At the time of registration, three copies of a signed and dated patient Informed Consent form with Bill of Rights will be available (an original for patient's medical chart; one copy for the patient; and the other for the PI's file).

15.0 BIOHAZARD CONTAINMENT

N/A

16.0 ETHICAL AND REGULATORY CONSIDERATIONS

All institutional and Federal regulations concerning the Informed Consent form will be fulfilled. The study will be conducted in adherence to ICH Good Clinical Practice.

17.0 REFERENCES

1. Caljouw MA, Hogendorf-Burgers ME. GYNOTEL: telephone advice to gynaecological surgical patients after discharge. J Clin Nurs 19:3301–6, 2010.

2. Moss G, Regal ME, Lichtig LK. Reducing postoperative pain, narcotics and length of hospitalization. Surgery 90:206-210, 1986.

3. Patel M, Schimpf MO, O'Sullivan DM, et al. The use of senna with docusate for postoperative constipation after pelvic reconstructive surgery: a randomized, double-blind, placebo-controlled trial. Am J Obstet Gynecology 202:479.e1-5, 2010.

4. McNanley A, et al. Bowel function after minimally invasive urogynecologic surgery: a prospective randomized controlled trial. Female Pelvic Med Reconstruc Surg. 2012 Mar-Apr;18(2):82-5.

5. Bayliss WM, Starling EH. The movements and innervations of the small intestine. J Physio Lond 24:99-143, 1899.

6. Kenwenter J. The vagal control of duodenal and ileal motility and blood flow. Acta Physiol Scand 63:1-68; 1965.

7. Dubois A, Weise VK, Kopin IJ. Postoperative ileus in the rat: physiology, etiology and treatment. Ann Surg 178:781-6; 1973.

8. Holzer P, Lippe IT. Inhibition of gastrointestinal transit due to surgical trauma or peritoneal irritation is reduced in capsaicin-treated rats. Gastroenterology 91:360-3, 1986.

9. Bult H, Boeckxstaens GE, Pelckmans PA, Jordaens FH, Van Maercke YM, Herman AG. Nitric oxide as an inhibitory non-adrenergic non-cholinergic neurotransmitter. Nature 345:346-7, 1990.

10. Espat NJ, Cheng G, Kelley MC, Vogel SB, Snisky CA, Hocking MP. Vasoactive intestinal peptide and substance P receptor antagonists improve postoperative ileus. J Surg Gres 58:719-723, 1995.

11. Kalff JC, Wolfgang HS, Simmons RL, Bauer AJ. Surgical manipulation of the gut elicits an intestinal muscularis inflammatory response resulting in post-surgical ileus. Ann Surg 228:652-663, 1998.

12. Schurizek BA, Willacy LHO, Kraglund K, Andreasen F, Juhl B. Effects of general anesthesia with halothane on antroduodenal motility, pH and gastric emptying in man. Br J Anaesth 62:129-37, 1989.

13. Siegel JD, Di Palma JA. Medical Treatment of Constipation. Clinics in Colon and Rectal Surgery 18:76-80, 2005.

14. Coman ML. Management of postoperative constipation in anorectal surgery. Dis Colon 22:149-51, 1979.

15. DMuller-Lissner SA, Volker K, Wolfgang B, Jutta K, and Peter L. The perceived effect of various foods and beverages on stool consistency. Eur J Gastroenterol Hepatol 17:109-12, 2005.

16. Lever, EJ Cole PE and Whelan K. The effect of prunes on gastrointestinal health – a systematic review of randomised controlled trials. Proc Nutr Soc 71:28, 2012.

17. Scott, S. Mark, and Charles H. Knowles. "Constipation: Dried Plums (prunes) for the Treatment of Constipation." Nat Rev 8: 306-07, 2011.

18. Stacewicz-Sapuntzakis, M., P. E. Bowen, E. A. Hussain, and B. I. Damayanti-Wood. "Chemical Composition and Potential Health Effects of Prunes: A Functional Food?" Crit Rev Food Sci Nutr 41:251-68, 2001.

19. Yao, C. K., HL Tan, D. R. Van Langenberg, J. S. Barrett, R. Rose, K. Liels, P. R. Gibson, and J. G. Muir. "Dietary Sorbitol and Mannitol: Food Content and Distinct Absorption Patterns between Healthy Individuals and Patients with Irritable Bowel Syndrome." J Hum Nutr Diet 27:263-75, 2013.

20. Holte K and Henrik K. Postoperative ileus. Drugs 62:2603-615, 2002.

21. Asgeirsson T, El-Badawi KI, Mahmood A. Postoperative ileus: it costs more than you expect. J Am Coll Surg 210:228-31, 2010.

22. Watkins DT and Robertson CL. Ileus following gynecological surgery: Water-soluble radiocontrast material in the treatment of postoperative Ileus. Am J Obstet Gynecol 152:450-55, 1985.

APPENDICES

Appendix I - Informed Consent

Study Title: Effect of prunes on gastrointestinal function after gynecological surgery: A randomized controlled trial

Principal Investigator: Begüm Özel, MD

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: _____ Time: _____

Signature: _____
(Research Participant)

Signature: _____
(Parent or Legally Authorized Representative)

If signed by other than the research participant, indicate relationship: _____

INFORMED CONSENT

TITLE: Effect of prunes on gastrointestinal function after gynecological surgery with docusate: A randomized controlled trial

PRINCIPAL INVESTIGATOR: Begum Ozel, MD

DEPARTMENT: Department of Obstetrics and Gynecology

24-HOUR TELEPHONE NUMBER: 323-409-3061

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

This study is about the effect of prunes on bowel function after gynecologic surgery. We hope to learn if eating prunes will help with constipation after surgery. You are invited as a possible participant because you are having gynecological surgery. 140 participants will take part in the study.

WHAT IS INVOLVED IN THE STUDY?

If you decide to take part, this is what will happen:

1) You will complete a brief survey about your normal bowel habits.
2) After your surgery, you will randomly be assigned to one of two groups. One group will receive a small bag of prunes, and one group will not have any prunes.
3) You will keep a diary to track how many prunes you eat each day, whether or not you have had a bowel movement, and if you had to take any additional laxatives. Please mail in the diary in the stamped envelope provided to you.
4) You will be called three and/or five days after your surgery and will be asked about how many prunes you ate, your first bowel movement and your general opinion about the surgery.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks and discomforts you could experience during this study from prunes include: mild abdominal pain, cramping, increased flatulence, diarrhea, or rashes.

Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions that make you uncomfortable.

There is a small risk that people who are not connected with this study will learn your identity or your personal information.

WILL YOUR INFORMATION BE KEPT PRIVATE?

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. The University of Southern California's Institutional Review Board (IRB) may review your records. The IRB is a research review board that is made up of professionals and community members who review and monitor research studies to protect the rights and welfare of research participants. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

This research involves obtaining / collecting your protected health information, you will be asked to sign a separate HIPAA Authorization for Research form. This form explains how your protected health information will be obtained, used, and disclosed.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

The possible benefits to you for taking part in this study may include increased comfort post-operatively and sooner first bowel movement after surgery.

You may not receive any direct benefit from taking part in this study. However, your participation in this study may help us learn if prunes can help post-operative constipation for women after gynecologic surgery.

WHAT OTHER OPTIONS ARE THERE?

An alternative would be not to take part in this study, and continue with your current care.

WHAT ARE THE COSTS?

There is no cost to you for taking part in this study.

what happens if you get injured or need emergency care?

If you think you have been hurt by taking part in this study, tell the study doctor immediately. If you require treatment because you were injured from participating in this study, treatment will be provided. You or your health plan/insurance will be billed for the cost of this treatment.

There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this study is voluntary. Your decision whether or not to take part will not affect your current or future care at this institution. You are not giving up any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study at any time. You will not lose any rights if you decide to stop being in the study. If the withdrawal must be gradual for safety reasons, the study doctor will tell you.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Dr. Begüm Özel, MD at 323-409-3061 with any questions, concerns, or complaints about the research or your participation in this study. If you feel you have been hurt by taking part in this study, please contact Dr. Christina Dancz at 323-409-8848. If you have questions, concerns, or complaints about the research and are unable to contact the research team, contact the Institutional Review Board (IRB) Office at 323-223-2340 between the hours of 8:00 AM and 4:00 PM, Monday to Friday. (Fax: 323-224-8389 or email at irb@usc.edu).

If you have any questions about your rights as a research participant, or want to talk to someone independent of the research team, you may contact the Institutional Review Board Office at the numbers above or write to the Health Sciences Institutional Review Board at LAC+USC Medical Center, General Hospital Suite 4700, 1200 North State Street, Los Angeles, CA 90033.

You will get a copy of this consent form.

AGREEMENT:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant	Signature	Date Signed (and Time*)

I have personally explained the research to the participant using non-technical language. I have answered all the participant's questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time*)

A witness is required when: (1) the participant cannot see, read, write, or physically sign the consent form, or (2) the Short Form method is used to obtain consent. In these situations, the witness must sign and date the consent form. If no witness is needed, leave this signature line blank.

Name of Witness	Signature	Date Signed

** If a study procedure is done on the same day the informed consent is signed, the time and date are required. No study procedures may be done before the participant has signed the informed consent.*

Appendix II - Contact Information Sheet

Participant # _____

Name:
Date of birth (MM/DD/YEAR):
Address:

Preferred contact phone number:

Alternate contact number (if available):

Appendix III – Data collection sheet

Prunes study screening questionnaire

Screening questions

Are any of the following exclusion criteria met? Yes No

1. Under age 18
2. Diabetes mellitus
3. Inflammatory bowel disease, gastroparesis, or other bowel disorder
4. History of bowel resection or presence of colostomy
5. Regular (at least weekly) laxative use
6. At least one bowel movement each week
7. Allergy to docusate or prunes
8. Unable or unwilling to take docusate or prunes for any reason
9. Unable to give informed consent
10. Unwilling to follow protocol
11. Emergency surgery
12. Outpatient surgery
13. Active malignancy

If Yes to any of the above, do not enroll.

Prunes Data Collection Sheet
Baseline data collected at time of study enrollment

Participant number # _____

Age _____ years
Race White Black or African American Asian
American Indian or Alaska Native Native Hawaiian or Pacific Islander
Other Multiple races

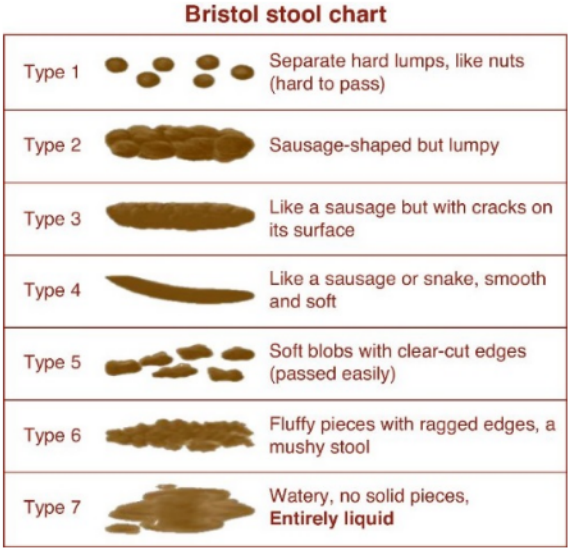
Hispanic Ethnicity Yes No
Parity _____
Height _____ cm
Weight _____ kg

Menopausal Yes No Unsure/Not known

Baseline frequency of bowel movements
Multiple times daily Once a day Once every other day
Twice a week Once a week
Have you needed to use a laxative at any time in the last 3 months? Yes No
Do you take fiber daily or almost daily? Yes No

Are you on any of the following medications on a regular basis? Yes No
Antimuscarinics (such as Detrol, Ditropan) Yes No
Iron Yes No
Calcium channel blocker (such as nifedipine, amlodipine, verapamil, diltiazem) Yes No
Opiods (such as Percocet, Oxycodone, Tramadol, etc.) Yes No
Tricyclic antidepressant (such as amitriptyline, imipramine) Yes No

Bristol Stool Scale (Describe usual stool consistency) _____ (Indicate number)



Prunes Data Collection Sheet

Data collected at time of randomization

Are any of the following exclusion criteria met? Yes No

1. Intraoperative enterotomy or any bowel surgery (not including posterior colporrhaphy) performed at the time of surgery
2. Patient unable to initiate oral intake on post op day 1 for any reason

If Yes to any of the above, do not randomize.

Was preoperative bowel prep administered? Yes No

Primary indication for surgery

- Adnexal mass
- Abnormal uterine bleeding (with or without fibroids)
- Fibroid uterus (without abnormal uterine bleeding)
- Pelvic organ prolapse
- Other (Please indicate) _____

Procedures performed

- Open abdominal hysterectomy
- Open sacral colpopexy
- Open surgery, other
- Vaginal hysterectomy
- Other vaginal only surgery
- Laparoscopic or robotic hysterectomy (including laparoscopic or robotic assisted vaginal hysterectomy)
- Laparoscopic or robotic sacral colpopexy
- Laparoscopic or robotic surgery, other
- Posterior colporrhaphy
- Burch urethropexy alone
- Other (Please indicate) _____

Estimated blood loss _____ ml

Surgery start time _____

Surgery end time _____

Prunes Data Collection Sheet
Data collected on post op day 3

Day of discharge to home (if discharged)	1	2	3
Time of discharge to home (if discharged)	_____		

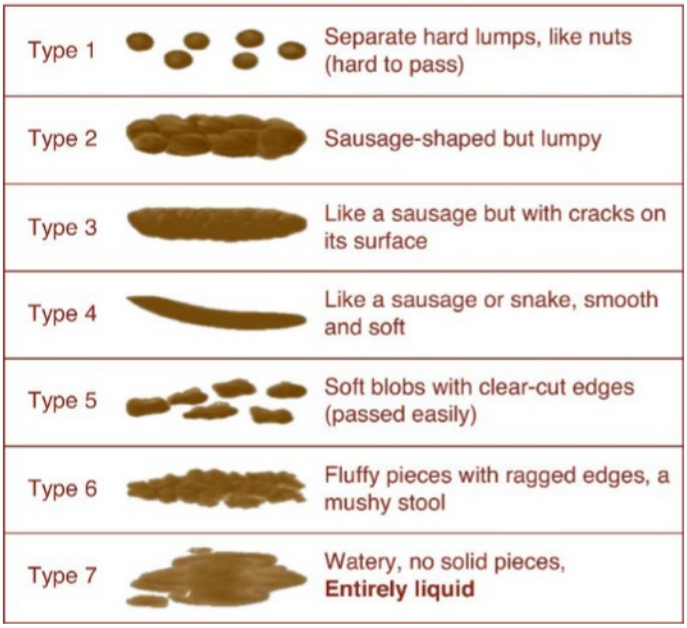
Prunes Data Collection Sheet
Self administered survey

Have you had a bowel movement since surgery? Yes No
If Yes, When did you have your first bowel movement?
Date _____ Time _____

How *painful* was your first bowel movement?
Not at all painful 0 1 2 3 4 5 6 7 8 9 10 Very painful

Which picture best describes your bowel movement (Circle one number)?
1 2 3 4 5 6 7

Bristol stool chart



How satisfied were you with the treatments you received to help you with bowel movements after the surgery?
Not at all satisfied0 1 2 3 4 5 6 7 8 9 10 Extremely satisfied

How satisfied were you with your surgery overall?
Not at all satisfied0 1 2 3 4 5 6 7 8 9 10 Extremely satisfied

How many docusate did you take on day 1? _____
How many docusate did you take on day 2? _____
How many docusate did you take on day 3? _____
Did you use any laxatives? Yes No
If yes, what? _____
If yes, what day? _____

If in study group (prunes):
How many prunes did you eat on day 1? _____
How many prunes did you eat on day 2? _____
How many prunes did you eat on day3? _____

Prunes Data Collection Sheet
Self administered survey – Spanish

¿Ha tenido una evacuación intestinal desde la cirugía? ○ Sí ○ No

Si la respuesta es Sí, ¿Cuándo tuvo su primer movimiento intestinal?

Fecha _____ Hora _____

¿Cuán doloroso fue su primer movimiento intestinal?

Nada doloroso 0 1 2 3 4 5 6 7 8 9 10 Muy doloroso

¿Qué imagen describe mejor su movimiento intestinal (encierre en un círculo un número)?

1 2 3 4 5 6 7

Bristol stool chart

Type 1		Heces en bolas duras y separadas. Como frutos secos.
Type 2		Heces con forma alargada como una salchicha pero con relieves como formada por bolas unidas.
Type 3		Heces con forma alargada cmo una salchicha, con grietas en la superficie.
Type 4		Heces con forma alargada como una salchicha, lisa y blanda.
Type 5		Heces blandas y a trozos separadas o con bordes defractos.
Type 6		Heces blandas y a trozos separadas o con bordes pegados como mermelada o pure.
Type 7		Heces liquidas sin trozos solidos.

¿Cuán satisfecho estuvo con los tratamientos que recibió para ayudarle con los movimientos intestinales después de la cirugía?

Nada satisfecho 0 1 2 3 4 5 6 7 8 9 10 Extremadamente satisfecho

¿Qué tan satisfecho estuvo con su cirugía en general?

Nada satisfecho 0 1 2 3 4 5 6 7 8 9 10 Extremadamente satisfecho

¿Cuántos docusate tomó el día 1? _____

¿Cuántos docusate tomó el día 2? _____

¿Cuántos docusate tomó el día 3? _____

¿Utilizó algún laxante? ○ Sí ○ No

Si sí, ¿qué? _____

Si sí, ¿qué día? _____

Si en el grupo de estudio (ciruelas pasas):

¿Cuántas ciruelas comió el día 1? _____

¿Cuántas ciruelas pasas comiste el día 2? _____

¿Cuántas ciruelas comió el día 3? _____

Appendix IV: Prune Diary

Mark on the chart below what time you ate a prune.
Marque en la tabla debajo de qué hora usted comió una ciruela pasa.

	Day 1	Day 2	Day 3
6am			
7am			
8am			
9am			
10am			
11am			
12noon			
1pm			
2pm			
3pm			
4pm			
5pm			
6pm			
7pm			
8pm			
9pm			
10pm			
11pm			
12midnight			
1am			
2am			
3am			
4am			
5am			

Appendix V: Stool softener diary

Mark on the chart below what time you took your stool softener medication.

Marque en la tabla debajo de qué hora tomó su medicación suavizante de heces.

	Day 1	Day 2	Day 3	Day 4	Day 5
6am					
7am					
8am					
9am					
10am					
11am					
12noon					
1pm					
2pm					
3pm					
4pm					
5pm					
6pm					
7pm					
8pm					
9pm					
10pm					
11pm					
12midnight					
1am					
2am					
3am					
4am					
5am					