PROTOCOL FOR FOLEY CATHETER STUDY

**Study Title**: Foley Catheter insertion into Defunctioning ileostomy

To reduce Postoperative Ileus after Major Colorectal Surgery

**Lay Title**: Foley Catheter study

A Prospective, Randomized Controlled Study

**Principal Investigator:** Dr.Suheelan Kulasegaran ( MBChB, PG DipSurg Anat)

**Sub Investigator:** Dr. Carolyn Vasey (MBChB, FRCS)

**Senior Investigator**: Mr Mike Hulme Moir (MBChB, FRCS)

**Senior Investigator**: Mr John Jarvis (MBChB, FRCS)

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INTRODUCTION:

Colorectal cancer is an important public health issue in New Zealand. Incidences of this condition here rank among the highest in the world1. As of 2006, it was the most common cancer registered and the second most common cause of death related to cancer in New Zealand. The incidence of colorectal cancer in Maori patients is considerably lower compared to non-Maori. In 2006, colorectal cancer was the third most commonly registered cancer for Maori, and the third leading cause of death from cancer *2.*  Despite a lower prevalence of this condition in this group, Maori have a higher relative increase in incidence of colorectal cancer. This is significant as it may represent and increase need for service provision in this population in the near future. (1)

The surgical management of colorectal cancer is complex and involves a multi-disciplinary team. An improved understanding of the pathophysiology and the modernization of surgical technique has led to an increase in the use of sphincter preserving surgery in particular for those with rectal cancers. An example of this type of operation would be an anterior resection operation for rectal cancer. One of the most devastating complication of this type of operation would be an anastomotic leak. The incidence of this has been reported up to 17 % and can result in re-operations, permanent stoma, pelvis sepsis and death3. In order to mitigate the consequences of an anastomotic leak, Defunctioning ileostomies are frequently used to provide temporary proximal faecal diversion. The main benefit is that it provides protection of the distal colonic anastomosis during its healing phase. This stoma is is usually closed within 12 weeks of initial surgery. A systematic review conducted by Huser et all demonstrated lower leakage and re-operation rates in those patients with defunctioning ileostomies after low anterior resection. The rate of leakage when using a defunctioning [stoma](http://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0022253) (OR 0.32, 95% CI 0.17 to 0.59, I2 = 0%; four RCTs). There was a lower rate of re-operation in the group with a defunctioning stoma (OR 0.27, 95% CI 0.14 to 0.51, I2 = 0%; four RCTs). Mortality was similar in both groups4.

The main disadvantage of a defunctioning ileostomy are the complications related to stoma formation. Stoma related complications can greatly impact on the quality of life of patients. The incidence of complications post loop ileostomy is highly variable ranging between 3% and 93 %. These can vary from minor skin complications to more serious complications such as retraction, small bowel obstructions requiring re-operation. 5. Here we will focus on small bowel obstruction in particular at the level of the stoma maturation site. Here we hypothesise that post-operative oedema and the resultant swelling of bowel at the level of the fascia may be contributing to reduced bowel motility and obstruction at that level resulting in longer times to stoma output. One of the current treatment methods for this is to introduce a Foley catheter into the proximal efferent limb and decompress the obstruction.

Our proposal is to prophylactically introduce a Foley catheter into the proximal efferent limb of the ileostomy at the end of the operation. This has the potential to alleviate the obstruction at the level of the fascia and help promote bowel motility and improve time to stoma output. This is an innovative and novel approach to managing this problem. We aim to assess the feasibility and efficacy of this innovative but cheap and simple intervention. The clinical significance of this maybe immense - with the possibility of reducing the morbidity associated with ileus, reducing length of stay, facilitating early patient recovery and thus potentially economically beneficial. If found to be safe and effective, it may be introduced to existing enhanced Recovery after surgery programmes. It is expected that this intervention can be adopted by colorectal surgeons at a minimal cost and minimal risk to the patient.

Foley Catheter:

A foley catheter is a very commonly used thin hollow sterile tube that comes in a variety of sizes. Usually made of synthetic silicone, latex, rubber material. It is usually introduced into the bladder via ureter to drain the bladder. It is commonly used and is often left for prolonged periods of time. It is safe and Is usually left in place by inflating the balloon to hold it in Place.

ENHANCED RECOVERY AFTER SURGERY (ERAS) PROGRAMME:

ERAS is a multimodal perioperative care pathway designed to achieve early recovery for patients undergoing major colorectal surgery. The ERAS pathway is centred on patient knowledge and involvement, and driven by a multidisciplinary approach to reduce the physiological and psychological stress of undergoing surgery. This is achieved by providing pre-operative education alongside a revision of traditional surgical care practice, optimising aspects such as pain relief, nutrition, fluid therapy and early mobilisation. As this is standard hospital care the catchment of participants will be all offered the same standard treatment after surgery. It is intended that this will provide a fair analysis of outcome. Surgeons at the NSH use the ERAS treatment algorithm post-operatively. This protocol is available readily on the NSH online database and is currently in use for a majority of patients undergoing bowel surgery.

HYPOTHESIS:

The insertion of a foley catheter into a defunctioning ileostomy will significantly reduce the incidence of an ileus as a complication after colorectal surgery.

STUDY DESIGN AND RANDOMISATION:

A Prospective, Controlled, Randomized study. Eligible subjects will be randomized in a 1:1 allocation ratio to either Foley catheter treatment or Standard of care treatment. Sealed envelopes will randomly allocate the treatment in order to avoid any potential bias. The best interests of the patient will be of main priority; therefore, if randomized intervention is not able to be carried out intra operatively in regards to the patient’s best interest, by authority of the surgeon, the patient will be an intraoperative failure with regards to the study.

STUDY POPULATION:

Subjects undergoing major elective colorectal surgery with a defunctioning ileostomy. It is planned that a minimum of 50 subjects will be randomized from North Shore Hospital, Auckland only.

PRIMARY ENDPOINT:

Time taken to tolerate low residue diet without nausea/vomiting.

SECONDARY ENDPOINTS:

Time taken until stoma output

Time taken until flatus

Length of stay

Incidence of adverse events;

Incidence of adverse events that are potentially related to post operative ileus

SAFETY:

Adverse events will be collected from time of randomization, throughout the Follow‐up period approximately 7 days after surgery or until hospital discharge.

FUNDING:

This clinical trial will be funded by the colorectal surgical research funds at North Shore Hospital.

ETHICAL APPROVAL:

This clinical trial has undergone Ethics review and was approved on ………….. Dated ……………………. Ethics Reference Number: ……………………………………………….

CULTURAL CONSIDERATIONS:

This protocol has undergone Maori consideration at North Shore Hospital by the Maori Research Advisor and has received written approval. Cultural support will be offered to all potential participants as per routine standard at the hospital to allow participants to make an informed choice. North Shore Hospital provides Māori cultural support. Alternatively patients may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324. Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor can also be accessed via telephone for advice. North Shore Hospital also offers Asian health support service via the WDHB. This information as well as contact details are included in the patient information sheet.

CONFIDENTIALITY:

All participants are identified with a unique randomization number. Clinical study data and Principal Investigator and Mandatory documents are maintained in the surgical research nurse office located in the hospital. Electronic data is only accessible via password which is held by the study research team only.

INCLUSION CRITERIA:

* Subjects > 18 years of age, requiring elective/acute Colorectal surgery with a defunctioning loop ileostomy
* English speaking, if not then must have an interpreter
* Subjects must be willing to participate in the study and to provide written informed consent
* Entering the Enhanced Recovery After Surgery (ERAS) programme as per standard hospital policy
* Patients with malignant and non-malignant disease will be included

EXCLUSION CRITERIA:

* Subjects with any intra-operative findings identified by the surgeon that may preclude conduct of the study procedure
* Involved in another colorectal study
* Subjects unable to maintain the ERAS programme post operatively
* If Foley catheter falls out- investigators will only re-insert Foley 3 times with the patient’s permission. After that- patient will be excluded from study. This will be done by surgical registrar/consultant/research nurse.

PROCEDURE:

*Screening and baseline:*

1. Potential participants are initially approached about the study in colorectal outpatient clinic by their attending surgeon or registrar, as meeting inclusion and exclusion criteria. The patient is given the study information sheet, cultural advice and contacts to take home and read and discuss with family/Whanau.
2. The patient will be contacted via telephone by the surgical research nurse to answer any questions or concerns with regard to the study.
3. At the next colorectal outpatient clinic appointment the research nurse will meet with the patient to again discuss the study and to gain written informed consent if the patient wishes to participate. At this stage baseline measurements will be taken including age, ethnicity, medical co-morbidities and documented using a unique screening number

*Randomization:*

1. Biostatistician (Arier Lee) provides a random computer generated random number generated list. Each patient randomly allocated onto treatment arm. There are 6 Colorectal surgeons and 1 Colorectal fellow (Dr C.Vassey) at North Shore Hospital. The random generated number will be created for each surgeon ( i.e. each surgeon will be provided a random list) - to account for inter-surgeon variability and also differing number of ileostomies each surgeon performs.
2. On the day of surgery patients who have given written informed consent are randomly allocated into either the treatment or standard of care group by the research nurse by opening the randomization envelope.

*Standard of care arm:*

1. Patient receives the usual standard surgery and no Foley catheter is inserted
2. The procedure is entered into the patients clinical notes along with a clinical trial alert form and a copy of the written informed consent form

*Treatment arm:*

1. A size (16 f) 2 way. foley catheter is inserted into the proximal efferent limb of defunctioning ileostomy by the surgical consultant/registrar at the end of the operation.. The catheter is stabilised in place by inflation the catheter balloon 3mls using the standard technique. The procedure is entered into the patient’s clinical notes along with a clinical trial alert form and a copy of the written informed consent form.

*Day 1 post op (this is seen as the day after surgery):*

1. The research nurse assesses the patient on the ward for adverse events, stoma output, flatus, adherence to ERAS and the toleration of solid food. Everytime patient is seen by research nurse/surgical registrar/student- entry will be made into notes.
2. This follow up is continued every 1 – 5 days by the research nurse until the patient is discharged from hospital.

*Criteria for removal of Foley:*

1. Upon patient discharge
2. When stoma has output recorded by nurse.
3. Complications from Foley- such as pain/discomfort/issues with managing stoma
4. Surgeon Discretion
5. After day 5 of admission- Foley will be removed.
6. If Foley is reinserted more than 3 times, then Foley catheter is removed.

DATA MANAGEMENT

1. All identifiable information kept in safety and confidence with principle investigator in a single file.
2. All patients get a study ID number for the datasheet.
3. No identifiable information will be published.

ANALYSIS:

1. Baseline patient characteristics ( Age, Gender, ASA,Comorbidity)- pre-operative details
2. Operative Details- duration, technique, eras, lap vs.open
3. Anaesthetic details- ASA ( American society of anaesthesiologist criteria)
4. Statistical analysis of primary and secondary outcome- mean, median, Confidence interval, difference in mean. Biostatistician consulted.

*Power calculation:*

We are planning a study of a continuous response variable from independent control and experimental subjects with 1 control(s) per experimental subject.  In a previous study the response within each subject group was normally distributed with standard deviation 206.  If the true difference in the experimental and control means is 20 hours, we will need **to study 22 experimental subjects and 22 control subjects** to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.9.   The Type I error probability associated with this test of this null hypothesis is 0.05. To account for drop out- we have included 25 on each arm. This stastistical analysis was done with the assistance and guidance of Dr Arier Lee (University of Auckland Biostatistician).

1. How many defunctioning ileostomies each year at NSH- approx. 60
2. Normal time to tolerance of low residue diet based on literature6: Approx 2.25 days
3. What would be a reduction of time that would be clinically significant- 1 day

DISSEMINATION & OUTCOME:

1. Publications- International surgical journals
2. Local/international oral and poster presentation
3. Local and international colorectal meetings

No potential conflict of interests, and there are no commercial funds for this study.

STUDY CONDUCT:

Ethical Considerations:

1. Requires: Local/HDEC/Maori research approval
2. Clinical Trial registered with Awhina- Waitemata District Health Board.

Risks:

1. Small bowel injury as a result of Foley insertion ( highly unlikely)
2. Difficulty managing stoma bag post-operatively ( research nurse/stoma nurse will assist patients with this)
3. Risk of obstruction at the level of stoma ( unlikely)
4. Bleeding at the level of stoma ( unlikely)

Resource Requirements:

1. Foley catheter
2. Surgical registrar/education fellow- self funded
3. Research Nurse ( S.Nisbet)- wdhb funded
4. Time
5. Biostatistician- power calculation ( Arier Lee)

Time Frame

2 years (23/4/15- 23/4/17)

PEER REVIEW:

Professor Ian Bisset : Professor of Colorectal Surgery and Head of Surgery Auckland Hospital/University of Auckland.

KEY CONTACTS:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name** | Mr Mike Hulme Moir **( Senior Author )** | | | | **Title** | Surgeon |
| **Institution** | North Shore Hospital, Takapuna, Auckland | **Dept.** | Surgery | | | |
| **Mobile phone** | 021 718 249 | **E-mail** | | Mike.Hulme-Moir@waitematadhb.govt.nz | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Name** | Mr John Jarvis **( Senior Author )** | | | | **Title** | Surgeon |
| **Institution** | North Shore Hospital, Takapuna, Auckland | **Dept.** | | Surgery | | |
| **Mobile phone** | 021 814 269 | **E-mail** | John.Jarvis@waitematadhb.govt.nz | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | Dr. Suheelan Kulasegaran1 **( Principle Investigator)** | | | **Title** | Surgical Registrar |
| **Institution** | North Shore Hospital, Takapuna, Auckland | **Dept.** | Surgery | | |
| **Mobile phone** | 021 994 707 | **E-mail** | suheelan.kulasegaran@gmail.com | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | Dr. Carolyn Vassey **(**2nd Investigator**)** | **Title** | Colorectal Fellow |
| **Institution** | North Shore Hospital, Takapuna, Auckland | **Dept.** | Surgery |
| **Mobile phone** | 0272995300 | **E-mail** | Carolyn.Vasey@waitematadhb.govt.nz |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | Sherry Nisbet | **Title** | Surgical Research Nurse |
| **Institution** | North Shore Hospital, Takapuna, Auckland | **Dept.** | Surgery |
| **Mobile phone** | 021 081 64915 | **E-mail** | Sherry.Nisbet@waitematadhb.govt.nz |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | Bacil 'Otutaha | **Title** | University of Auckland 4th year medical student |
| **Institution** | North Shore Hospital, Takapuna, Auckland | **Dept.** | Surgery |
| **Mobile phone** | 021 215 5446 | **E-mail** | botu001@aucklanduni.ac.nz |

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