

A close adherence to a Stoma-Therapeutic Pathway improves immediate stoma-related outcomes and reduces the length of hospital stay

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Study protocol

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Abstract

Purpose: New stoma creation is related with a wide range of implications and stoma-related complications could occur frequently. Aim was to assess the impact of a close stoma-therapeutic-care pathway (STCP) in terms of length of stay, autonomy in the management of the pouch, readmission rate and stoma-related complications

Methods: Patients undergoing surgery for colorectal disease and first stoma creation from January 2017 to December 2020 were analyzed. All patients enrolled had joined the ERAS protocol.

Results: Among 143 enrolled, 56 (40%) didn't follow completely the STCP (group A), whereas 87 (60%) demonstrated a strictly compliance (group B). The hospital stay was 8 days in the group B vs 11,5 in the group A ($p=0,001$). The first look at the stoma needed 1 day in the group B vs 3 days in the group A ($p<0,001$), emptying the pouch 2 day in the group B vs 5 days in the group A ($p<0,001$) and ability to change the pouch 3 day in the group B vs 6 days in the group A ($p<0,001$).

Stoma related complications were 9 (16.1%) in the group B and 16 (18.4%) in the group A, and 30 days readmission was 10,1% in the group B and 11,5% in the group A, $p=0,82$ and $p=1$, respectively, not significant.

Conclusions: The STCP has been shown to reduce the hospital stay and to have a protective role making the patient autonomous in the management of the stoma.

Introduction

Stoma creation may cause discomfort in acceptance of new physical and psychological condition¹. Stoma related complications occur in 20–70% and patients need to acquire knowledge and skills in order to reduce such problems^{2, 3, 4}. The Stoma-Therapeutic education represent actually an effective arm provided by experienced and trained nurses inserted in a multidisciplinary team^{5, 6, 7}.

Recently, with the diffusion of Enhanced Recovery Protocols (ERAS), the hospital stay, notably after colorectal surgery, is quite reduced. Despite this, stoma creation represents a condition that could delay the hospital discharge and several authors indicate this condition as a frequent reason for readmission^{8, 9, 10}.

A rigorous Stoma-therapeutic-care-pathway (STCP) (from the preoperative assess to the period after discharge) could prevent and reduce the stoma-related complications¹¹.

The aim of this study was to evaluate impact of adherence to the STCP with strong educational component of patients undergoing colorectal surgery in ERAS context.

Methods

The study population included all consecutive patients operated on for colorectal disease and first stoma creation at the Division of Oncologic and General Surgery of Mauriziano Hospital in Turin, from January 2017 to December 2020. All patients enrolled joined the ERAS protocol and were divided in two groups. In the group A the patients were not able to attempt completely the STCP, in the group B the patients demonstrated a strictly compliance for the STCP (over 70% of all items of the pathway). The items evaluated are shown in the Table 1.

Table 1
Items considered to assess the STCP compliance

Attendance in stoma-therapeutic counselling
Pre-operative stoma site marking
Attendance in stoma-therapeutic counselling in post-operative day 1
Attendance in stoma-therapeutic counselling in post-operative day 2
Attendance in stoma-therapeutic counselling in post-operative day 3
Attendance in stoma-therapeutic counselling in post-operative day 4
Achievement of educational objectives
Peristomal skin assessment with a standardized tool
Attendance in stoma-therapeutic follow up
Attendance in ≥ 3 stoma-therapeutic consultations

The reasons of low compliance against the STCP were various: clinical, logistic and sometimes due to difficult in acceptance of new behavior.

Exclusion criteria were:

- condition of mental or physical incapacity
- discharge to other hospital
- disagree in attendance at follow up

Clinical data from the Stoma Care Center were retrospectively extracted from a prospectively maintained institutional database that collects 60 variables including patients' history and characteristics like gender, age, body mass index (BMI), kidney failure, Insulin Dependent Diabetes Mellitus (IDDM) or non-Insulin Dependent Diabetes Mellitus (NIDDM), pulmonary disease, heart diseases, smoke habit, dietary path, but also presence of road-bridge, level of independence in look at the stoma, emptying the pouch, ability in stoma care, adherence the STCP, hospital stay, one month readmission and three months postoperative complications and stoma-related complications.

The study was approved by the local institution review board.

Stoma-therapeutic Pathway

The STCP team includes the Stoma-therapist nurse and the Surgeon and takes care of patients before admission.

The pathway provides:

- a first counseling (in pre-hospitalization assess), aimed to expose to the patient and to the caregiver the educational objectives and providing instructions on the management of the stoma. The patients are explained about their own role in retraining so that they understood the importance of their own efforts. Pictures of stoma could be shown and the interview tries to highlight changes in relationships, sexuality and various activities of daily life, such as bathing and showering. During this examination a first planning of the stoma site is made and reported on the clinical chart with anthropometric measurements. The duration of the first counselling is about 45–60 minutes.

Information about stoma surgery are given previously during a separate surgical examination

- the day before surgery the stoma site marking is made
- in postoperative day 1 (PD1), or the same day of surgery, the patient looks at the stoma for the first time and listens to instructions on how to change the pouch. In this specific counseling the stomatherapist proposes to the patient an "educational agreement" aimed to focus the goals to gain. An informative booklet is provided as well.
- in PD 1 or 2 new session on teaching about real life with the stoma and first try to empty the pouch under the direct supervision of the nurse
- in PD 2–3 session on nutrition and physical activity. During this session the patient changes the pouch by himself/herself (under supervision too)
- in PD 4–5 the patient is autonomous in management of the stoma-device. New session on early stoma-related complication and check of the knowledge

After the discharge the follow up schedule provides:

After 3–4 days the patient calls the stomatherapist according to the protocol and refers about the trend of the stoma.

After 7–10 days surgical and stomatherapeutic examination

After 20–30 days new stomatherapeutic examination and dietological assessment

Every three months after surgery till the stoma reversal or till one year a stomatherapeutic examination
The STC unit was created in 2003 and has grown close to the ERAS protocol. Each year the stomatherapeutic group takes care of 1300 patients operated on for major colorectal surgery. The team comprehends also the Urologist, the Gastroenterologist, the Dietician, the Psychologist, a Social Worker and nurses. From 2016 the team had formalized a rehabilitation program with a strong educational component dedicated to the patient with stoma. The Team offers to patients an informative brochure specific for colostomy or ileostomy and for different shape (end or loop stoma) and inherent to contacts to facilitate the counseling program, new body scheme, disease related items, how to clean the stoma, how to manage the stoma-devices and how to empty the bag,

“real life” problems (job, travels, clothing, showering), nutritional aspects and indications for “patients’ associations”.

Primary endpoint was the length of hospital stay. The discharge criteria were: postoperative pain controlled with per oral medication (VAS < 4), autonomy in mobilization and out of bed more than 6 h/day, appropriate bowel function with accurate output counting and ability to tolerate solid food without nausea, absence of conditions requiring in-hospital treatment.

Secondary endpoints were achieving autonomy in the management of the pouch (so that the patient is proficient enough) readmission rate and stoma-related complications.

Statistical Analysis

Categorical variables were compared using the chi square test or Fisher’s exact test, as appropriate. Continuous variables were compared between groups using the Wilcoxon test. The Kaplan-Meier estimator with no censored event was used to estimate time to event probabilities, which were compared using the log-rank test. All P values were two-sided, and values of $P < 0.05$ were considered statistically significant. All statistical analysis was performed using SPSS statistic.

The ethic committee approved data auditing and the study has been reported according the Strengthening The Reporting of Observational Studies in Epidemiology¹².

Results

Overall, among patients undergoing major colorectal surgery at the author’s institutions between 2017 and 2020, 143 patients underwent a first stoma creation. Patients were divided in two groups. Fifty-six patients (40%) didn’t follow completely the STCP (group A), 87 patients (60%) demonstrated a strictly compliance for the STCP (group B).

Patient characteristics

Table 2 summarizes patients’ history and characteristics. The two groups were similar in terms of gender, body mass index (BMI), kidney failure, Insulin Dependent Diabetes Mellitus (IDDM) or non- Insulin

Dependent Diabetes Mellitus (NIDDM), pulmonary disease, heart diseases, smoke habit, dietary path, surgical procedures, type of stoma (ileostomy, colostomy, terminal, lateral), presence of supporting rod. The median age was significantly lower in the group B (58) than in the group A (66), $p = 0,006$.

Table 2
Baseline characteristics

	no adherence to the SCTP	Adherence to SCTP	<i>p</i>
n	56	87	
age (median [IQR])	66.00 [58.75, 74.00]	58.00 [46.00, 68.00]	0.006
BMI (median [IQR])	25.00 [22.10, 27.10]	24.10 [22.00, 26.50]	0.642
sex = 1 (%)	26 (46.4)	36 (41.4)	0.606
chronic kidney disease = 1 (%)	2 (3.6)	2 (2.3)	0.645
IDDM = NA (%)	1 (1.8)	0 (0.0)	0.392
NIDDM = 1 (%)	7 (12.5)	6 (6.9)	0.372
pulmonary disease = 1 (%)	0 (0.0)	1 (1.1)	1.000
cardiac disease = 1 (%)	22 (39.3)	28 (32.2)	0.473
more than 2 comorbidities = 1 (%)	4 (7.1)	5 (5.7)	0.737
smoking habit = 1 (%)	19 (33.9)	18 (20.7)	0.083
rod = 1 (%)	6 (10.7)	2 (2.3)	0.057
type of surgery (%)			0,349
left colectomy	3 (5,4)	1 (1,1)	
low anterior resection	22 (39,3)	29 (33,3)	
abdominoperineal resection	7 (12,5)	8 (9,2)	
hartmann procedure	2 (3,5)	5 (5,7)	
ileocolic resection	0	1 (1,1)	
total colectomy	7 (12,5)	11 (12,6)	
total proctocolectomy + IPAA	8 (14,2)	15 (17,2)	
stoma	7 (12,5)	17 (19,5)	
laparoscopy = 1 (%)	51 (91.1)	73 (83.9)	0.313
type_ostomy (%)			0.921
end ileostomy	7 (12.5)	14 (16.1)	
lateral ileostomy	33 (58.9)	48 (55.2)	
end colostomy	10 (17.9)	14 (16.1)	

	no adherence to the SCTP	Adherence to SCTP	<i>p</i>
lateral colostomy	6 (10.7)	11 (12.6)	
preop site marking = 1 (%)	52 (92.9)	86 (98.9)	0.077
preop nutrition = 1 (%)	43 (76.8)	75 (86.2)	0.178

Statistically significant differences were observed in the hospital stay (8 days in the group B vs 11,5 in the group A $p = 0,001$), in the postoperative day the patient was able to look at his stoma (1 day in the group B vs 3 days in the group A $p < 0,001$), in the postoperative day the patient was able to empty the pouch (2 day in the group B vs 5 days in the group A $p < 0,001$) and in the postoperative day the patient was able to change the pouch (3 day in the group B vs 6 days in the group A $p < 0,001$)

Stoma-related complications didn't show significant differences (9 (16,1%) in the group B and 16 (18%) in the group A, $p = 0,82$). Thirty days readmission rate was 10,1% (6 patients) in the group B and 11,5% (10) in the group A ($p = 1,000$). (Table 3)

Table 3
Results

	no adherence to the SCTP	Adherence to SCTP	<i>p</i>
	56	87	
hospital stay (median [IQR])	11.50 [8.00, 18.25]	8.00 [6.00, 13.50]	0.001
30 day readmission = 1 (%)	6 (10.7)	10 (11.5)	1.000
postop day flatus (median [IQR])	1.00 [1.00, 2.00]	1.00 [1.00, 2.00]	0.908
postop day open stool (median [IQR])	2.00 [1.00, 3.00]	2.00 [1.00, 3.00]	0.948
postop day sitting on chair (median [IQR])	1.00 [1.00, 1.00]	1.00 [0.00, 1.00]	0.055
tolerated fluid intake (median [IQR])	1.00 [0.00, 1.00]	1.00 [0.00, 1.00]	0.727
urinary catheter (median [IQR])	4.00 [2.00, 7.50]	3.00 [2.00, 5.00]	0.194
nasogastric tube removal (median [IQR])	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	0.389
look at the ostomy, postoperative day (median [IQR])	3.00 [2.00, 3.00]	1.00 [1.00, 1.00]	< 0.001
emptying the pouch, postoperative day (median [IQR])	5.00 [4.00, 6.00]	2.00 [2.00, 2.00]	< 0.001
change the pouch, postoperative day (median [IQR])	6.00 [5.00, 7.00]	3.00 [2.00, 3.50]	< 0.001
peristomal skin disorder (%) SACS scale			0.502
0	51 (91.1)	83 (95.4)	
l1t2	1 (1.8)	0 (0.0)	
l1t23	1 (1.8)	1 (1.1)	
l1t34	1 (1.8)	0 (0.0)	
l1tv	2 (3.6)	1 (1.1)	
l2t2	0 (0.0)	1 (1.1)	
l2t2t3	0 (0.0)	1 (1.1)	
stoma complications = 1 (%)	9 (16.1)	16 (18.4)	0.823
complications (Clavien Dindo) (%)			0.045
0	21 (37.5)	38 (43.7)	
1	1 (1.8)	3 (3.4)	

	no adherence to the SCTP	Adherence to SCTP	<i>p</i>
2	0 (0.0)	8 (9.2)	
2a	22 (39.3)	28 (32.2)	
3 a	8 (14.3)	4 (4.6)	
3 b	0 (0.0)	2 (2.3)	
3b	4 (7.1)	3 (3.4)	
4	0 (0.0)	1 (1.1)	

Time-to-event estimates of same items are reported in Fig. 1

Discussion

The creation of the stoma is related with a wide range of complications and implications and new stoma patients have to face significant physical, psychological and body image settings¹³. All this in addition to the concern due to the disease itself. It could be difficult for the ward nursing staff to properly assist the patients during the hospital stay as well after the discharge.

The strong application of STCP showed better results in terms of the length of hospital stay and the level of independence if compared with patients who didn't attempt to the path despite the inclusion in the ERAS protocol.

A recent paper describes a "clinical 4-day in-hospital educational stoma pathway". This pathway hesitated in improving the "level of independence" (LOI) of new stoma patients and significantly reducing the need for "home nursing care services" with an impact on cost-benefit analysis¹⁴. In this paper, however, the authors didn't analyze data about hospital stay or readmission. Our data demonstrated that a close adherence to STCP hesitated in better results in terms of hospital stay and management of the stoma. The over mentioned paper stated that nurses were instructed to engage patients and caregivers in their "Stoma Care pathway" and guide them to become independent as soon as possible. Our STCP, instead, is carried on by dedicated Stoma-therapists. This evidence could represent a limitation to reproducibility in other not specialized surgical setting, but is an advantage for patients in this contest and after the discharge from the hospital.

The readmission rate was not significantly reduced by the strictly adherence to the path but remains much lower than that observed in the literature¹⁵. The reason of this evidence is that the STCP protocol includes a close telephone follow up made by the stoma-therapist after the discharge and focused to the assessment of stoma patients water balance. On the basis of the balance the stoma-therapist, according to the protocol and under the supervision of the physician, manages the condition in order to reduce the necessity of readmission¹⁶.

Stoma-related complications didn't differ among two groups but the global count (16,1% in the group A and 18,4% in the group B $p = 0,823$) is much lower than that observed in the literature^{17,18}. Out of 143 patients just 5 didn't receive the preoperative site mark of the stoma (3%). In a large number of papers the preoperative site marking is significantly associated with lower rate of stoma related and skin complications¹⁹. Baykara et al. published a multicenter retrospective study and found higher complication rates among patients without stoma site marking than among those whose stoma site has been marked²⁰. Furthermore, the quality of life of the patients whose stoma sites had been preoperatively marked was significantly better than that of the unmarked patients as shown by a recent systematic review²¹.

The rod bridge was rarely used in our Center (5%) and patients without the rod are immediately suitable of close STCP. In the two groups the rod was placed in 6 patients in the group B (10,7%) and in 2 (2,3%) in the group A. The presence of the rod prevents the possibility of early education and increases the risk of peristomal skin complications²².

A recent controlled, randomized trial compared patients treated with ERAS program and extended stoma education and patients treated with standard care and current stoma education. The authors concluded that the length of stay after elective colorectal surgery with the need for stoma creation can be reduced significantly with peri-operative education and guidance by dedicated stoma nurses as part of an ERAS care pathway if compared to current stoma education in a traditional standard care pathway²³. The substantial difference between our study and previous is that the reduce in hospital stay observed is completely due to the adherence to the STCP because all patients analyzed had followed the ERAS protocol with all its items.

The present study has several limitations. First, it was a retrospective analysis, even if data were collected prospectively. The other bias is the younger age observed in the group B, where patients were definitely more fit for early discharge from the ward and more willing to the autonomous management of the stoma. However, even if age represents a risk factor for stomal and peristomal complications²⁴, there are no significant differences between the two groups in terms of complications so the better outcomes observed seem to be related to a possible protective role of the STCP.

In conclusion the STCP demonstrated to have a protective role making the patient and the care giver (if present) autonomous and reducing the length of hospital stay. Event if not significantly, the stoma related complications and the readmission rates appears much lower than those showed in recent papers.

Declarations And Statements

The authors declare to not have any financial interest directly related to the work and to not have any conflict of interest.

No funds were used for the research.

Authors contribution statements

Michela Mineccia and Antonio Valenti designed the study and wrote the manuscript.

Federica Gonella with Marco Palisi and Paolo Massucco filled the dataset and wrote the manuscript

Andrea Ricotti did the statistical analysis.

Alessandro Ferrero supervised and wrote the manuscript.

Data availability statement

The dataset generated and analyzed during the current study are available from the corresponding author on reasonable request.

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Figures

Figure 1

Time-to-event estimates of length of hospital stay in days (A), the postoperative day the patient was able to look at his stoma (B), the postoperative day the patient was able to empty the pouch (C), the postoperative day the patient was able to change the pouch (D).