

# Evaluation of sphincter-preserving surgery for rectal cancer

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**Background:** Rectal carcinoma constitutes a health problem, previously managed with abdomino-perineal resection (APR) which has the impact of poor patient quality of life. With the introduction of the concept of total mesorectal excision (TME) and stapler technology, sphincter saving surgery (SSS) with its better local control and functional status is a better choice than APR. We tried to evaluate the operative safety, long-term oncologic and functional outcomes of SSS in rectal carcinoma.

**Patients and methods:** Between October 2008 and October 2012, patients with rectal carcinoma who presented electively to Sohag University Hospital underwent SSS based on sharp mesorectal excision in the form of anterior resection, low anterior resection and intersphincteric resection were evaluated. Patients were followed up for four years.

**Results:** A total of 60 patients underwent SSS, regarding operative complications; there were 2 ureteric injuries and one bladder injury. Postoperatively, anastomotic leakage occurred in 6.7% of cases. Local recurrence and distant metastases were detected in 8.3% 13.3% respectively. During follow-up, disease-free survival rate was 66.9%, overall survival rate was 93%, 22% of patients had a degree of incontinence. 21.66% had temporary bladder dysfunction. Sexual dysfunction became evident in 30% of male patients.

**Conclusion:** SSS with TME provides a better alternative to APR in rectal carcinoma when feasible.

**Key words:** Sphincter saving surgery, total mesorectal excision, stapler.

## Introduction:

Rectal cancer constitutes 5% of malignant tumors, and ranks as the fifth most common cancer in adults.<sup>1</sup> It is curable when localized to the bowel, radical resection makes cure in 50% of cases.<sup>2</sup>

Preservation of anal sphincter, bladder, and sexual function with maintenance or improvement in quality of life besides local control and long-term survival are the main goals while managing rectal carcinoma.<sup>3</sup>

APR is now considered unnecessary in most patients with rectal cancer and more patients can be treated with SSS due to the increased understanding of the spread of the disease. Distal mural spread of the disease was shown to be rarely more than 2 cm,<sup>4</sup>

this allowed the increased use of SSS. Also the advances of mechanical stapling devices and the development of the double stapling technique made anastomoses at the distal rectum or the anal canal possible and safe.<sup>5</sup>

The recognition of TME for colorectal cancer surgery [with careful dissection of the avascular plane between the mesorectum and parietal fascia, the envelope of the mesorectum (which encompasses tumor cells) is kept intact, thereby preventing the dissemination of cancerous cells] is of significant importance.<sup>6</sup> TME has improved the local control with/ or without the use of neo-adjuvant radiotherapy, with reduced recurrence rate from 30% down to less than 10% thus improving the overall survival.<sup>7,8</sup>

Most patients have tumors confined to the rectum and mesorectum and may be cured by TME based surgery.<sup>9</sup> However, 10–15% of patients have locally more advanced tumors, i.e. tumors which are fixed to adjacent structures within the pelvis<sup>10</sup> and those with a local recurrence, multidisciplinary treatment strategies are needed.<sup>9</sup>

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.<sup>11</sup>

### **Aim of the work:**

The purpose of this study was to evaluate the outcome of SSS in management of rectal carcinoma.

### **Patients and methods:**

This study was conducted prospectively over patients who had non-fixed rectal carcinoma and presented electively from October 2008 to October 2012, at Sohag University Hospital, admitted through the outpatient clinic.

Patients were included in the study if they had a well functioning anal sphincters and the tumor was as low as 2 cm above the dentate line.

Patients were excluded if their tumors infiltrated the anal sphincter, women requiring posterior vaginectomy for adequate tumor clearance, those who received adjuvant therapy for a previous pelvic cancer, and resection for recurrent disease.

All patients had medical history, clinical examination, digital examination, endorectal ultrasonography and colonoscopy with biopsy. Tumors were divided into; low, middle, or high rectal tumors if their lowest edge were 0 to 5 cm, 5.1 to 10 cm, and 10.1 cm to 15 cm from the anal verge respectively.

All patients underwent abdomino-pelvic computed tomography (CT), magnetic resonance imaging and cystoscopy in patients with urinary symptoms. Laboratory investigations included serum carcino-embryonic antigen (CEA) and routine tests for physical fitness. All patients underwent routine mechanical and chemical preparation.

Data collected were patients' demographics, co-morbidities, operative details, operative morbidity and mortality, histological results, short and long-term outcomes.

### **Surgical techniques:**

Surgical management was performed by SSS including anterior resection for high-rectal tumors, low anterior resection for mid-rectal tumors and inter-sphincteric resection for low-rectal tumors. All patients underwent resection using a sharp perimesorectal excision technique.<sup>12</sup> In all cases a trial was paid to preserve the pelvic autonomic nerve trunks medial to the parietal fascia.<sup>13</sup>

Restoration of gut continuity after a thorough irrigation of the pelvic cavity and irrigation of the rectal stump with povidone iodine was accomplished by double-stapling; transverse stapler, circular stapler of the appropriate size (Ethicon Endosurgery® USA), or hand sewn colorectal anastomosis.

A transanal coloanal anastomosis was performed when the transverse stapler could not be applied with adequate margin below the tumor. After full abdominal mobilization of the rectum, the surgeon completed the excision transanally at the dentate line. A hand sewn interrupted single layer anastomosis was performed at the dentate line. Our distal resection margin (DRM) was 1 cm for T1-2 lesions and 2 cm for T3-4 tumors.<sup>14</sup> Intersphincteric resection (ISR) was performed in a low rectal cancer (tumor located <2 cm from the anal ring, T1-2, not infiltrating the external anal sphincter and with favorable pathology) after pelvic dissection from the abdominal approach with division of the full thickness of the internal sphincter transanally, 1 to 2 cm distal from the tumor, or removal of the upper one-half of the internal anal sphincter for tumors located between 3 and 5 cm from the anal verge (partial ISR). A diversion stoma was created in case of technical difficulty, a positive leakage test, incomplete doughnuts, or a very low anastomosis within 3 cm from the anal verge.

The resected tumors were evaluated

macroscopically for tumor site, size, depth of invasion and distance from proximal and distal surgical resection margins. The perirectal lymph nodes were carefully dissected counted and sampled for assessment of metastasis. The histological tumor type, grade, depth of invasion (T-stage), lymph node deposits (N-stage) were evaluated microscopically.

Patients were followed up every 3 months during the first 2 years and then every 6 months for the further two years, average follow-up 20 months. Follow-up included history, physical examination, and serum CEA. Digital rectal examination was performed to detect any anastomotic stricture or local recurrence. If recurrence was suspected, endoscopic examination and CT scan were performed to determine whether salvage surgery could be performed. Continence was assessed by Kirwan-Fazio classification,<sup>15</sup> patients with stoma were assessed after stoma closure.

Adjuvant radiation therapy was not routinely given to patients with stage II or stage III. Postoperative chemo-radiation was given when there is doubt of local clearance. Chemotherapy based on 5-fluorouracil was prescribed to patients younger than 75 years with TNM stage II or stage III disease.

### Statistical analysis:

The commercially available statistical software (IBM-SPSS version 19.0 for Windows; IBM Inc) was used for data analysis. The frequencies of a categorical observation among different groups was compared by Chi-Square Test and Fisher's Exact Test and the correlation between categorical variables and other continuous variables was by Spearman's rho Test. Kaplan Meier Survival analysis was used to calculate the recurrence rate and to estimate the Log-Rank among different groups. The association of different clinical and operative factors and risk of recurrence of the disease was evaluated by Binary Logistic regression analysis. The cut-off for significance of all used statistical analyses was rated as  $P < 0.05$ .

### Results:

This is a descriptive single arm prospective study which included 60 patients with rectal carcinoma, confirmed by histopathologic study as adenocarcinoma, who fulfilled the inclusion criteria. Of them 40 patients (66.7%) were females and 20 patients (33.3%) were males. Their age ranged between 16 to 72 years with a mean of  $(43.82 \pm 15.43)$  and a median of 43.5 years. In our study; 9 patients (15%) had high rectal tumor, 47 patients (78.3%) had mid-rectal tumor and 4 patients (6.7%) had low-rectal tumor. Operative time ranged between 90 and 240 minutes. The mean was  $(152 \pm 35)$  and the median was 150 minutes.

The anastomosis was completed by stapler using a double stapling technique in 39 patients (65%); all of them were mid-rectal cancer. Hand sewn anastomosis was used in 21 patients (35%) of whom four (6.6%) were low and eight (13.33%) were middle and nine (15%) were high rectal tumors. Thirty-seven patients (61.7%) had no diverting stoma, four patients (6.7%) had loop ileostomy and 19 (31.7%) had protective transverse colostomy.

Operative complications were managed intra-operatively and postoperative complications were managed conservatively and responded well, both were summarized in **Table (1)**.

The factors which may be responsible for the occurrence of fecal fistula were analyzed; small DRM was significantly associated with fecal fistula (Pearson Chi Square = 14.08,  $P < 0.01$ ). None of the tumor site, method of anastomosis, type of the covering stoma, tumor grade or tumor stage had a significant relationship to fecal fistula ( $P=0.32$ ,  $=0.65$ ,  $=112$ , and  $=0.727$  respectively). Also there was no correlation between operative time and fecal fistula (Spearman's rho correlation coefficient,  $P = 0.161$ ).

Histopathologic evaluation revealed that 24 patients (40%) had well differentiated adenocarcinoma, 34 patients (56.7%) had moderately differentiated adenocarcinoma and two patients (3.3%) had poorly differentiated adenocarcinoma. DRM varied according to the site of the tumor, it ranged

from 1-5 cm. It was 1 cm in seven cases, 2 cm in twenty-nine cases, 3 cm in nine cases, 4 cm in five cases and 5 cm in ten cases, resected specimens were examined histopathologically and were free. TNM staging of the tumors based on histopathologic examination of resected specimens (for T and N), revealed that T1, T2, T3 and T4 were represented in 4 (6.7%), 26 (43.3%), 29 (48.3%) and 1 (1.7%) cases, respectively. Eighteen cases (30%) had no lymph nodal deposits (N0), 29 cases (48.3%) had N1 nodal stage and 13 cases (21.7%) had N2 nodal stage. None of the patients had distant metastasis (M0). There was not any operative mortality.

During follow-up there was local recurrence in five cases (8.3%), 4 patients were mid-rectal carcinoma and 1 was low-rectal carcinoma. Both tumor site and method of anastomosis had no significant relationship to the local recurrence. Contrary to site of the tumor and type of anastomosis, there was an inverse significant relationship between the DRM and local recurrence. Regarding tumor grade; high grade tumors tend to have more local recurrence in comparison to low grade tumors, but this relationship does not reach the significance level. Although the relation of T stage of the primary tumor was insignificant, local recurrence of the tumor was significantly associated with higher nodal stage **Table (2)**.

Multivariate statistical analysis was made for factors which could be related to local recurrence. These factors included tumor site, tumor grade, T stage, N stage, type of operation, method of anastomosis, DRM in addition to operative time. There was no single independent variable correlated with local recurrence based on Binary Logistic Regression Multivariate analysis as shown in **Table (3)**.

Distant metastasis happened in eight patients (13.3%) of whom 5 cases had liver deposits, 2 cases had lung deposits and 1 case had multi-organ metastasis.

Disease free survival by Kaplan Meier test was 66.9% during the study period and the overall survival rate by Kaplan Meier test was 93% **Figure (1,2)**. There were two deaths; 1

due to multiple metastases and the other due to pulmonary metastasis.

We evaluated the relation of different disease findings to continence status. The tumor site had a significant impact; low-rectal tumors had a highly significant increased risk of incontinence. Type of anastomosis had a direct effect, according to our results stapler completed anastomosis significantly had less risk of incontinence compared to hand sewn anastomosis. Additionally smaller DRM was more likely to be associated with disturbed postoperative anal sphincteric function. In the same respect, T stage of the tumors and overall stage had no correlation **Table (4,5)**.

There were temporary bladder dysfunction (<3 months) in association with SSS in 13 patients (21.7%) and were managed conservatively by Foley's catheter and one patient had permanent bladder dysfunction (>3 months) which proved to be neurogenic bladder. In the respect of sexual function, of 20 male patients who had rectal resection, 6 patients (30%) had sexual dysfunction, 2 of them had erection problems and the other 4 had ejaculation problems.

### **Discussion:**

The ideal treatment of rectal cancer should preserve the anal sphincter with low morbidity and mortality and favorable oncologic outcomes. Following the introduction of TME by Heald and the development of staplers, SSS became a better alternative to APR.<sup>16</sup> In the last years, anterior resection with TME excision has become the optimal treatment of rectal cancer.

Still the tumor level is an important factor for the type of the adopted surgery, a DRM of 2 cm is sufficient for a SSS which wouldn't affect the survival or local recurrence in patients with rectal cancers.<sup>17</sup> In the last few years there is a developing trend to decrease the DRM to 1 cm, as it proved to have appropriate clearance for most rectal cancers.<sup>18</sup> In the current study, a distal margin clearance with a 2 cm DRM for stage I or stage II tumors was performed and we did not find any tumor beyond this margin histopathologically. Our operative time was

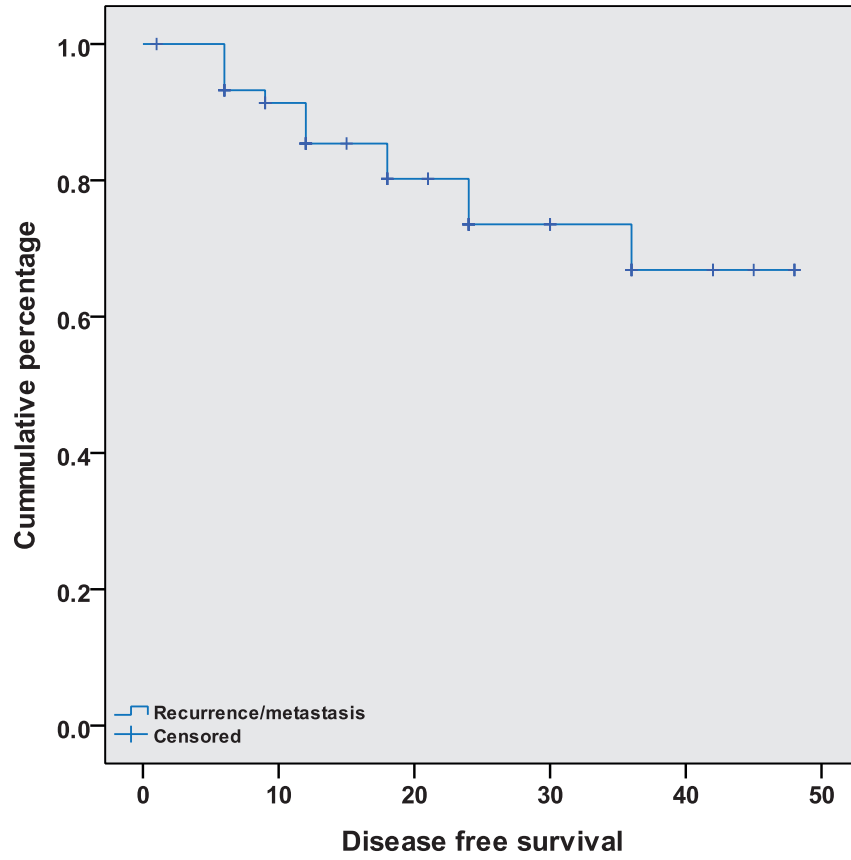


Figure (1): Disease free survival.

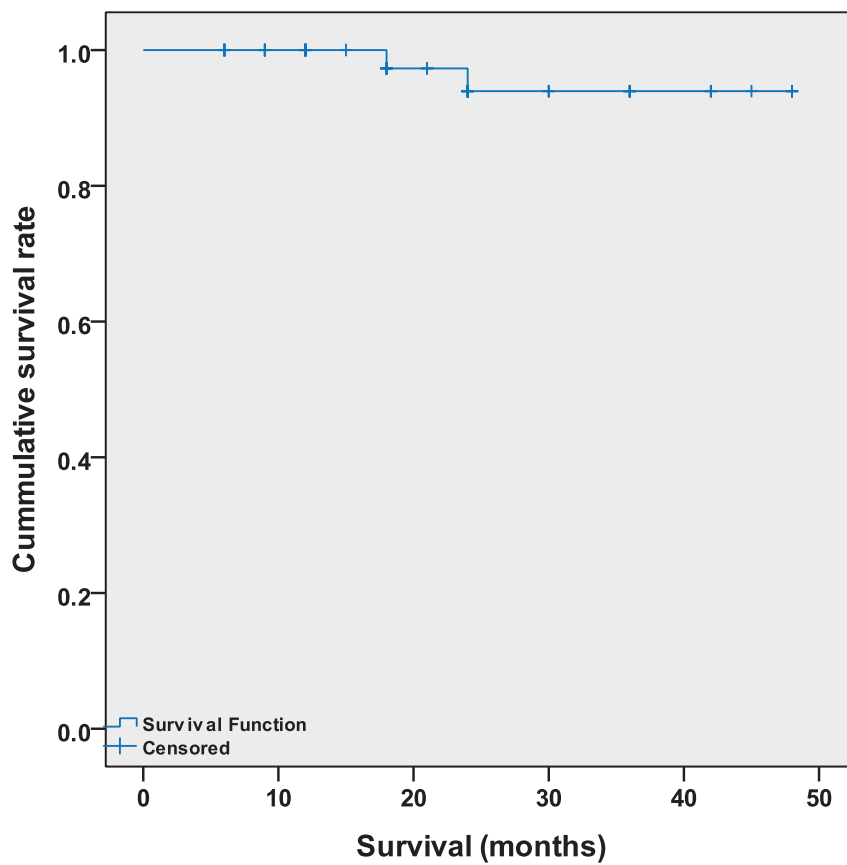


Figure (2): Overall survival.



**Table 1: Operative and postoperative complications.**

Complications	Number of patients (%)
Operative complications	
Ureteric injury	2 (3.3)
Bladder injury	1 (1.7)
Postoperative complications	
Wound healing disturbances	9 (15)
Intra-abdominal infection	2 (3.3)
Fecal fistula	4 (6.7)
Stricture	1 (1.7)

**Table 2: Factors affecting local recurrence.**

	Total number =60 (%)	Number of recurrent cases =5 (%)	Chi square	P value
Tumor site				
Mid-rectal	47 (78.3)	4 (80)	2.275	0.32
Low-rectal	4 (6.7)	1 (20)		
Method of anastomosis				
Stapler	39 (65)	1 (20)	0.539	0.46
Hand sewn	21 (35)	4 (80)		
Distal resection margin				
1 cm distal margin	7 (11.7)	3 (60)	13.32	< 0.05
2 cm distal margin	29 (48.3)	1 (20)		
3 cm distal margin	9 (15)	1 (20)		
4 cm distal margin	5 (8.3)	0 (0)		
5 cm	10 (16.7)	0 (0)		
Tumor grade				
Poorly differentiated (grade III)	2 (3.3)	1 (20)	5.1	0.078
Moderately differentiated (grade II)	34 (56.7)	3 (60)		
Well-differentiated (Grade I)	24 (40)	1 (20)		
T stage of the primary tumor				
T1	4 (6.7)	0 (0)	0.622	0.89
T2	26 (43.3)	2 (40)		
T3	29 (48.3)	3 (60)		
T4	1 (1.7)	0 (0)		
Nodal stage				
N0	18 (30)	2 (60)	6.52	< 0.05
N1	29 (48.3)	0		
N2	13 (21.7)	3 (40)		
Overall stage				
Stage I	7 (11.7)	0	2.11	0.348
Stage II	11 (18.3)	2 (40)		
Stage III	42 (70)	3 (60)		
Stage IV	0 (0)	0		

\* Factors with bold letters were significant.

\* Values in parentheses are percentages.

**Table 3: Multivariate analysis for risk factor of local recurrence.**

	P value
Tumor site	0.998
Tumor grade	0.728
Type of anastomosis	0.998
Operative time	0.149
Type of stoma	0.290
Distal resection margin	0.122
T stage of primary tumor	0.833
N stage	0.250
Constant value	0.996

**Table 4: The relation of different disease findings to the continence status.**

Disease findings	No	Perfect bowel function (%)	Incontinence for flatus	Minor soiling	Chi-square	P value
The tumor site						
High,	9	9 (100)	0 (0)	0 (0)	21.16	<0.0001
Mid	47	36 (76.6)	10 (21.3)	1 (2.1)		
Low	4	2 (50)	0 (0)	2 (50)		
Type of anastomosis						
Stapler	39	32 (82%)	6 (15.4)	1 (2.6)	5.88	0.05
Hand sewn	21	15 (71.4%)	4 (19.1)	2 (9.5)		
Distal resection margin						
1 cm	7	5 (71)	0 (0)	2 (29)	13.9	0.085
2 cm	29	21(72.4)	7 (24.1)	1 (3.5)		
3 cm	9	7 (78)	2 (22)	0 (0)		
4 cm	5	4 (80)	1 (20)	0 (0)		
5 cm	10	10 (100)	0 (0)	0 (0)		
T stage						
T1	4	4 (100)	0 (0)	0 (0)	0.636	0.48
T2	26	18 (69.2)	5 (19.2)	3 (11.6)		
T3	29	24 (82.7)	5 (17.3)	0 (0)		
T4	1	1(100)	0 (0)	0 (0)		
Overall stage						
Stage I	7	5 (71.4)	2 (28.6)	0 (0)	2.549	0.636
Stage II	11	10 (90.9)	1(9.1)	0 (0)		
Stage III	42	32 (76.2)	7 (16.7)	3 (7.1)		
Stage IV	0	0 (0)	0 (0)	0 (0)		

\* No = number.

\* Factors with bold letters were significant.

in accordance with other reports,<sup>19</sup> although it was expected that time would become longer due to the meticulous dissection of the

mesorectum but the use of stapler completed anastomosis saved much time.

One of the complications after surgery

**Table 5: Continence results according to Kirwan's classification.**

Stage	Frequency (%)
I (Perfect)	47 (78.3)
II (Incontinence flatus)	10 (16.7)
III (Minor soiling)	3 (5.0)
V (Incontinent requiring colostomy)	0 (0)

was anastomotic leak which was reported previously to vary between 11 and 18%.<sup>20</sup> Our rate was 6.7% which was described by others; 2–9 %.<sup>21</sup> The only factor found to be significantly associated with fecal fistula was the smaller distal resection margin, this mandates protective colostomy or ileostomy in such cases.

Before introduction of the modern surgical modalities for treatment of rectal carcinoma, the achievement of radicality with APR was in expense of the patients' quality of life with a considerable recurrence rate of 30%.<sup>7,8</sup> In our study, SSS with TME, local recurrence happened in 8.3% which is comparable to others.<sup>22</sup> Some may consider this recurrence rate as being low and attribute this to a claimed short term follow-up (mean = 20 months) which reached 4 years especially that our patients did not receive neoadjuvant therapy, it is known that 80% of the local recurrences occur within the first 2 years after surgery and with neoadjuvant therapy the local recurrence rate reached 1.5%.<sup>23</sup>

Factors that are possibly associated with local recurrence were analyzed, of which DRM was found to have a significant inverse relationship with local recurrence, tumor with shorter surgical distal margin has been found to have a significant higher potential of local recurrence. Also local recurrence was significantly associated with higher nodal stage of rectal adenocarcinoma.

The cancer free survival doesn't differ between SSS and APR;<sup>18</sup> we reported a cancer-specific survival of 66.9%, which is comparable with others' results.<sup>24</sup>

Our final continence results after SSS were accepted by most of our patients. Seventy eight percent of the cases had perfect postoperative bowel functions.

None of the patients had occasional major soiling or incontinence requiring colostomy. All anastomoses were end-to-end and it is well established that direct end-to-end anastomosis of proximal colon to the anorectal junction results in poorer functional results in the earlier postoperative period,<sup>25</sup> so our results are generally satisfactory. Although some encourage pouch formation, most studies showed that pouch and straight coloanal anastomosis function becomes comparable after 1-2 years.<sup>26</sup> According to our results low rectal tumors had a highly significant increased risk of incontinence, 2 cases (66.7%) with minor soiling were low rectal cancer as all of these cases (low-rectal cancer) were managed by hand sewn anastomosis transanally in which there was removal of part of the internal sphincter during ISR, accordingly an element of anal-sphincter insufficiency occurred leading to a degree of incontinence.<sup>27</sup> The partial loss of sphincter control disappeared spontaneously, as in most reported studies.<sup>28</sup>

Postoperative good quality of life as a requirement of the surgical outcome doesn't entail the avoidance of colostomy only, but also the avoidance of the postoperative functional disorders of the bladder and sexual organs. Although sphincter saving operations have problems of frequent bowel movement, urgency, flatulence, and need for frequent medication but they are superior to APR regarding quality of life.<sup>29</sup>

Earlier evaluations have shown that after extensive conventional resection, bladder dysfunction due to neurological complications has been reported in up to 54% of patients after surgical resection of the rectum.<sup>30</sup> In contrast, the introduction of TME was followed by a reduction in the



neurological complication rates to less than 5.3%.<sup>29</sup> In this study 21.66% had temporary bladder dysfunction (<3 months) and were managed conservatively by Foley's catheter. Rectal resection was associated with sexual dysfunction in up to 59% of patients.<sup>13</sup> In our study 30% of our male patients who had rectal resection, suffered sexual dysfunction.

### Conclusion :

SSS should be considered in patients with a good functioning anal sphincter mechanism and the tumor is more than 2 cm above the dentate line. It neither compromises operative safety nor oncologic outcomes.

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