

## Sphincter Sparing Procedures: Is it a standard for Management of Low Rectal Cancer

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### ABSTRACT

**Purpose:** The purpose of this study is to determine whether the type of operation, sphincter sparing procedures (SSP) or abdomino-perineal resection (APR) for primary adenocarcinoma of the rectum at or below the peritoneal reflection affects survival and recurrence after curative surgery.

**Material and Methods:** A prospective controlled study of seventy nine patients with low rectal carcinoma was done between January 1999 and March 2003. Two types of operations were done; SSP (43 patients) including a low anterior resection with either double-stapling technique (DST) (18) or hand-sewn colorectal anastomosis (HSA) (25), and APR (36 patients). The outcome factors evaluated were operative time, intraoperative blood loss, mortality, morbidity, disease-free survival and tumor recurrence. Patients have been followed-up for a minimum of 12 months (mean time 32 months).

**Results:** Out of 43 patients who underwent SSP, there was one mortality, and 7 morbidities. Anastomotic leakage occurred in 4 cases; one patient needed colostomy. In APR group, no mortalities and 6 morbidities were found. Morbidity was similar in both groups. The local recurrence rates for SSP and APR were 13.8% and 22.2%, respectively ( $p = 0.540$ ), and the distant metastases rates were 11.1% and 8.3%, respectively ( $p = 1.000$ ). Two-year disease-free survival rates for SSP and APR patients were 73.3% and 66.7%, respectively ( $p = 0.121$ ). Intraoperative blood loss was significantly lower in SSP groups.

**Conclusions:** Sphincter saving procedures can be performed to all patients with rectal carcinoma regardless of the site of the lesion so long the distal and lateral margins are clear. Survival and the risk of local recurrence are similar to that obtained by standard abdomino-perineal resection. Unlike abdomino-perineal resection, sphincter saving procedures preserve the continence and give accepted good quality of life.

**Key Words:** Sphincter sparing - Rectal cancer.

### INTRODUCTION

Colorectal cancer is the fourth most prevalent cancer in the world in both sexes and second most common cause of cancer mortality after lung cancer [1].

If APR is the standard or procedure of choice, it must be shown to be better than the alternative, i.e., a sphincter sparing procedures (SSP). Optimal surgical treatment of rectal cancer in the lower one-third remains controversial because of the absence of randomized trials [2].

The ability to perform a sphincter-saving procedure such as a low anterior resection has been enhanced by the application of the circular stapler device introduced by Knight and Griffen [3] in 1980, and the increasing acceptance of a short distal margin has also contributed to the increased use of the sphincter-saving procedure for low-lying tumors [2]. Many investigators have shown that 2cm or less distal margin does not increase local recurrence or reduce survival [4,5]. Others have shown that 1cm margin is enough providing there is no residual disease distally and clear radial margin [6].

Numerous studies have compared the oncologic results of a SSP as low anterior resection with an APR. When a low anterior resection is properly performed with a 2cm distal resection margin, the low anterior resection can achieve comparable local recurrence and survival rates in comparison with APR [7].

Indeed, recently developed techniques, such as total mesorectal excision, coloanal anasto-

nosis, colon pouch construction and neo-adjuvant therapies, increase the acceptance that SSP is a standard treatment of low rectal carcinoma [8].

In this prospective study, we compared the mortality, morbidity survival and recurrence rates after a SSP and APR for adenocarcinoma located in the rectum at or below the peritoneal reflection.

### PATIENT AND METHODS

#### *Patients:*

The study population consisted of 79 patients with low rectal carcinoma attended to the National Cancer Institute during the period from January 1999 and March 2003. All patients had stage I and II disease. There was 26 women and 53 men; median age, 46.3 (range, 32-71) years.

Preoperative diagnostic evaluation included digital and colonoscopic examinations, biopsies, abdominopelvic computed tomography. Cystoscopy was done for 9 patients with urinary symptoms and were all free. None of the patients received preoperative radiotherapy or chemotherapy. All patients submitted to colonic preparation and prophylactic antibiotics.

#### *Surgical Management was Performed by One of Two Procedures:*

1- SSP (43 patients) including a low anterior resection with either double-stapling technique (DST) (18) or hand-sewn colorectal anastomosis (HSA) (25), of these only one was done by transanal approach.

2- APR (36 patients).

#### *Operative Technique:*

The abdominal parts of the SSP or APR were performed using exactly the same techniques. After the abdomen is opened and explored, the sigmoid and left colons are dissected from their left peritoneal attachment and the retro-peritoneum. The splenic flexure is mobilized and the marginal artery is preserved. The inferior mesenteric artery and vein are tied and transected. Dissection continues into the pelvis, mobilizing the mesorectum off the sacrum along the avascular plane of the endopelvic fascia via sharp dissection following the lipoma like outer surface of the rectum. The plane between the rectum and anterior pelvic structures (seminal

vesicle and prostate) for males and posterior vaginal wall for (females) is sharply dissected, this allows preservation of the pelvic autonomic nerves, reduces sexual and bladder dysfunction. The choice of operation (SSP or APR) depended on the location of the tumor relative to the dentate line. Our policy has been to perform anastomosis in the abdomen by DST whenever possible, we used TA-55 stapler to close the distal stump (Fig. 1) and the EEA-29 for the colorectal anastomosis (Figs. 2-A,B,C). We have routinely used rectal washout using diluted povidone iodine solution before anastomosis and after resection of the carcinoma, as patients with colorectal cancer have viable tumor cells in bowel lumen and these cells are capable of implanting and causing tumor growth. If an anastomosis could not then be achieved in the abdomen, then transanal coloanal anastomosis (CAA) was performed. In SSP the distal rectum was divided with a 2cm distal resection margin (Figs. 3,4). The patients who could not have such distal resection margin clearance were indicated for an APR. In an APR, the distal rectum was not transected and the anus and rectum were widely excised. After SSP we test the anastomosis by injecting 200cc of diluted povidone iodine solution through the anus then we perform anal dilation. Operative specimen and distal safety margins were sent for histopathological examination.

#### *Follow-up:*

The patients were examined at 3-month intervals for the first 2 postoperative years and every 6 months thereafter. Evaluation included complete clinical examinations, tumor marker, trans rectal ultrasound every 3 months, total colonoscopy, and abdominal computed tomography. The median follow-up was 32 (range, 12-46) months for patients alive at the conclusion of the study. A minimum 1-year follow-up was available for all patients.

#### *Outcome:*

Outcome of surgery was evaluated through intraoperative data including operative time and blood loss. Postoperatively, urinary and sexual disorders were observed in addition to the rate of recurrence. Finally, overall and disease-free survival was evaluated. The disease-free survival was defined as the time from the date of operation to the date of first recurrence.

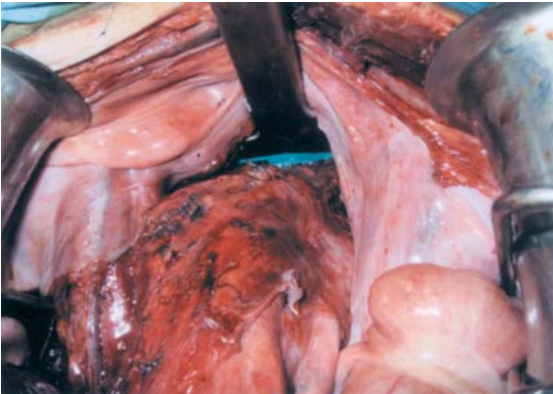


Fig. (1): TA-55 stapler inserted.



Fig. (2-A): EEA-29 stapler in proximal stump.



Fig. (2-B): EEA-29 and donuts.



Fig. (2-C): Anastomosis completed after using stapler.



Fig. (3): Postoperative specimen.



Fig. (4): Postoperative specimen.

#### Statistical Analysis:

Continuous data were expressed as the mean  $\pm$  standard deviation. A comparison of the continuous data between the two groups was conducted using the un-paired *t*-test. The categorical data were analyzed by either the Chi square or Fisher's exact test. The influence of each variable on the survival time was calculated according to the Kaplan-Meier method, and differences

between survival times were tested for significance using the log-rank test. All tests were two-tailed and a *p* value of less than 0.05 was considered to be significant.

#### RESULTS

Out of 79 patients, 53 patients were males and 26 patients were females with a median age of 46.3 years (range, 32-71 years).

**Operative Morbidity and Mortality:**

In Group I (SSP) there was one mortality (pulmonary embolism at 9<sup>th</sup> postoperative day), and 7 cases with morbidities; 4 cases had leakage out of them 1 patient needed colostomy and 3 patients managed conservatively, one case had ureteric injury and one case had bladder injury managed intraoperatively, 3 patients develop wound sepsis managed conservatively. Operative time ranged between 110 and 165 minutes. Intraoperative blood loss was 300-700cc. Three patients suffered from urinary retention and 2 patients from sexual disorders.

In Group II (APR) there was no mortality and 6 morbidities; three cases had bladder injury managed intraoperatively, 3 patients developed wound sepsis 2 managed conservatively and one needed drainage and later secondary sutures. Operative time ranged from 120 to 160 minutes. Intraoperative blood loss was 550-1500cc. Seven patients suffered from urinary retention and three patients from sexual disorders.

Table (1): Operative morbidity and mortality.

	SSP	APR	<i>p</i> -value
Operative time (min.)	110-165	120-160	0.352
Blood loss (cc)	300-700	550-1500	<0.001
Urinary retention [No.(%)]	4 (9.3%)	7 (19.4%)	0.307
Mortality (No.)	1	0	
Morbidity [No.(%)]	7 (16.3%)	6 (16.7%)	0.967
Ureteric injury	0	1	
Bladder injury	1	2	
Sepsis	3	4	
Leakage	4	0	
Sexual disorders	2	3	
Postoperative hospital stay	7.2±2.3	10.3±2.4	<0.001

There was no significant difference regarding the operative time and morbidity, but postoperative stay and Intraoperative blood loss was less in SSP (Table 1).

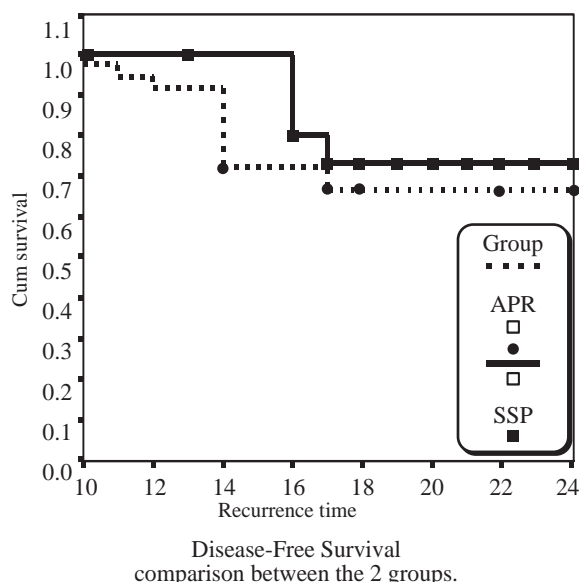
Postoperative pathology was adenocarcinoma grade I 14 patients, II 53 patients and III 12 patients. There was 4 patients stage I and 75 patients stage II. Surgical margins were free in all patients.

Post operative radiation therapy was given to all patients with stage II disease (75 patients). None of the patients received adjuvant chemotherapy.

Table (2): Outcome of operation in the two groups.

	SSP	APR	<i>p</i> -value
Recurrence rate	9 (20.9%)	11 (30.5%)	0.436
Loco-regional	5 (11.6%)	8 (22.2%)	0.337
Distant	4 (9.3%)	3 (8.3%)	1.000
Average time to recurrence (months)	16.2±0.44	13.5±1.9	0.004
Mean survival after recurrence (months)	9.5±1.2	3.4±0.8	<0.001
Disease-free survival after 2 years	73.3	66.7	0.1211

There was no significant difference regarding the recurrence rate and disease-free survival, but there was significant difference in average time to recurrence and mean survival after recurrence (Table 2).

**DISCUSSION**

Oncological surgery was born in excessive radicality, but modern oncological surgery has become organ sparing and restorative. This is related to improved knowledge of cancer pathology, diagnostic and therapeutic technology, and skills, and to societal philosophy being more concerned about body image and quality of life [9]. It is generally accepted that upper

rectal cancer can adequately be removed by sphincter-preserving procedures, but many textbooks and even more surgeons still advocate APR as a standard procedure for low or distal rectal cancer [10].

Our aim was to document as objectively as possible whether APR still is the standard procedure for low rectal cancer, or whether it should be limited to those cases in which a SSO is contraindicated.

The level of the tumor is still probably the most important factor influencing the type of operation in patients with resectable low rectal cancer. "A distal resection margin of 2cm [4] in SSP has been shown to neither compromise survival nor local recurrence in carefully selected patients with rectal cancers." Shirouzu et al. [4] reported that distal spread was observed in only 3.8% (19 of 505 patients), but this was confined to within a 1cm length. Most patients with distal spread had a lower survival rate and died of distant metastasis rather than local recurrence, even after curative surgery.

Tohru [11] concluded that a distal margin with a resection of 1cm may be an appropriate clearance for most rectal cancers. In the current study, a distal margin clearance with a 2cm distal resection margin for stage I or stage II tumors, was performed and we did not find any tumor beyond this margin.

Di Bitta [12] and his colleagues mentioned that postoperative morbidity after APR and SSP is comparable and postoperative mortality decreased to 2% or less. In this study there was no significant difference regarding the operative morbidity, the two operations were comparable regarding the operative time. In SSP group the maximum operative time was 165 minutes versus 160 minutes in APR cases, now due to the perfection of the stapling technique we spend less time in doing coloanal anastomosis. The postoperative stay and Intraoperative blood loss was less in SSP (Table 1).

Quality of life is significantly inferior after APR, although patients treated by SSO may present problems of frequent bowel movement, urgency, flatulence, and need for frequent medication [12].

In a study done by Tohru et al. [11] he found that disease-free and disease-specific survivals,

and the frequency and location of recurrence after surgery did not differ between the two types of operations (SSP or APR). Multivariable analyses showed that the type of operation was not a significant independent variable in predicting disease-free survival or in the development of both local and distant recurrences after surgery. In addition, tumor-related factors (stage or histologic grade) were significant predictors of the outcome after surgery. Also Topal [10] have compared the oncologic results of SSP with APR for cancer limited to the lower third of the rectum and conclude that the type of operation (SSP or APR) was not a significant predictor of recurrence and survival after curative surgery.

In our study, disease-free survival after curative surgery did not differ between the two types of operations (SSP or APR). In SSP cases disease free survival was 73.3% versus 66.7% in APR group (Table 2).

To achieve local tumor control, there are still several important problems with respect to optimal pelvic dissection for tumors in the rectum located at or below the peritoneal reflection whatever the type of operation used: Namely, circumferential resection margin, "total mesorectal excision", and lateral lymph node dissection. A positive circumferential margin appeared to be an independent predictor of both local recurrence and survival [13]. Heald and Karanjia [14] stressed the importance of a total mesorectal excision, thus reporting a local recurrence rate of only 4%. Japanese surgeons who performed lateral lymph node dissections reported similar results. The widest possible circumferential resection margin has also been obtained, A lateral lymph node dissection with the removal of the autonomic nerves has been performed for selected patients with stage III tumors [11]. We have routinely removed the whole mesorectum with the widest possible circumferential resection margin during SSP and APR.

In conclusion, the type of operation [SSP or APR] did not compromise the chance for cure among patients with tumors located at or below the peritoneal reflection. These results suggest that SSP if performed correctly, can therefore provide a good quality of life without the need to perform a permanent colostomy for patients with cancer of the rectum at or below the peritoneal reflection.

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