New approach method in minimally invasive surgery for rectal cancer: transanal endoscopic surgery

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Abstract

Introduction: Apply and assess the early results of Transanal Total Mesorectal Excision (TaTME) for mid and low rectal cancer.

Material and Methods: A prospective study in 45 patients (31 men and 14 women) suffering from mid and low rectal cancer, undergoing TaTME in Department of Gastrointestinal Surgery, 108 Military Central Hospital, from July 2017 to August 2018.

Results: Pre-operative stages were mrT2: 8.9%, mrT3: 66.7%, mrT4a: 11.1%; mrTx: 13.3%. mrN (+): 73.3%, mrN(-): 20%, mrNx: 6.7%. The mean age was 64.56 ± 10.97 years, the mean body mass index was 20.5 ± 2.5 kg/m^2. Low rectal cancer was 60% and mid rectal cancer was 40%. The mean operative duration was 145.33 ± 22.47 minutes. Operative morbidity rate was 33.3%, no operative mortality was detected. The macroscopic quality assessment of the resected specimen was complete in 77.8% nearly complete in 17.8%, the distal resection margin negative rate was 100% and the circumferential resection margin negative rate was 88.9%; The mean number of harvested lymph nodes was 4.52 ± 3.74. Postoperative stages were pT0: 6.7%, pT1: 2.2%, pT2: 31.1%, pT3: 53.3%, pT4a: 6.7%; pN-: 68.9%, pN+: 31.1%. Kirwan classification in anorectal function after 6 to 9 months of the operation was: Kirwan I and Kirwan II: 81.2%.

Conclusion: TaTME technique was feasible and safe with the good early outcomes, the high-quality of TME specimens and sphincter-sparing resections for treatment in mid and low rectal cancer.

1. Introduction

Anatomical pathology result is the most important goal in the surgery of rectal cancer, followed by the conservation of sphincters in order for patients to avoid bringing colostomy. Achieving both goals is still a big challenge for surgery.

Total Mesorectal Excision (TME) is considered as the gold standard in rectal cancer treatment [1]. The up to down approach of TME in laparoscopic surgery has not been satisfactory for anatomical pathology result in patients with low rectal cancer [2], [3]. Difficulties are common in patients with narrow pelvis, obesity, large tumors ... [3], which leads to incomplete mesorectal excision and incorrect

estimation of safe distance to low border of the tumor as well as low rate of sphincter preservation.

TaTME method was first reported by Sylla in 2010 with a down to up approach [4]. There have been a number of authors who have applied and demonstrated that this technique could be safely performed but still maintained the principle of anatomical pathology result in TME and increase the sphincter preservation rate, for that reason it may be possible to consider applying this method as a new development in the treatment of rectal cancer [5], [6], [7], [8].

Our study reported the initial experience in 45 patients who underwent TaTME in treating the mid and low rectal cancer for the purpose of implementing and evaluating the initial results of TaTME surgery treatment for rectal cancer.

2. Materials and methodology

Subjects

A total of 45 patients with the tumor located in mid and low part of rectum at 108 Military Central Hospital from July 2017 to July 2018. The cancer was diagnosed with 3.0 Tesla MRI, colonoscopy, histopathologic biposy and treated by TaTME surgery.

Inclusion criteria: Patients with tumor stage ≤ mrT4a, distance from the tumor to anal verge ≤ 10 cm on MRI, ASA score from I to III. Pre-surgery radiotherapy 25Gy x 5 days for T1-T3 tumors and / or N1-N2 lymph node metastasis, immediately followed by surgery. Chemotherapy - 50.4Gy for 28 days plus Capecitabine for T4 tumors, surgery after 6-8 weeks of treatment.

Method: Prospective study.

Procedure: Divided into 2 phases: transanal endoscopy surgery and laparoscopy surgery. Prior to anal endoscopy surgery, patients were performed laparoscopy using a 10mm trocar at the navel.

Stage 1: Transanal endoscopic surgery.

Placed Lone Star valve to expose the anus and assess the tumor. Mucosal closure sutured below the tumor ≥ 1cm. Dissected through rectal wall below the sutures ≥ 1cm facing the outside of the mesorectum and gradually upward until to sufficient space to place the Gelpoint Path valve. Continued dissecting the mesorectum, always follow the outside of the mesorectum until perforating through the peritoneum fold on the front.

Stage 2: Laparoscopic surgery.

Techniques such as laparoscopic surgery removed the rectum in the front line to meet the area of the anus road.

The specimen collected through the anus, located the cutting position and got the specimen. We performed sigmoid colon - anus tube manually or automatic joint cutter.

Research targets: Patient characteristics (age, gender, BMI, ASA), surgery duration, complications, tumor characteristics, some early results, pathological findings. Evaluated sphincter function by Kirwan criteria standard and local recurrence, metastases once per month in the first year, once per 6 months the following years.

Data analysis: Using SPSS 16.0 software for data analysis

3. Results

(Table 1, Table 2, Table 3, Table 4, Table 5)

4. Discussions

15/45 patients (33.3%) in the study received pre-surgery chemoradiotherapy, in which 5 patients (11.1%) had tumour stage of mrT4b and 15 patients (33.3%) had mrN+. In the postoperative period, 6 patients (13.3%) could not been evaluated the primary tumor (mrTx) and 3 patients (6.7%) were not assessed the regional nodal metastasis (mrTx) .

With good experience in endoscopic surgery for rectal cancer, we found that high BMI or narrow pelvis (usually in male) were predict factors of the difficulties. The mean BMI in the study was 20.5 ± 2.5 kg / m^2, lower than in other studies: 25.2 [5]; 27 [6]. 31/45 patients (68.9%) in the study were men with narrow pelvis but we had no difficulty in performing TaTME surgery for these patients, which was an advantage of TaTME surgery. The mean

Table 1. Pre-operative patient characteristics

Characteristics		Results	Characteristics	Results
Gender, n (%)	Male	31 (68,9)	T staging pre-chemoradiotherapy	n (%)
	Female	14 (31,1)	mrT3	9 (20)
BMI (X ± SD)		20,5 ± 2,5 (16 - 26,2)	mrT4a	1 (2,2)
	ASA I	10 (22,2)	mrT4b	5(11,1)
ASA, n (%)	ASA II	31 (68,9)	N staging pre-chemoradiotherapy	n (%)
	ASA III	4 (8,9)	mrN-	0
Abdominal surgery history		5 (11,1)	mrN+	15 (33,3)
Tumour site	1/3 mid	18 (40)	T staging pre-operation	n (%)
	1/3 low	27 (60)	mrT2	4 (8,9)
Distance from the tumor to anal verge (cm):		4,6 ±1,4 (2,2 - 8,2)	mrT3	30 (66,7)
Pre-operative support treatment		n (%)	mrT4a	5 (11,1)
Chemoradiotherapy		15(33,3)	mrTx	6 (13,3)
	Radiotherapy	23(51,1)	N staging pre-operation	
	Chemotherapy	1 (2,2)	mrN-	9 (20)
	None	6 (13,3)	mrN+	33(73,3)
			mrNx	3 (6,7)
			M staging pre-operation	
			M0	43 (95,6)
			M1a	2 (4,4)

Recurrence, n (%)		
	No recurrence	119 (90,8)
	Local spread	1 (0,8)
	Metastasis	8 (6,1)
	Local spread & metastasis	2 (1,5)
	No connection	1 (0,8)
	Trocar site recurrence	0
Survival rate, n (%)		
	Surviving	136 (97,1)
	Death	4 (2,9)
	Cancer death	3 (2,1)
	Death from other causes	1 (0,7)

Table 2. Surgery outcomes

Features	Results
Surgery duration	145,33 ± 22,47
minutes (X ± SD)	(100 - 185)
V blood loss in operation	72,67 ± 42,35
ml	(30 - 225)
Blood transfusion	3 patients
postoperation, n, ml	(250-500-1050)
Anastomosis, n (%)	
Hand sewn	35 (77,8)
Mechanical	10 (22,2)
Drainage in ileum, n (%)	
Yes	32 (71,1)
No	13 (28,9)
Changing surgery technique n (%)	
	0
Peristalsis tie, days	2,5 ± 0,79 (1 - 4)
Hospital stay, days	12,27 ± 6,07 (4 - 29)

Table 3. Anatomic pathology results

Features		Results
Tumour size		3,2 ± 1,7 (1,1-10)
Distance from the tumour to the cuts, cm		
To the proximal		11,9 ± 6,2 (5-38,6)
To the distal		2,3 ± 0,7 (1,4-4,5)
Cut area qualities n (%)		
Complete cut		35 (77,8)
Nearly complete cut		8 (17,8)
Incomplete cut		2 (4,4)
Proximal cut area (-)		45 (100)
Distal cut area (-)		45 (100)
Circumferential cut area (-)		40 (88,9)
Mean harvested lymph nodest		4,52 ± 3,74(0 - 17)
T stages n, (%)	T0	3 (6,7)
	T1	1 (2,2)
	T2	14 (31,1)
	T3	24 (53,3)
	T4a	3 (6,7)
N stages n, (%)	N -	31 (68,9)
	N +	14 (31,1)
Local spread		0
Metastasis		1(2,2%)

Table 4. Complications

Complications,		Bleeding	Rectal perforate		**Total**
n (%)		1 (2,2%)	1 (2,2%)		**2 (4,4)**
Early complications	Urinary retention	Intestinal obstruction	Bleeding	Rectovaginal fistula	
n (%)	7 (15,6)	2 (4,4)	1 (2,2)	1(2,2)	**11(24,4)**
(Clavien - Dindo)	I	II	I	IIIb	
Late complications		Anastomotic leak	Rectovaginal fistula + anastomotic stricture		
n (%)		1 (2,2)	1 (2,2)		**2 (4,4)**
(Clavien - Dindo)		IIIa	IIIb		
					15 (33,3)

Table 5. Evaluate the function of anal sphincter by the time

	Kirwan classification, n (%)					
	Kirwan I (Very good)	Kirwan II (Good)	Kirwan III (Moderate)	Kirwan IV (Bad)	Kirwan V (Very bad)	Total
< 1 month	0	0	3(18,8)	13(81,2)	0	16(100)
1 - <3 months	0	1(4,2)	18(75)	5(20,8)	0	24(100)
3 - <6 months	0	11(50)	9(40,9)	2(9,1)	0	22(100)
6 - <9 months	6(37,5)	7(43,7)	3(18,8)	0	0	16(100)
9 - 12 months	5(71,4)	2(28,6)	0	0	0	7(100)
>12 months		1(100)	0	0	0	1(100)

distance from the inferior margin of the tumor to the anal verge was 4.6 ± 1.4 cm (2.2 to 8.2 cm). There were 27/45 patients (60%) with low rectal cancer in the study. For this group, our previously published studies showed that the incidence of sphincter conservation with TME surgery was less than 50%. Other studies showed that the distance was: 7.6 ± 3.6cm [5]; 4cm (0 - 5cm) [6]; 4cm (1-5cm). TaTME surgery could be a major change in the treatment of low rectal cancer, especially considering the problem of sphincter preservation. Preservation of the sphincter helping to avoid permanent artificial anus and to improve the quality of life for patients was an important goal of low rectal cancer treatment.

Surgery duration depended on many factors, including skill and experience of surgeons, BMI, number of surgery teams ... Some large centers around the world usually had two simultaneous surgery teams for two phases: abdominal and anal phase, [6]. With current available equipments and human resources, we could only deploy one team with one machine and tools for laparoscopic surgery. Mean surgery duration was 145.33 ± 22.47 minutes, which was equivalent to Lacy's result of 166 ± 57 minutes.and shorter than other studies: 270 minutes; 244.9 minutes in the laparoscopic surgery group and 197 minutes in the open surgery group. The mean volume of blood loss in surgery in this study was 72.67 ± 42.35 ml (30 - 225). Three patients received postoperative blood transfusion with a total blood volume of 250, 500 and 1050 ml respectively, as they had preoperative anemia. In the study of Xu, mean blood loss volume was 60 ml and in COLOR II study, it was 200 ml in the laparoscopic surgery group and 400 ml in the open-surgery group. Ileum drainage in 32/45 patients (71.1%). Rate of other studies: 83.6%. Mean hospitalization stay: 12.27 ± 6.07 days was longer than Lacy's 7.8 ± 5.1 days, because in some patients with favorable postoperative lesions, we actively prolonged hospitalization stay in the treatment period to close ileum drainage. There was no cases requiring changing of surgery method, even in cases the tumor size was large or tumor position was low or very low. This was one of the advantages of TaTME surgery, with a combined approach of down to up and up to down, which in other studies was 3.7% [7], 0% [5]. A number of studies had shown that TaTME surgery helped to overcome many of the limitations encountered in traditional laparoscopic surgery such as: large tumors, narrow pelvis, obesity, pre-operative chemoradiotherapy or male patients with prostatic hypertrophy.

The quality of mesorectal and excision sites were important factors in the success of rectal cancer surgery in terms of local recurrence rate and duration of survival. Quirke said that total mesorectum excision and negative circumferential cut site was more important than the distance

from distal cut site to tumor from 1 cm to 2 cm. According to Quirke's mesorectum quality criteria [9], we found that total mesorectum excision rate was 77.8%, near total was 17.8%. These rates were similar to some other authors: Tuech was 84% and 16%, respectively. Penny was 85% and 11% respectively. Lacy was 97.1% and 2.1% respectively. For laparoscopy to treat low rectal cancer, total mesorectum excision rate was only 17% and partial was 3%. Xu's study showed that TaTME surgery achieved 100% total mesorectum excision and laparoscopy was only 75.6%.

Results in Table 3 showed that 3/45 patients (6.7%) had no evidence of primary tumors (pT0). These patients had preoperative chemotherapy. 100% of proximal and distal excision site was (-) with mean distances from tumors to proximal and distal site were 11.9 ± 6.2 cm and 2.3 ± 0.7 cm respectively. Penna's study showed that distal excision site (+): 2.7% [10], Simillis: 0.3%. Our study had 5/45 patients (11.1%) having circumferential excision margin (+), this ratio in some other researches was 6.8%, 5.3% and 5%.

We believed that the good results in terms of mesorectum quality and excision site are due to the effectiveness of the down to up approach to implement TME in the TaTME method.

A multicentre cohort showed complication rates of TaTME surgery was about 35%, of which the leakage rate was 6.1%. According to Lacy this rate was 34%. Penna was 32.6% and dangerous described complication was urethra injury [10]. COLOR II study was 40% in the laparoscopy group and 37% in the open surgery group. Complications in study were presented in Table 3. Early complications were ≤ 30 days postoperatively and the complications were classified according to Clavien - Dindo (CD) criteria. Complication rate in the study was 33.3%, in which 2/45 patients (4.4%) included: 1 patient suffering from prostate bleeding, treated with cauterization. This was also our first small pelvis male patient treated with down to up approach and not much experience, 1 patient suffering from ruptured rectum while dissecting through anus, treated with suture and Betadine solution. Complications encountered 13/45 patients (28.9%), in which most were early and mild 10/45 patients, 22.2% (CD I + II), complications needed surgery intervention 6,7% (CD III) including: 1 patient with anastomosis leakage, 1 rectovaginal fistula, 1 patient with anastomosis stricture and rectovaginal fistula. The treatment were to suture the anastomosis or to reconstitute the rectum – vagina wall or to enlarge the anastomosis and to make artificial anus. According to Lacy BC, the need for surgery intervention was 10% (CD III and IV). The rate of leak and narrowing of the anastomosis according to study of Xu were: 2.7% and 16.2% respectively. According to the studies of some authors, complications of leak or narrow anastomosis were associated with radiotherapy, the cause was attributed to lack of nourishment in the previously radiated region.

Evaluation of anal sphincter function in patients without artificial anus and those who did but were closed by surgery in the first, third and sixth months according to Kirwan criteria had results shown in Table 5. The assessment results of the anal sphincter function in our study were also consistent with those of Zhang HW et al. when analyzing the pressure in the anal tube to assess the sphincter muscle tone after transanal endoscopic surgery, indicating the decrease in sphincter function peaking in the second week after surgery, gradual improving in the following weeks and regaining functions as prior to surgery in 6 months.

TaTME surgery had initially shown that this was a viable and safe method of treating mid and low rectal cancers with advantages in patients with large tumors, narrow pelvis or obesity. There was no change in surgical methods, acceptable complication rate, increased sphincter preservation rate for low rectal cancer. Outstanding results on the quality of mesorectum was an important prognostic factor for rectal cancer. Thus, TaTME surgery was a promising minimally invasive method.

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