

Cost comparison between endoscopic submucosal dissection and transanal endoscopic microsurgery for the treatment of rectal tumors

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Purpose: To compare medical costs of endoscopic submucosal dissection (ESD) and transanal endoscopic microsurgery (TEM) for the treatment of rectal tumors.

Methods: The records of 80 patients who underwent ESD and 32 who underwent TEM for the treatment of rectal tumors were collected. Factors compared in the two groups included patient age, sex and clinical characteristics, as well as hospital stay, procedure time, instrument use, medications, postoperative complications, and imaging and laboratory findings. Costs were analyzed based on medical insurance fees, as set publicly by the Ministry of Health & Welfare, Korea. Medical costs were also divided into patient copayments and National Health Insurance (NHI) Corporation charges.

Results: Patient characteristics, including age, sex, and comorbidities, were similar in the two groups, as were procedure time, histologic diagnosis, tumor size and distance from the anal verge, hospital stay, and complication rates. Median total hospital costs were significantly lower in the ESD than in the TEM group (1,214 United State dollars [USD] vs. 1,686 USD, $P < 0.001$). The costs for consumables, drugs and laboratory as well as operation fee were also significantly lower in the ESD than in the TEM group. However, patient copayments in the ESD group were significantly higher than in the TEM group (928 USD vs. 496 USD, $P < 0.001$), because ESD procedure for rectal tumors is not yet covered by the Korean NHI.

Conclusion: Overall direct medical costs were significantly lower for ESD than for TEM in the treatment of rectal tumors. [Ann Surg Treat Res 2015;89(4):202-207]

Key Words: Endoscopic surgical procedure, Transanal endoscopic microsurgery, Rectal neoplasms, Local excision, Costs and cost analysis

INTRODUCTION

Colorectal cancer is one of the most common cancers not only in Western countries but also in Eastern countries including Korea [1,2]. The development of endoscopic technology has increased the early detection of colorectal cancers, allowing local treatments rather than radical surgery in patients with early tumors without metastasis [3-5].

Transanal endoscopic microsurgery (TEM), defined as full-

thickness rectal wall resection under general anesthesia in the operating room using a special device, is widely performed for local excision of rectal tumors in Western countries [6]. In contrast, most healthcare providers in Eastern countries, including Korea and Japan, prefer endoscopic submucosal dissection (ESD), because it has shown better oncologic outcomes than conventional endoscopic mucosal resection for the local excision of colorectal tumors [4,5,7-9].

Compared with conventional radical surgery, ESD and

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TEM are less invasive and hence less traumatic to patients, affording less pain, faster recovery, and more rapid return to daily life and the community [10,11]. Although cost-benefit analysis has shown that ESD and TEM are more beneficial than conventional open or even laparoscopic surgery, no study to date has compared the costs of ESD and TEM for the local treatment of rectal tumors.

This study therefore compared the direct medical costs of ESD and TEM for the local treatment of low rectal tumors.

METHODS

Patients and setting

The direct procedural costs of TEM and ESD for local excision of rectal tumors were set by the Korean Ministry of Health and Welfare in April 2010 and November 2011, respectively. This study therefore included patients who underwent TEM from April 2010 to May 2013 and those who underwent ESD from November 2011 to May 2013.

The hospital records of these patients who underwent TEM or ESD for local excision of rectal tumors, including rectal carcinoids, adenomas and rectal cancers, at the National Cancer Center, Korea, were retrospectively collected. Patients were excluded if they (1) received preoperative chemoradiation therapy, (2) underwent palliative procedures, or (3) experienced recurrent tumors after previous treatment. Finally, 80 patients who underwent ESD and 32 who underwent TEM were enrolled. The study protocol was approved by National Cancer Center Institutional Ethics Review Board (IRB No. NCCNCS-13-778).

Procedures

All rectal tumors were carefully evaluated by expert endoscopists using magnification and/or chromo-endoscopy before choosing the treatment method. For suspicious malignant lesions, imaging studies such as CT, magnetic resonance, and endoscopic ultrasound were performed for evaluating the depth of invasion and tumor metastases. Endoscopic resection was preferentially performed in well lifted tumor after submucosal saline injection. The choice of procedure (ESD or TEM) was also influenced by the patients' comorbidity, treatment compliance of the patient and the preference of the physician.

All patients underwent bowel preparation with polyethylene glycol on the day prior to ESD or TEM. The procedure of TEM was performed as previously described [12,13], using a TEM Instrument System (Richard Wolf GmbH, Knittlingen, Germany). All procedure for TEM was performed in the operating room, under general or spinal anesthesia. ESD procedures were performed using a single-channel endoscope (CF-H260AL, Olympus Optical Co., Tokyo, Japan) or dual-channel (GIF-2TQ260M, Olympus Optical Co.) endoscope and a high-

frequency generator with an automatically controlled system (VIO 300D, ERBE, Tuebingen, Germany), as described [14]. A transparent cap was attached to the tip of the endoscope and submucosal dissection was performed using a dual (KD-650Q, Olympus Optical Co.) or flex (KD-630L, Olympus Optical Co.) knife. All procedure for ESD was performed in the endoscopy room under conscious sedation with analgesia.

Patients received a single prophylactic dose of antibiotics before TEM or ESD, and oral intake was restricted for 12 hours after the procedures. Patients were discharged after confirming good oral intake and no immediate complications.

Cost analysis

Medical costs can be categorized as direct, indirect, and intangible costs. Direct costs are those related to treatment or direct patient care, including hospital admission fees, procedure charges, costs of consumables, operating room fees, costs of using surgical instruments, pharmacy charges, nursing care, costs of laboratory and medical imaging tests, and food services. Indirect costs include losses in patient productivity caused by disease-related morbidity and mortalities, including administrative and patient care support during treatment. Intangible charges are those associated with pain, suffering and nonfinancial outcomes associated with disease [15]. This study analyzed only the direct medical costs of ESD and TEM, based on charges billed to the patient. Overall hospital costs were estimated at aggregate account by fee-for-service for each treatment except the specialist's fee. All costs were adjusted for inflation to the value of the Korean won (KRW) in 2013, based on the inflation rate calculated by the Korean Statistical Office, and expressed in US dollars (USD) at the April 2014 exchange rate (1,040 KRW = 1 USD).

Since National Health Insurance (NHI) is mandatory in Korea, all hospital costs are divided into benefit-service and non-benefit-service costs. Inpatients with benign disease are reimbursed for 80% of the benefit service costs by the NHI Corporation, with patients having to pay the remaining 20% of the benefit service costs. In contrast, patients diagnosed with any type of malignancy pay only 5% of the benefit-service charges for cancer-related treatment [16], with the remaining 95% reimbursed by the NHI Corporation. However, patients must pay all non-benefit-service charges. Patient copayments were therefore calculated based on the procedural costs set by the NHI. Specialist fees were excluded from this study.

Statistical analysis

Statistical analyses were performed using SPSS ver. 14.0 (SPSS Inc., Chicago, IL, USA). Clinical factors in the two groups were compared using Fisher exact test. Because cost data showed a skewed distribution, median costs in the two groups were compared using the Mann-Whitney U-test. A P-value less than

0.05 was considered statistically significant.

RESULTS

The clinical characteristics of patients in the ESD and TEM groups, including median age, sex, and comorbidities, were similar, as were the median distance from the anal verge, median tumor size and median procedure time (49.1 minutes vs. 42.6 minutes) (Table 1). There was no difference in the indication for each procedure according to tumor location. There was no case of the tumor in anal canal. One patient in each group experienced a complication. In the ESD group, one patient experienced a small rectal wall perforation during

submucosal dissection; immediately, endoscopic clips were applied during procedure, with an oral diet allowed 3 days later without any further symptoms, including fever, chills or pain. One patient in the TEM group experienced urinary retention after spinal anesthesia; this patient was treated with a Foley catheter for 5 days. No patient in either group experienced a complication requiring additional intervention or surgical management. The rate of negative resection margin was 83.8% in ESD and 87.5% in TEM group. The median total hospital stay was 6 days in the TEM group and 4 days in the ESD, while the preoperative stay was 2 days in the TEM and 1 day in the ESD, with no significant between group differences (Table 1). However, the postoperative period was the same as 2 days in

Table 1. Clinicopathologic characteristics of patients and early outcomes of ESD and TEM

Characteristic	ESD (n = 80)	TEM (n = 32)	P-value
Age (yr)	54.6 (26–82)	52.5 (29–75)	NS
Sex			
Male : female	44 : 36	21 : 11	NS
Body mass index (kg/m ²)	24.1 (17.6–34.9)	24.5 (20.4–31.2)	NS
ASA grade			NS
I : II : III	64 : 15 : 1	18 : 13 : 1	
Tumor size (mm)	14.6 (1–72)	13.3 (2–55)	NS
Tumor location, distance from anal verge (cm)	6.4 (1–16)	5.8 (2–10)	NS
Pathology			NS
Adenoma	5	1	
Carcinoid	55	24	
Tis	11	1	
T1	9	6	
Procedure time (min)	49.1 (10–340)	42.6 (20–93)	NS
Complications			NS
During procedure	1 (perforation)	0	
Post procedure	0	1 (urinary retention)	
Postprocedure admission day (day)	1.9 (1–4)	2.7 (2–6)	NS
Total hospital stay (day)	3.8 (2–6)	5.8 (4–11)	NS

Values are presented as median (range) or number.

ESD, endoscopic submucosal dissection; TEM, transanal endoscopic microsurgery; NS, not significant; ASA, American Society of Anesthesiologists.

Table 2. Direct medical costs during hospitalization for ESD and TEM

Variable	ESD (n = 80), USD	TEM (n = 32), USD	P-value
Admission	151 (54–329)	253 (150–553)	<0.001
Operation	417 (394–1,021)	444 (417–464)	<0.001
Sedation/anesthesia	189 (72–295)	131 (80–224)	<0.001
Consumables	265 (10–544)	357 (93–997)	0.024
Pharmacy	132 (34–337)	233 (150–478)	<0.001
Laboratory	53 (15–240)	172 (39–388)	<0.001
Radiology	5 (5–57)	95 (0–306)	<0.001
Total	1,214 (728–2,107)	1,686 (1,218–3,120)	<0.001

Values are presented as median (interquartile range).

ESD, endoscopic submucosal dissection; TEM, transanal endoscopic microsurgery; USD, United States dollars.

Table 3. Costs of ESD and TEM covered and not covered by the Korean National Health Insurance

Cost	ESD (n = 80), USD	TEM (n = 32), USD	P-value
Covered costs			
Admission	151 (54–329)	253 (150–553)	<0.001
Operation	0 (0)	444 (417–464)	<0.001
Sedation/anesthesia	0 (0)	126 (47–224)	<0.001
Consumables	19 (2–360)	70 (28–304)	<0.001
Pharmacy	115 (23–334)	204 (145–356)	<0.001
Laboratory	50 (15–216)	158 (39–372)	<0.001
Radiology	6 (5–56)	20 (8–64)	<0.001
Total	341 (85–940)	1,275 (965–2,118)	<0.001
Noncovered costs			
Admission	16 (5–154)	22 (5–60)	<0.001
Operation	417 (394–1,021)	28 (22–91)	<0.001
Sedation/anesthesia	189 (72–295)	13 (4–95)	<0.001
Consumables	252 (4–504)	292 (42–945)	0.004
Pharmacy	30 (10–337)	42 (3–216)	0.125
Laboratory	7 (0–91)	23 (2–73)	<0.001
Radiology	16 (0–293)	76 (0–252)	<0.001
Total	928 (612–1,027)	496 (161–1,168)	<0.001

Values are presented as median (interquartile range).

ESD, endoscopic submucosal dissection; TEM, transanal endoscopic microsurgery; USD, United States dollars.

both groups.

Cost comparisons showed that the median direct medical cost was 472 USD lower in the ESD than in the TEM group (1,214 USD vs. 1,686 USD, $P < 0.001$) (Table 2). The additional costs in the TEM group were mainly due to charges not directly related to surgery, such as preoperative laboratory examinations, including electrocardiograms, chest radiographs, blood typing for possible transfusions during surgery, costs of drugs and monitoring device for general anesthesia and a median 2 days longer total hospital stay. When costs were divided into those billed to the patient and those paid by the NHI, patient copayments were 432 USD higher (928 USD vs. 496 USD, $P < 0.001$), while NHI charges were 934 USD lower (341 USD vs. 1,275 USD, $P < 0.001$), in the ESD than in the TEM group (Table 3).

DISCUSSION

TEM and ESD are considered alternative treatment options for the local excision of rectal tumors [7,9]. Although the standard therapy for rectal tumor is radical excision, local excision modalities are suitable for some benign rectal tumors and early cancers expected to be free of nodal metastasis. Local excision can not only avoid the potential morbidity and mortality of major abdominal surgery, but can also reduce the rates of functional complications, including compromised bladder, bowel habit changes, and sexual dysfunction, that affect patient quality of life after treatment [9,10]. ESD is a major endoscopic excision technique, especially for the removal of large, superficial neoplastic lesions. In addition,

ESD has therapeutic advantages over conventional endoscopic techniques for rectal tumors, increasing the en bloc resection rate and enhancing curability. TEM is an accepted treatment option for selected rectal tumors, with lower complication rates than conventional radical surgery. ESD and TEM have been reported equally effective, as well as oncologically safe, for the removal of rectal tumors, including carcinoids, adenomas and even early cancers [17,18].

Several factors must be considered in deciding whether ESD or TEM should be performed in individual patients with low to mid rectal tumors. ESD, which is performed under conscious sedation with intravenous drugs in the endoscopy unit, is regarded as more difficult technically, whereas TEM is performed under anesthesia in the operating room and requires expensive surgical equipment [19]. For ESD group, there were 13 cases for incomplete resection such as positive resection margin with neuroendocrine tumor (six cases), adenoma (three cases) and carcinoma (four cases). Two patients underwent additional radical surgery of laparoscopic low anterior resection and the others have been taken close follow-up without additional treatment by their own considerations. For TEM group, there were four cases had positive resection margin and among them, two patients underwent laparoscopic ultralow anterior resection. But we did not assess the cost for additional treatment in our study, because the aim of this study was the analysis of the direct medical costs during hospital stay for local excision such as ESD and TEM. This study assessed the medical costs of the two procedures, to determine the advantages and disadvantages of each. Although this study evaluated only the

direct medical costs, it is, to our knowledge, the first study comparing the costs of ESD and TEM for new treatment option. Present study is important because it could be helpful in decision making for health care policy in the future, especially novel technology field. Although this study was designed to evaluate total hospital cost for TEM and ESD, postoperative 30 days complication was rare. There were no local recurrences in both groups during the follow-up period; median follow-up time was 17 months in ESD and 33 months in TEM, respectively. Several previous studies have also reported acceptable long-term outcomes in submucosal invasive colorectal carcinomas treated with colorectal resection or endoscopic resection [20,21].

Since the NHI is mandatory in Korea, all new medical technology must be evaluated by the Korean Ministry of Health and Welfare, with all charges by individual hospitals set by the government. The direct procedural costs of TEM and ESD were set by the Korean Ministry of Health and Welfare in April 2010 and November 2011, respectively. Therefore, this study collected data after the costs were set. Although there was a 6-month difference between the two groups, there was no difference in patients' characteristics in both groups. The study found that the overall medical costs for the removal of rectal tumors were lower for ESD than for TEM. The additional medical costs of TEM were mainly due to extraoperative charges. Although overall complication rates were low, the average hospital stay was 2 days longer in the TEM group due to procedures associated with general anesthesia, such as preoperative laboratory tests, drugs and monitoring. Interestingly, however, the out-of-pocket costs were greater for patients who underwent ESD than TEM, because the NHI does not yet cover the costs of ESD in Korea. If ESD continues to show good clinical outcomes, its costs will be covered by the NHI in near future.

The clinical benefits, patient satisfaction and quality of life were not compared in patients who underwent ESD and TEM, thus limiting the findings of our study. In addition, indirect and intangible costs of these procedures were not analyzed. Additional costs related to transportation and care-giving are more difficult to determine. Moreover, medical charges for outpatient clinic visits were not included, although the follow-up schedule was standardized in our center and was almost the same for both groups.

In addition, ESD and TEM are both difficult to perform, with

outcomes depending on the experience and skill of the operators. This can result in large differences, including in margin status, *en bloc* resection, recurrence and outcomes [8]. Use of more experienced operators would therefore increase the costs of both ESD and TEM, with these additional specialist fees not covered by the NHI. In our study, all patients were treated by an expert surgeon or endoscopist, each of whom had more than 7 years of experience at a specialized cancer center. Such treatment may have shortened procedure time and overall hospital stay, as well as reducing complication rate.

Because noninvasive procedure or local excision has been often conducted in treatment for colorectal neoplasms recently, there are various considerations in patient selection on appropriate procedure such as medical cost [22,23]. Since there are almost no studies about medical cost for the treatment up to now, we first analyzed only direct medical costs for the two local treatment methods for rectal tumors.

Medical practice patterns in various countries may be affected differently by health care resources and medical budgets. Therefore, our results may not be uniformly applicable to other institutions or other countries. Economic evaluations of ESD and TEM may be affected therefore by medical health service systems, as well as by the costs of the individual procedures. Nevertheless, our results indicate the medical costs required for the local excision of rectal tumors. In addition, these cost comparisons may help patients in Korea choose their optimal and cost effective therapy.

In conclusion, this report of direct hospital costs at a single center in Korea indicated that the overall costs of TEM were greater than those of ESD for the treatment of low to mid rectal tumors, including rectal carcinoids, adenomas and early rectal cancers. However, patient out-of-pocket costs were higher for ESD because the Korean NHI does not yet cover the costs of ESD. Further studies are required to compare the indirect and intangible costs of these procedures, as well as their long-term outcomes.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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