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THE EFFECT OF PREOPERATIVE STOMA SITE MARKING
ON QUALITY OF LIFE IN PATIENTS UNDERGOING OSTOMY SURGERY

BY

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THESIS

Submitted to the University of New Hampshire

in Partial Fulfillment of

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in

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ABSTRACT**THE EFFECT OF PREOPERATIVE STOMA SITE MARKING
ON QUALITY OF LIFE IN PATIENTS UNDERGOING OSTOMY SURGERY**

by

Susan Cantara

University of New Hampshire, September, 2008

The purpose of this study was to determine if preoperative stoma site marking by a Wound, Ostomy, Continence (WOC) nurse affects patient quality of life. This study used a descriptive design with a convenience sample of 25 ostomy patients. Sixty-three surveys were mailed to study participants and the response rate was 40%.

Ten subjects (40%) had their stoma site marked by a WOC nurse preoperatively and fifteen subjects did not. Eleven participants reported that their ostomy was permanent (44%), while fourteen of the participants (56%) state they had a temporary stoma. Thirteen of the subjects had elective ostomy surgery (52%) and twelve (48%) had an ostomy created under emergent conditions.

Overall quality of life scores did not differ between the marked and unmarked subjects. However, subjects who did not have their stoma site marked preoperatively had greater problems with pouch leakage ($p=.0055$) than those who were marked preoperatively.

CHAPTER I

INTRODUCTION

When patients have surgery that lead to the creation of an ostomy, whether it is a colostomy, ileostomy, or urostomy, they face many challenges in adapting to their altered body image and body function (Orsted, 2007). Adaptation to an ostomy is not always easy. The effect of having a stoma may be quite profound and cannot always be predicted. It is thought that the psychological effects of stoma creation are greater than the overall physical effects (Orsted, 2007). A person with an ostomy may grieve the loss of organs and normal body function, relocation of a body orifice, and possibly loss of fertility and libido which can all contribute to changes in quality of life.

With the increase in life-expectancy in the post-World War II era and the growing number of patients suffering from chronic diseases, life quality has taken on an importance almost equal to life quantity (Snoek, 2000). Quality of life was introduced by MEDLINE as a heading in 1975, and accepted as a concept by Index Medicus in 1977 (Bowling, 1995). Since the 1970's, there has been an explosion of interest in the subject, with an increasing number of citations of quality of life in the medical literature (Bowling, 1995).

Health-related quality of life is now recognized as an important issue in the management of chronic diseases and is widely monitored in chronically ill patients (Sen, Gupchup & Thomas, 1999). Today's concept of health related quality of life includes three domains: biological functioning, psychological functioning, and social functioning (Orsted, 2007). Measurements of quality of life are used in the evaluation of treatment and the allocation of resources for chronic diseases.

An ostomy is a surgical opening into the intestine or urinary tract for external drainage. The word stoma is derived from Greek and means mouth. A stoma is located on the abdomen and is where the ostomy drains stool or urine. Patients with specific conditions of the gastrointestinal, urinary, and reproductive systems sometimes require surgery that removes or controls disease, but necessitates the creation of a stoma.

The concept of a stoma was in existence long before these external openings could be created surgically. Anecdotal accounts of stomas can be found in writings dating back as early as 1750. One such account tells of a patient who developed a "spontaneous colostomy" as the result of a strangulated hernia (Rozen, 1997). In the late 1800s, surgical procedures that resulted in stoma formation became more common due to advances in anatomy, pathology, and anesthesia.

As ostomy surgery became more commonplace, the need for greater attention to quality of life issues emerged. Dr. Rubert Turnbull, Jr. of the Cleveland Clinic was the first to recognize that patients who required an ostomy needed counseling and support to help with their adaptation to living with an ostomy (Rozen, 1997). Dr. Turnbull hired a former patient who had a permanent ileostomy to meet with his patients and provide practical information relative to living with an ostomy. In 1968, Dr. Turnbull met with several former patients of the Cleveland Clinic and formed the first enterostomal therapy program. In 1971, the organization officially changed its name to the International Association of Enterostomal Therapists (Rozen, 1997). Membership in the Association began with lay “ostomy teachers” who were typically patients that were living with an ostomy. Eventually the position of the Enterostomal Therapy (ET) nurse was developed as the role expanded to include not only care of ostomy patients, but also management of patients with wounds and continence problems. In the late 1990s, the International Association of Enterostomal Therapists changed its name to the Wound, Ostomy, and Continence Nurse’s Society (WOCN).

The Wound, Ostomy, Continence (WOC) nurse plays an essential role in the preoperative preparation of persons undergoing ostomy surgery. One of the most important tasks performed by the WOC nurse, stoma site marking, is advocated in nursing textbooks on principles of ostomy nursing (Colwell & Gray, 2007). A poorly positioned stoma will result in appliance malfunction, skin

problems, herniation, and require either local revision or relocation of the stoma (Fleshman & Lewis, 2007). Because of the potential for complications related to poor stoma location, it is best to mark the potential stoma site before the patient is under anesthesia. Marking the stoma site before anesthesia is administered allows the WOC nurse to evaluate style of dress, life style, body habitus, and activity level when considering the best position for the anticipated stoma (Fleshman & Lewis, 2007).

Preoperative stoma site marking by the WOC nurse is preferred over other care providers because the WOC nurse has specialized training on how to assess the patient for correct location of the stoma site. When marking a stoma site, the rectus muscle is identified and the site is located within the border of the rectus muscle. The site selected must avoid skin folds, deep creases, scars, bony prominences, and the belt line. The selected site must provide approximately 2.5 inches of abdominal surface for adhesion of the pouching system. Once a site is selected, the patient needs to be able to look down and visualize the sight. The WOC nurse also provides assessment of the patient's overall physical ability which includes eyesight, dexterity, physical strength and mobility. The WOC nurse assesses the patients other interests, hobbies, and occupation which might influence stoma placement in terms of posture and movement. This detailed assessment by the WOC nurse requires approximately 60-90 minutes to perform.

According to Kelman and Minkler (1989), quality of life is synonymous with many terms: symptom distress, social dependence, life satisfaction, physical condition, normal activities, personal attitudes and “that which makes life worth living”. Quality of life encompasses self-care and the physical, psychological, social and economic factors which could affect a patient’s self-esteem. Living with a stoma may have a significant effect on any or all of the factors which contribute to quality of life (Azizah, Yunos, Choen & Keng, 1998). Adjustment to an ostomy is difficult and lengthy under the best of circumstances. Maladaptive behaviors are exacerbated when an ostomy is constructed poorly or positioned poorly on the abdominal wall (Rozen, 1997). This is because stomas that are poorly located lead to leaking ostomy pouches, skin irritation, social isolation, disturbed sleep as well as many other negative consequences.

An early study by Leenan and Kuypers (1989), found the overall complication rate for patients who had a stoma created to be 36%. Ratliff, Scarano and Donovan (2005) found a 16% stoma complication rate, with the highest rate being among subjects with a urostomy. The decrease in stoma complication rate during the sixteen year span is puzzling. There is no clear reason for the decrease, but advances in minimally invasive and laparoscopic surgical techniques as well as the increase in specialty ostomy products may account for some of the variation. Many people who undergo ostomy surgery will likely

experience some type of complication during the time that they live with their stoma. Stoma complications cause day to day management issues as well as emotional, psychological and possibly financial problems that can have a negative impact on quality of life (Turnbull, 2003).

It is generally accepted that preoperative stoma site marking can reduce complications related to poor pouch wear time, leakage, and skin irritation in some patients. However, there is sparse research evidence that demonstrates that preoperative stoma site marking by a WOC nurse can decrease stoma complications. No research evidence exists that demonstrates that preoperative stoma site marking by the WOC nurse can increase patient quality of life.

CHAPTER 2

REVIEW OF LITERATURE

Preoperative stoma site marking is recommended by the American Society of Colorectal Surgeons (ASCRS) Clinical Practice Guidelines for enterostomal therapy. In 2007, the ASCRS and the WOCN published a joint position statement on the value of preoperative stoma marking for patients undergoing fecal ostomy surgery (ASCRS & WOCN, 2007). It is generally accepted by these experts that preoperative placement of the stoma site can reduce the complications related to poor pouch wear time, leakage, and skin irritation in some patients.

A review of the literature was conducted in the electronic databases MEDLINE, CINAHL, Pre-CINAHL, CINAHL Plus, Nursing and Allied Health Collection Basic, Health Star, Cancerlit, Health Source Nursing/ Academic Edition, and the Cochrane Database. The review was undertaken using the following key words and search terms: quality of life, stoma site marking, ET nurse, WOC nurse, stoma, ostomy, colostomy, and stoma complications. The literature review yielded three studies that discussed preoperative stoma site marking, two studies that looked at the effects of stoma creation on quality of life,

and one literature review that reviewed three studies that looked at preoperative stoma site marking and its impact on surgical outcome. No published studies were found that looked at the effect of preoperative stoma site marking on patient quality of life.

Cottam (2005) found that body mass index (BMI), diabetes, and emergency surgery were significant risk factors for complications. BMI is a calculation of height and weight that classifies subjects into one of the following four categories: underweight (BMI \leq 18.5), normal weight (BMI between 18.5-24.9), overweight (BMI between 25 -29.9), and obesity (BMI of 30 or greater). Almost two thirds of Americans are affected by overweight or obesity (Eckel, 2008).

Bass, DelPino, Tan, Pearl, Orsay, and Abcarian (1997) conducted a retrospective study with a sample of 593 patients who had elective ostomy surgery. The enterostomal therapy (ET) nurse marked 292 of the patients preoperatively (Group I), and 301 were not marked (Group II). The dependent variable, postoperative stoma complications, was well defined in this study. The authors defined early complications as those occurring within 30 days of surgery and late complications as those occurring 30 days after surgery. The authors did not define "skin problems" which was the most commonly occurring postoperative complication. Several of the measured complications such as necrosis, stenosis, prolapse, peristomal hernia, bleeding, and fistula formation

are more likely to be affected by surgical technique rather than stoma position on the abdominal wall (Fleshman & Lewis, 2007).

The total number of overall complications in Group I was 32.5% and 43.5% in Group II (Bass et al., 1997). The difference in total complications was found to be statistically significant. The authors found the difference in early complications to be statistically significant, however the difference in late complications was not statistically significant. This study was limited in that the two groups did not have the same surgical procedure and were left with varying lengths of bowel segment. A longer length of bowel segment provides more normal stool consistency and is less apt to create leakage problems. The study demonstrated statistical and clinical significance for preoperative stoma site marking.

The second study conducted by Sawa, Meisner, and Wille-Jorgensen (1999), reported that stoma site marking was indicated for all emergency colorectal surgery and for any elective surgery with a chance of stoma formation. This study used a retrospective design with a sample of 192 patients who had surgery for colorectal cancer. Preoperative stoma site marking was used in 75% of emergency operations and 65% of elective operations. The study reported a 30% complication rate, but did not specify in which group. The results and discussion did not support the author's stated objective of promoting preoperative stoma site marking for patients affected by colorectal cancer. The authors

assumed that stoma site marking preoperatively was necessary to decrease postoperative stoma complications. Data could have been analyzed by complications in patients marked and not marked preoperatively, which would have been helpful in determining if stoma site marking was valuable or not.

Park, DelPino, Orsay, Nelson, Pearl, Cintron, and Abcarian (1999) conducted the third study found on stoma complications. This was a retrospective study with a sample of 1,616 patients having had stomas created by various surgical services at one hospital over a span of 20 years. Data was analyzed using a logistic regression model to determine those variables that were predictive of increased stoma complications. The variables analyzed were age, weight, gender, operating service, preoperative stoma site marking by the ET nurse, emergency status, stoma type, and stoma configuration. Variables that were found to influence postoperative stoma complications were patient age, operating service, stoma type and configuration, and preoperative stoma site marking by the ET nurse. Logistic regression analysis demonstrated that preoperative stoma site marking by the ET nurse decreased the incidence of postoperative stoma complications, however the relationship was not seen when early and late complications were evaluated separately.

Azizah et al. (1998) studied the effects of stoma creation on quality of life in a random sampling of 47 patients from a large tertiary teaching hospital in Singapore. The authors stated that quality of life encompasses self care and the

physical, psychological, social and economic factors which can affect a patient's self-esteem. The authors reported that 57% of respondents had not suffered any loss of control or independence, while 43% felt their activities had been restricted since their operation and that they were not able to engage in any strenuous activity. Eighty-seven percent of respondents indicated they were responsible for self-care of the stoma, while 13% required help from their spouses due to poor eyesight, arthritis, or prior stroke. The majority of the respondents, 66%, did not feel their stoma had adversely affected other family members. Thirty-six percent of respondents had experienced problems in sexual relationships. There was no discussion of the instrument used to collect the data. The authors concluded that in general, the patients seemed to cope well with their stoma.

Nugent, Daniels, Stewart, Patankar, Johnson, and Chir (1999) also studied the quality of life in stoma patients. The authors had patients recall whether or not their stoma site was marked by an ostomy nurse, but did not analyze this variable. The authors summarized that preoperative stoma siting and counseling was deficient, despite the fact that 42% of patients with a colostomy and 61% of patients with an ileostomy recalled the stoma site being marked preoperatively.

Collwell and Gray (2007) conducted a review of the literature and found three studies that looked at preoperative stoma site marking and how it impacted surgical outcome. The authors stated that there was insufficient evidence to

conclude that preoperative stoma site marking reduced the incidence of postoperative complications. One of the three studies in the literature review was published in Lithuanian with a very brief English-language abstract. This made it impossible to draw conclusions about the methodology or its impact on the existing evidence. The studies used in the review were limited by many factors including preoperative stoma site marking being combined with preoperative teaching, combination of emergent and elective cases, preoperative stoma site marking being done by both ostomy nurses and “other” nurses, and the comparatively small number of non-sited stomas.

In summary, a review of the literature revealed only three studies and one literature review that discussed preoperative stoma site marking. Two of the three studies could demonstrate a clear benefit to preoperative stoma site marking. There was insufficient evidence in the literature review to suggest that preoperative stoma site marking by a WOC nurse would reduce the incidence of postoperative complications. One study was found that discussed quality of life in patients that have a stoma, but there was no mention of preoperative stoma site marking. Very little research has been done in this area to demonstrate that preoperative stoma site marking by the WOC nurse decreases stoma complications and improves patient outcomes. No studies were found that discussed stoma site marking in relation to quality of life.

The specific aim of this study was to determine if preoperative stoma site marking by the WOC nurse affects patient quality of life.

CHAPTER 3

METHODOLOGY

Research Design

A descriptive design was used to answer the research questions of this study.

Research Questions

The purpose of this study was to determine if preoperative stoma site marking by the WOC nurse affects patient quality of life with the following research questions:

1. Does quality of life differ from those marked and those not marked preoperatively by a WOC nurse?
2. How does preoperative stoma site marking by a WOC nurse affect stoma complications?
3. Is there a positive relationship between stoma complications and quality of life?

Setting

This study took place at a 600 bed tertiary care hospital. The setting was selected because approximately 20 ostomy surgeries are performed each month across the various surgical specialties.

Sample/Subjects

The subjects included a convenience sample of patients who had undergone ostomy surgery between 1/1/07 and 6/30/07. Participants were selected if they had a colostomy, ileostomy, or urostomy, and were 18 years of age or older. Power analysis was performed to determine adequate sample size. For a large effect 26 subjects were needed, and 87 were needed for a moderate effect (Cohen, 1988). The recruitment of 87 subjects was beyond the scope of this study. The decision was made to look at data in a descriptive manner.

Instrument

The questionnaire used for this study was adapted by the investigator from the City of Hope Quality of Life Ostomy Tool. The original tool was created by Grant, Ferrell, Dean, Uman, Chu, and Krouse in 2004 and was developed as a comprehensive, multidimensional, self-report questionnaire for measuring quality of life in patients with intestinal ostomies. The conceptual framework used to develop the original tool focuses on four dimensions of quality of life: physical well-being and symptoms, psychological well-being, social well-being, and spiritual well-being (Grant et al., 2004). Reliability of the original tool was computed by the authors with Cronbach's alpha of .95 (Grant et al., 2004). Content validity of the original tool was supported with interviews of patients with ostomies, review of the questionnaire by a panel of experts, and

consideration of the literature (Grant et al., 2004). Construct validity for the tool was established using a factor analysis technique. The three most important factors were found to be psychological well-being, physical well-being, and symptom control (Grant et al., 2004).

The original tool posed several open ended questions to the respondent. These open ended questions required a different type of analysis and were therefore omitted for the purpose of this study. Two questions were added by the researcher to elicit whether the stoma site was marked preoperatively and if the surgery was emergent or elective. The adapted questionnaire contained 56 items and required approximately 20 minutes to complete. Demographic data was collected in the first eleven questions, sexual satisfaction was addressed in the next four yes/no questions, followed by ten questions on psychological concerns, clothing, and diet. The next 31 questions were rated on a scale of 0-10 and looked at the physical and psychological variables of quality of life. Twenty-three of the questions are ranked as "0" being no problem and "10" being a severe problem. The remaining eight questions are ranked in the reverse order with "0" being a severe problem and "10" being no problem. No identifying data was requested on the questionnaire.

Protection of Human Subjects

Approval for this study was obtained from the Institutional Review Board of the University of New Hampshire. Permission was obtained from the hospital's Institutional Review Board before the study was conducted.

Research Protocol

The Clinical Coordinator for Surgical Research in the Department of Surgery identified subjects based on ostomy Current Procedural Terminology (CPT) codes. The CPT codes used are listed in Appendix A. Once patients with ostomy CPT codes were identified, mailing addresses were obtained by the Clinical Coordinator for Surgical Research from the patient records department.

Subjects that had a colostomy, ileostomy or urostomy and were 18 years of age or older were invited to participate in the study. Subjects were excluded from the study if their surgery was performed by any of the pediatric surgeons. A research packet containing a letter of invitation, survey explanation, questionnaire with a stamped return envelope, and a complimentary ostomy product as an incentive for participating in the study was mailed to 63 patients. The research packet was mailed by the Clinical Coordinator for Surgical Research in the Department of Surgery within two months of surgery. Consent was implied by the patient's voluntary completion and return of the survey.

Data Protection and Analysis

The primary investigator did not have access to any names and addresses and no identifying data was requested on the questionnaire. Data was coded and entered into the Statistical Packages for the Social Sciences (SPSS) program version 15.0. Descriptive and inferential statistics were utilized to analyze the data. Frequencies were calculated on the quality of life and demographic variables. The measure of central tendency was analyzed using mean scores and standard deviations were used to analyze measures of dispersion. T tests were performed on the physical and psychological variables between marked and unmarked subjects.

CHAPTER 4

RESULTS AND DISCUSSION

Sample

Sixty-three surveys were mailed to study participants after being identified by ostomy CPT codes. The response rate was 40% (n= 25). Four surveys were returned as unable to deliver.

The mean age of subjects was 55.3 years of age (SD 12.6, range 25-77 years of age). Ten subjects had their stoma site marked by a WOC nurse preoperatively (40%), and 15 subjects (60%) did not. Males represented 56% of the sample. Most of the subjects had an ileostomy (52%). Table 1 summarizes the distribution of ostomy by type.

Table 1**Ostomy Types**

Type of Ostomy	n	Percent
Ileostomy	13	52%
Colostomy	8	32%
Urostomy	4	16%

Subjects were asked to identify the illness that led to the creation of their stoma. Illnesses included inflammatory bowel disease (ulcerative colitis, familial adenomatous polyposis, and Crohn's disease), diverticular disease, cancer of the colon, rectum or bladder, and other varied diagnoses from "massive fecal blockage" to rectovaginal fistula. Table 2 summarizes the percent of illness leading to stoma formation.

Table 2**Illness Leading to Stoma Formation**

Illness	n	Percent
Inflammatory Bowel Disease	8	32%
Diverticular Disease	5	20%
Cancer of Colon or Rectum	3	12%
Bladder Cancer	3	12%
Other Illness	6	24%

Eleven participants reported that their ostomy was permanent (44%), while fourteen of the participants (56%) stated they had a temporary stoma.

Thirteen of the subjects had elective ostomy surgery (52%) and twelve (48%) had an ostomy created under emergent conditions.

Quality of Life

Findings were analyzed to show how the demographic variables (age, marked vs. unmarked, gender, elective vs. emergent, permanent vs. temporary, illness, and type of stoma) related to quality of life and extent of physical and psychological problems experienced.

Using the mean age of 55.3 years, quality of life did not differ significantly for those older than 55 and those younger than 55, with mean quality of life scores of 6.92 (SD 3.08) and 6.36 (SD 2.61) respectively. Mean quality of life scores did not differ between patients marked preoperatively and those not, with mean scores of 6.7 (SD 2.8) and 6.6 (SD 3.0) respectively. Mean quality of life in male subjects was 7.2 (SD 2.6) and 6.0 (SD 3.1) in female subjects, and was not statistically significant. Quality of life did not differ between subjects with a permanent or temporary ostomy with mean scores of 6.4 (SD 3.2) and 6.9 (SD 2.5) respectively. Mean quality of life scores did differ between elective and emergently constructed stomas. Elective procedure's had lower mean quality of life at 5.9 (SD 3.2) than emergent procedures at 7.7 (SD 2.0).

The highest quality of life score was reported by the one subject with Familial Adenomatous Polyposis (FAP), while the lowest quality of life scores were reported by subjects with Crohn's Disease. Table 3 summarizes mean quality of life scores by illness.

Table 3**Mean QOL by Illness**

Illness	n	Mean QOL	Standard Deviation
FAP	1	9.0	0
Diverticulitis	5	8.3	2.2
Ulcerative Colitis	3	8.3	1.5
Rectal Cancer	2	6.0	4.2
Bladder Cancer	3	5.3	4.0
Colon Cancer	1	4.0	0
Crohn's Disease	4	3.8	2.2

Mean quality of life scores were higher among subjects with a colostomy at 7.3 (SD 3.3) than for subjects having a urostomy or ileostomy. A one-way ANOVA revealed no significant differences among the means of subjects with a colostomy, ileostomy or urostomy. Table 4 summarizes mean quality of life by type of stoma.

Table 4**Mean QOL by Stoma Type**

Type of Stoma	n	Mean QOL	Standard Deviation
Colostomy	8	7.3	3.3
Ileostomy	13	6.9	2.3
Urostomy	4	4.8	3.5

Further analysis between subjects marked and not marked was performed using the physical and psychological dimensions in the tool. Patients not marked preoperatively had greater problems of pouch leakage ($t= 3.16$, $p=.0055$) than those that were marked. The standard deviations in quality of life scores by variable were very large, showing great variation among subjects. Table 5 compares the mean scores of the physical and psychological dimensions between the marked and unmarked subjects.

Table 5**Mean Scores Physical/Psychological Dimensions**

Physical/ Psychological Dimensions	Marked (n=10)	Unmarked (n=15)
Privacy at Home	9.7 (SD 0.9)	8.4 (SD 2.6)
Support by Others	7.4 (SD 3.2)	7.0 (SD 3.6)
Privacy when Traveling	6.6 (SD 2.4)	5.0 (SD 3.5)
Satisfying Appearance	6.6 (SD 3.4)	4.9 (SD 2.9)
Feel in control	6.2 (SD 2.7)	5.1 (SD 3.5)
Life Satisfaction	6.0 (SD 3.2)	6.1 (SD 2.8)
Sleep Disturbance	5.2 (SD 3.7)	4.2 (SD 3.1)
Family Distress	4.8 (SD 3.2)	6.2 (SD 3.6)
Positive Life Change	4.6 (SD 4.1)	3.2 (SD 3.7)
Adjustment to Stoma	4.5 (SD 3.2)	4.6 (SD 2.7)
Odor Problem	4.2 (SD 3.6)	3.2 (SD 2.0)
Embarrassed	4.0 (SD 3.6)	3.0 (SD 3.3)
Interferes with Sports	3.8 (SD 3.5)	5.6 (SD 3.7)
Interferes with Intimacy	3.8 (SD 4.3)	6.8 (SD 4.0)

Table 5 (Continued)**Mean Scores Physical/Psychological Dimensions**

Physical/ Psychological Dimensions	Marked (n=10)	Unmarked (n=15)
Anxiety	3.6 (SD 3.6)	4.3 (SD 3.1)
Interference with Travel	3.6 (SD 3.3)	5.4 (SD 3.2)
Passing Gas	3.4 (SD 2.5)	2.6 (SD 1.7)
Fatigue	3.2 (SD 3.4)	3.0 (SD 2.6)
Interferes with Social Life	3.2 (SD 2.7)	5.7 (SD 3.1)
Physical Wellbeing	3.1 (SD 3.3)	2.9 (SD 2.3)
Depression	2.5 (SD 3.0)	2.9 (SD 2.2)
Diarrhea	2.4 (SD 3.2)	1.8 (SD 1.9)
Skin Irritation	2.4 (SD 1.5)	4.2 (SD 3.3)
Looks at Stoma	2.3 (SD 3.6)	2.8 (SD 2.9)
Leaking Pouch	2.2 (SD 2.3)	6.1 (SD 3.4)*
Cares for Self	1.8 (SD 2.0)	3.5 (SD 3.4)
Isolation	1.8 (SD 2.8)	3.5 (SD 3.3)

*p=.0055

Table 5 (Continued)**Mean Scores Physical/Psychological Dimensions**

Physical/ Psychological Dimensions	Marked (n=10)	Unmarked (n=15)
Interference with Relationships	1.7 (SD 1.7)	3.2 (SD 3.3)
Difficulty Meeting People	1.5 (SD 2.1)	1.9 (SD 2.1)
Constipation	1.1 (SD 1.9)	1.3 (SD 2.1)

The mean weight of the subjects in this study was 157 pounds, with a range of weights from 92-225 pounds (SD 37.9). In this study, 36% of the sample was either overweight or obese. Mean BMI was calculated to be 24.1 (SD 4.8) in this study. Table 6 looks at the distribution of BMI between the four categories.

Table 6**Distribution of BMI**

Weight	Percent of Sample	Percent Male	Percent Female	Mean QOL
Underweight n=3	12%	0%	100%	3.0
Normal Weight n=13	52%	61.5%	38.5%	6.9
Overweight n=5	20%	60%	40%	6.8
Obese n=4	16%	75%	25%	8.5

Data on comorbidities, such as diabetes, was not collected in this study.

There is some evidence that suggests that the subjects that had an emergently created stoma did have a higher incidence of stoma complications and 84.6% (n=11) of these stomas were unmarked.

Discussion

Although quality of life did not differ between the marked and unmarked subjects, certain of the measured variables did have some extremes in reporting

between the two groups. When subjects were asked if the location of their stoma caused a problem, 30% of the marked group reported it to be a problem compared to 73.3% of the unmarked group that reported the location of their stoma to be a problem.

One possible reason that could account for the fairly consistent quality of life between the two groups was that 80% of subjects (n=12) with an unmarked stoma site also had a temporary stoma that will be reversed in the future. Eighty percent of the marked patients had a permanent stoma that they will have for the rest of their life. Also of interest, 76.9% of patients who had their stoma created emergently had a temporary stoma. This could account for the higher quality of life in that group. Mean quality of life was also higher in subjects with a temporary stoma 6.92 (SD 2.5) than those with a permanent stoma 6.36 (SD 3.2), but did not reach statistical significance.

It would seem that despite problems with pouch leakage, skin irritation, social isolation, poor stoma location, and other cited complications, the unmarked group of subjects had no difference in quality of life as those in the marked group. It would also seem that preoperative stoma site marking by the WOC nurse did have an impact on the incidence and severity of a few stoma complications, such as leakage and skin irritation. Data in this study does suggest that subjects that had an emergently created stoma did have a higher incidence of stoma complications and 84.6% of these stomas were unmarked.

Although the number of participants in this study may have been too small to detect a difference in quality of life between marked and unmarked patients, Bass et al. (1997) found that $NNT=9$. This is interpreted as nine patients would need to have their stoma site marked preoperatively in order to prevent complications in one patient. This is clinically significant in light of the fact that no harm is done when a stoma site is marked.

BMI was found to be a contributing factor in other studies (Cottam, 2005). This did not have an impact on stoma complications in this study as one might expect.

CHAPTER 5

CONCLUSION AND IMPLICATIONS FOR PRACTICE

Conclusions

Overall quality of life did not differ between those subjects marked and those not marked preoperatively by the WOC nurse. Mean quality of life scores were nearly equal between the two groups.

Preoperative stoma site marking by the WOC nurse did have an impact on complications. Increased incidence of pouch leakage was noted in patients that did not have their stoma site marked preoperatively. This complication can be very problematic for persons living with an ostomy. It can cause a vicious cycle of pouch leakage followed by skin denudation and inability to maintain pouch seal due to skin irritation which leads to more pouch leakage. This study was unable to establish a positive relationship between the incidence of stoma complications and quality of life.

Study Limitations

Typical response rates for mailed questionnaires are between 30% and 60% (Fain, 1999). The response rate of this study was 40%, which falls within that range. The 40% response rate does represent a problem in that there could be some degree of bias. Perhaps subjects with higher quality of life were more

likely to return the questionnaire than those with poorer quality of life. No reasonable assumptions can be made about those that did not respond.

The sample size of this study was $n=25$. A sample size of 26-87 subjects would have been needed to determine moderate to large effect in the sample. This study is limited as it is a convenience sample and does not have enough subjects to generalize the findings to a larger population. The sample also may not be a representative sample of ostomy patients at large. Further research with a larger sample size is needed to support the findings of this study.

This study was conducted at one institution. This may have limited the sample selection. Future research should be done at other institutions to determine if the findings of this study can be generalized between institutions.

The tool used for this study was originally developed to study quality of life in cancer patients with intestinal ostomies. Therefore it may not be valid for urostomy patients or patients with a diagnosis other than cancer.

Recommendations

Preoperative stoma site marking is a very low risk procedure. It helps to establish a relationship between the patient and the WOC nurse so that postoperative ostomy teaching can be more successful. The potential for clinical benefit would suggest that all patients who are to undergo ostomy surgery have their stoma site marked preoperatively by the WOC nurse. Recommendations

for further research in this area would include establishing reliability and validity of the revised tool used in this study, having a larger sample size, and conducting a multi-site study.

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APPENDIX A**OSTOMY CPT CODES USED TO IDENTIFY SUBJECTS**

44320, 44322, 44188, 44143, 45805, 45825, 44141, 44206, 45110, 44160,
45563, 57307, 4414, 45126, 44310, 44187, 44155, 44144, 44150, 44212,
44210, 45395, 43845, 44157, 44158, 50727, 50728, 50820, 51590, and
51595.

APPENDIX B**UNIVERSITY OF NEW HAMPSHIRE IRB APPROVAL**

University of New Hampshire

Research Conduct and Compliance Services, Office of Sponsored Research
Service Building, 51 College Road, Durham, NH 03824-3585
Fax: 603-862-3564

12-Jan-2007

Cantara, Susan
Nursing, Hewitt Hall
14 Westwood Drive
Biddeford, ME 04005

IRB #: 3873**Study:** The Effect of Preoperative Stoma Site Marking on Quality of Life in Patients Undergoing Ostomy Surgery**Approval Date:** 10-Jan-2007

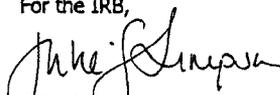
The Institutional Review Board for the Protection of Human Subjects in Research (IRB) has reviewed and approved the protocol for your study as Exempt as described in Title 45, Code of Federal Regulations (CFR), Part 46, Subsection 101(b). Approval is granted to conduct your study as described in your protocol.

Researchers who conduct studies involving human subjects have responsibilities as outlined in the attached document, *Responsibilities of Directors of Research Studies Involving Human Subjects*. (This document is also available at <http://www.unh.edu/osr/compliance/irb.html>.) Please read this document carefully before commencing your work involving human subjects.

Upon completion of your study, please complete the enclosed pink Exempt Study Final Report form and return it to this office along with a report of your findings.

If you have questions or concerns about your study or this approval, please feel free to contact me at 603-862-2003 or Julie.simpson@unh.edu. Please refer to the IRB # above in all correspondence related to this study. The IRB wishes you success with your research.

For the IRB,



Julie F. Simpson
Manager

cc: File
Fetzer, Susan

APPENDIX C

MAINE MEDICAL CENTER IRB APPROVAL



OFFICE OF RESEARCH ADMINISTRATION

To: Susan Cantara, RN
14 Westwood Drive
Biddeford, ME 04005

Re: Notice of Exemption

(IRB# 3118X) The Effect of Preoperative Stoma Site Marking On Quality of Life in Patients Undergoing Ostomy Surgery

Date: 03/22/2007

This is to inform you that on 03/22/2007 Maine Medical Center IRB has exempted the above research project from review. The purpose of this study is to determine if preoperative stoma site marking by the Wound, Ostomy, Continence nurse affects patient quality of life. This project is Exempt from review on March 22, 2007 according to federal regulation 45 CFR 46.101(b)(2)(i)(ii).

Please be aware that this action will be brought before the full board for its sanction at the meeting on 04/24/2007.

Please call our office if you have any questions about the terms of this approval (Kristen Sullivan, 207-885-8195).


Jan L. Trott, CIP, IRB Chairperson Pro-Tem

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