Pilot study to evaluate the efficacy of Ostom-i alert system at decreasing dehydration related complications in patients with new ileostomies.

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A. Abstract

B. Background/Significance

Ileostomy creation is a common surgery performed in patients who have disease or injury to their colon requiring fecal diversion. The most common causes for ileostomy surgery include Crohn's disease, ulcerative colitis, colon and rectal cancer. Less common causes include bowel obstruction and familial polyposis. Ileostomy formation can be temporary, and is often used to protect anastomoses in colorectal resections. It can also be permanent, when disease or injury is more extensive. All patients undergoing an ileostomy face unique post-operative challenges due to the alteration of absorption and waste elimination pathways. Prior to surgery, patients are counseled about these challenges including the expected increase in frequency of liquid stools, which can have both bothersome and more serious complications.

Hospital readmissions in people who have recently undergone colon and rectal surgery are frequent, and can be costly and delay post-operative healing (Nagle, 2012). Current NSQIP colectomy readmission rates for open and laparoscopic colectomies over the past 12 months at Massachusetts General Hospital were 11.3% and 10.9% respectively. Average national readmission rates for open and laparoscopic colectomies over the past 12 months were 13.2% and 10.7% respectively. The most common reason for hospital readmission following surgery is dehydration, with other causes including infection, bowel obstruction, bleeding, wound dehiscence with leak, and pain (Nagle, 2012).

Dehydration is a serious but preventable complication in patients with new ileostomies. Even small changes in fluid intake or output can cause body fluid imbalances that promote dehydration and necessitate IV rehydration (Messaris, 2012). Previous research has shown that the use of pre-operative teaching, direct patient engagement from post-op day one, engaging patients to perform self-care for their stoma during hospitalization, and having patients track intake and output post-discharge can decrease readmission rates (Nagle, 2012). With implementation of this pathway over the course of 7 months, there was a decrease in the overall 30- day postdischarge readmission rate for patients with new ileostomies from 35.4% to 21.4%, with the rate for dehydration alone falling from 15.5% to 0% (Nagle, 2012).

The Ostom-i alert (OIA) is a discrete novel device which clips onto any ostomy bag from edge to edge and measures the horizontal tension between the edges over time, as a result of stool volume in the ostomy. It is an FDA approved medical device.

Until now, the OIA has been mainly used to warn patients when the ostomy bag is at risk of overflow thereby reducing the risk of leakage causing embarrassment to the patient and caregivers. It can also be used to evaluate the overall output of the ostomy. When patients leave the hospital, the OIA data is sent to the patient's smartphone through bluetooth technology and can be viewed on the internet in real time by the surgical team (stoma nurse, surgeon, clinical research staff). This would allow patients to monitor their output more accurately and allow them to contact clinical staff with questions or to help with bowel management when output is outside of established parameters (too little or too high output).

While all patients with ileostomy have a risk of dehydration, early identification of those at greater risk may lead to home intervention and decreasing hospital readmission. Decreased readmissions ultimately leads to faster post-operative recovery, decreased risk of sequela of readmission (nosocomial infection, pneumonia etc) and decreased healthcare costs.

C. Specific Aims

Study Aims

The aim of the study is to evaluate the efficacy of the Ostom-i device in decreasing readmission rates of subjects in the first 30 days post-operatively.

Hypothesis:

We hypothesize that readmission rates will decrease with use of Ostom-i device.

Primary Outcome:

To demonstrate a reduction in readmission of patients with new ileostomies.

D. Methodology

I. Subject Selection

All patients over the age of 18 undergoing procedures with new ileostomy creation at MGH will be offered the opportunity to take part in the trial. We plan to recruit 30 subjects for Ostom-i monitoring. Once subjects have consented to participate in the trial, they will be educated about the use of the OIA device and smartphone application as well as the discharge instructions. Specific eligibility criteria for participation in the study include: greater than 18 years of age, English speaking, creation of new ileostomy, access to smartphone with bluetooth technology to support OIA application, and must be able to give written consent.

II. Subject Enrollment

All patients who undergo new ileostomy creation at MGH first meet with the ostomy nurses pre-operatively, for an educational session and stoma marking, as per standard of care. All patients scheduled to undergo ileostomies will be offered the opportunity to participate in the study by research nurses. If patients are interested in participating in the study, they will be approached again 24 hours after their surgery, during their first stoma teaching session. Those who wish to participate will be offered the opportunity to ask any questions about the protocol and then sign consent. We will have a total of 30 subjects enrolled and using the device.

III. Study Procedures

Once appropriate IRB approved consent has been given, subjects will be given device and assisted in setting up the OIA app. They will be given education about parameters for ostomy output. All subjects will have additional teaching of specific monitoring parameters and education about the device.

Once subjects are trained on the device, they will monitor outputs on a daily basis including during initial hospitalization until 30 days post-op. Outputs will be recorded by the Ostom-i application, which will be shared via bluetooth technology with the surgeon and research nurses in real time. If outputs are less than 250mL or greater than 1200mL per day, subjects will be alerted by system and subjects will be instructed to call their surgeons who will adjust their medications and fluids accordingly.

Subjects will be monitored until the 30 day post-operative period is completed. Any phone calls to office due to high or low output will be documented. All patients are seen as standard of care by their treating physician and stoma nurses at 4-6 weeks post op. Any readmissions to outside hospitals are documented at the post-op visits.

E. Data Analysis

Intent-to-treat:

While a randomized study design is ideal, due to financial limitations, we are limited to 30 devices and therefore plan to treat a single cohort of 30 patients. The primary analysis outcome will be readmission rate for dehydration, and the analysis of this outcome will utilize an intent-to-treat analysis population including all 30 patients. Established readmissions rates will be used as a historical control group to compare readmission rates. Confounding will be minimized

because subjects will be treated per standard of care in addition to receiving education about the Ostom-i device.

Given previous studies suggesting that more awareness leads to a decrease of admission to 0% (Nagle, 2012), we expect that there will be no more than one readmission among these 30 patients. The study has 90% power to rule out a readmission rate for dehydration ≥15% in favor of a significantly reduced rate of <2% with $p<0.05$ by using an exact test.

If the study results appears promising (i.e., no or only one readmission), given the very low risk to patients, a larger scale randomized controlled trial will be considered by requesting additional funding.

F. Potential Benefits and Risks, Monitoring and Quality Assurance

I. Benefits

It is hoped that the OIA device will be able to provide more accurate real-time monitoring of ostomy output that will ultimately reduce readmission rates due to dehydration by allowing better management of fluids and hydration post-operatively. The results of this study may benefit future subjects long-term by allowing subjects access to technology which will influence the post-op treatment of dehydration and fluid imbalance following ileostomy surgery.

II. Risks and discomfort

This is a pilot study in which subjects will be followed by standard of care post-operative management with the exception that Ostom-i subjects will have a way to measure and transmit their stoma output to their provider in real time. This in theory should decrease subjects risk for dehydration. Subject data including outputs, phone calls, and any hospital admissions or EW visits for hydration will be shared with the surgeon/NP and documented. All subjects have the option to refuse or discontinue participation at any point during the study. Medical records and research materials will be kept confidential and in a password protected database. Subjects will be followed for post operative management as per standard of care.

The OIA device is discrete and is worn over the ostomy bag, underneath the subject's clothing. Subject information will only be shared with the subject's providers (MD, NP) and with the researchers participating in this study.

III. Monitoring and Quality Assurance

Monthly meetings will be organized to allow monitoring of recruitment of subjects, and to assure adherence of the IRB protocols. Unanticipated problems involving risks to subjects or others, including adverse events will be reported to the PHRC in accordance with PHRC reporting guidelines within 5 working days or 7 calendar days of the date the investigator first becomes aware of the problem. Accuracy and completeness of data collection, case report form entries, source documents and informed consent will also be reviewed. IRB will be notified of any major unforeseen complications associated with the study.

G. Appendix E: Case Report Forms

Complication/Unanticipated Event

SUBJECT NO. ☐☐☐ **INITIALS:** ☐☐☐

DATE OF SURGERY: ☐☐-☐☐-☐☐☐☐

DATE OF DISCHARGE: ☐☐-☐☐-☐☐☐☐

DATE OF 30 DAYS POST-OP: ☐☐-☐☐-☐☐☐☐

Follow-up Interval:

☐Screening ☐Post-operative period ☐ 4-6 week post-op visit.

List any complaints, adverse reactions, or problems noted by subject below.

Date of event	Details of event	Intervention

Patient Phone Log

SUBJECT NO. ☐☐☐ **INITIALS:** ☐☐☐

DATE OF SURGERY: ☐☐-☐☐-☐☐☐☐

DATE OF DISCHARGE: ☐☐-☐☐-☐☐☐☐

DATE OF 30 DAYS POST-OP: ☐☐-☐☐-☐☐☐☐

Date of phone conversation	Total output (in mL) in last 24hr prior to call	Action taken	Date of follow-up phone conversation	Resolution	Caller

30 Day Post-Operative Report

SUBJECT NO. ☐☐☐ **INITIALS:** ☐☐☐

DATE OF SURGERY: ☐☐-☐☐-☐☐☐☐

DATE OF DISCHARGE: ☐☐-☐☐-☐☐☐☐

DATE OF 30 DAYS POST-OP: ☐☐-☐☐-☐☐☐☐

Date of appointment	Outcome	Provider Plan	Name of Provider Answering
	□ IV fluids □ Improvement	□ increase fluids □ medication specify: _____ □ office visit	
	□ IV fluids □ Improvement	□ increase fluids □ medication specify: _____ □ office visit	
	□ IV fluids □ Improvement	□ increase fluids □ medication specify: _____ □ office visit	
	□ IV fluids □ Improvement	□ increase fluids □ medication specify: _____ □ office visit	
	□ IV fluids □ Improvement	□ increase fluids □ medication specify: _____ □ office visit	

I. Appendix F: References

REFERENCES

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