[1]**Study Protocol**

"IMPACT OF A PREOPERATIVE OUTPATIENT EDUCATION PROGRAM FOR OSTOMY PATIENTS: A COHORT-COMPARATIVE PILOT STUDY"

Introduction

Data reported from Spanish Ostomy Association estimate that 1.5‰ of total population are living with an ostomy.[1] Colorectal cancer is the most common diagnosis associated with stoma formation (80% of the total cases), followed by inflammatory bowel disease in about eight per cent.[2] Currently there´s no doubt about the role of specialized nurse in health education relative to stoma care and adaptation process. Preoperative stoma site marking is widely recommended by the main Scientific Societies related to colorectal and urological cancer. It is one of the most impactful measures provided by stoma care specialist nurses, as patients have less stoma-related complications and higher postoperative health-related quality of life scores.[3-5]

Stoma creation after colorectal surgery is recognized in some studies as an independent cause of prolonged hospital stay and readmissions.[6-7] However, other publications have not confirmed this point. Gumbao et al, in a retrospective study, reported no differences in postoperative complications or postoperative stay including readmissions between patients who underwent anterior rectal resection and anastomosis with or without a diverting ileostomy, in the setting of a multidisciplinary team and a multimodal rehabilitation program.[8] Studies suggest that preoperative education and counseling has proven to result in significantly better competence in self-care stoma and enhancement in self-management of complications.[9-10] Nevertheless, there is a lack of data regarding the optimal timing of planned teaching. Studies developed in other fields like breast cancer surgery, indicate that women

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postoperatively experience a decreased ability to direct attention and perform tasks.[11] This is consistent with the study published by Cupples concerning recovery from cardiac surgery, concluding that patients who received education 5 to 14 days preoperatively, a preoperative phone call, as well as postoperative teaching, had higher preoperative knowledge and lower postoperative anxiety states than patients who only received preoperative teaching after admission to the hospital.[12] Additionally, the incorporation of minimally invasive surgery results in shorter hospitalizations and less time gaining proficiency in stoma management.

Up to date, conventional practice in our team involved stoma education being imparted postoperatively. Given that, we questioned if implementing a preoperative program could influence postoperative course in new ostomate patients. The purpose of this study is to evaluate the effectiveness of preoperatively education in the outpatient setting in reducing length of stay for stoma patients, compared to standard postoperative care. Secondary end points will be minor and mayor morbidity, mortality, reoperation and readmission rates assessment.

Material and Methods

Consecutive colorectal surgery patients undergoing stoma formation in a single center will be recorded in a cohort study, during a 12-month period. Records will be retrospectively collected before outpatient information program establishment and prospectively in the second study period. Data and personal identities of individual participants are coded to ensure patient confidentiality. Patients in the standard group received stoma education after surgery, during hospital stay, and patients in the intervention group received the same information preoperatively in outpatient setting.

Inclusion criteria considered for scheduled preoperative clinic visit: patients older than 18 years of age undergoing elective colorectal resections that eventually would require formation of a stoma (colorectal cancer up to 20 cm from the anal verge, colonic poliposis and inflammatory bowel disease). Patients will be excluded from the study if they already had a stoma before the operation or in case of emergent surgery.

Patients in the study group have one individual consultation 45 minutes in duration several days before surgery with the stoma nurse specialist, following standard ostomy teaching plans (displayed in Table 1).

1. General information about what is a stoma and different types of stoma
2. Potential surgical procedure
3. Information about stoma marking (benefits and timing to perform)
4. How to care your ostomy
5. Effect of the diet on ostomy management
6. An overview on dietary advice
7. *Types of ostomy bags*
8. Complications that may arise after an incorrect apply of a new pouching system
9. How to manage peristomal skin irritation if necessary
10. Influence of stoma on quality of life
11. *Sports* and fitness *activities you are able to do with a stoma*
12. How and where get the pouches
13. Who to ask if you are in doubt about any procedure
14. Information for family and caregivers

Table 1. Information for ostomy patients

In both groups and in all cases, the stoma site will be marked the same day of surgery. Patients, except for specific contraindication, follow the Enhanced Recovery Pathways established in our colorectal Unit and approved by Local Quality Committee. All procedures will be performed or supervised by a specialist *colorectal* surgeon. Patients, irrespective of the group, are visited in the ward by the enterostoma therapist one or two days after stoma creation, emphasizing basic skills to optimize the ability to perform independently stoma care.

The discharge and readmission criteria are similar for both treatment groups and followed conventional protocols and care pathways set in our working group.

Data collected included age, gender, American Society of Anesthesiologists (ASA) grade, diagnosis, surgical approach and type of stoma. Measurement variables are complications and mortality rates (assessed by Clavien-Dindo Classification), reinterventions, readmissions within the first 30 days after surgery and length of hospital stay. Similar data will be retrospectively collected for patients prior to the introduction of the preoperative education program.

All statistical analyses are performed using SPSS version 20 (SPSS Inc., Chicago, IL, EE. UU.). Continuously variables were tested by Students T-test, Mann-Whitney U for numerical variables and Pearson's Two-sided Chi-square Test for dichotomous variables or Fisher test for qualitative variables. An alpha level of .05 was used to determine statistical significance.
The article will be reported in line with the STROCSS criteria.[13]

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