Master's Thesis

A Propensity Score-matched Analysis of Advanced Energy Devices and Conventional Monopolar Device for Minimally Invasive Colorectal Cancer Surgery : Comparison of Clinical and Oncologic Outcomes

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August, 2022

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A thesis submitted to the department of Medicine
in partial fulfillment of
the requirement for the degree of
Master of Medicine

August, 2022

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August, 2022

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1. Introduction

Laparoscopic surgery has gained increasing acceptance for colorectal cancer (CRC) treatment beyond clinical trials since the first report of this minimally invasive surgery (MIS) in 1991 (1). Robotic surgical systems in MIS were developed recently, in part to overcome several inherent limitations of laparoscopic surgery (2). MIS for resection of CRC is as effective as open surgery with no negative effect on the overall and disease-free survival rate of patients (3). Furthermore, this procedure is associated with lower mortality, lower complication rates, and a shorter median length of hospital stay than open approach (4).

In gastrointestinal oncologic surgery, lymphovascular dissection around the major feeding vessels is one of the most important parts. However, it is not easy to safely perform an oncologic radical surgery without complications such as massive bleeding (5). Since Dr. Bovie developed the electrosurgery in 1920s, the conventional monopolar electrosurgery device has been widely used for mesentery dissection and vessel control in MIS of CRC (6). However, it has several shortcomings including the risk of collateral thermal injury, difficult hemostasis, intraperitoneal temperature variations, smoke production and necessitating the use of additional tools such as bipolar graspers, sutures and clips (7). Several surgical energies have been developed in order to overcome these problems, including the electrothermal bipolar vessel sealer, ultrasonic coagulating shears, and device which integrates both ultrasonic and advanced bipolar energy device. These devices revolutionized laparoscopic surgery, allowing for rapid dissection and reliable hemostasis, leading to the ability to perform more complex procedures (8). Because of various advantages, the use of the advanced energy devices is gradually increasing, and applied to colorectal cancer surgery (7, 9, 10). Some previous studies have been proved the safety, efficiency and versatility of advanced surgical energy devices, having superiority for short-term outcomes such as amount of blood loss and operation time in colorectal cancer surgery than conventional monopolar device (6, 9, 11).

Recent studies on energy devices have focused on short-term surgical and short-term clinical outcomes. However, there is no study on the long-term oncologic outcomes according to types of surgical energy devices. We hypothesized that energy devices may affect oncologic outcome because they have more tumoricidal and sealing effect around lymphovascular chain than conventional monopolar device. The purpose of this study was to investigate the impact of surgical energy device on both operative and oncologic outcomes of minimally invasive colorectal cancer surgery.

2. Materials and methods

2.1. Patients

Between August 2015 and December 2017, a total of 316 patients underwent a laparoscopic or robotic colorectal cancer surgery at Keimyung University Dongsan Hospital, Daegu, Korea. Exclusion criteria were: patients with synchronous or previous malignancies, received palliative resections or emergency surgery, presenting distant metastasis, diagnosed with malignancies other than adenocarcinoma, and patients having missing data. The study group included 80 patients who underwent surgery using conventional monopolar device and 217 patients who underwent using advanced energy device. To minimize the influence of covariates affecting the outcomes, the propensity-score matching was performed, produced 63 pairs in each group, and total 126 patients were finally enrolled in this study. Information regarding patient demographics, perioperative outcomes, postoperative outcomes, pathologic outcomes and oncologic outcomes was obtained from a prospectively collected data. The study was approved by the local ethics committee. (IRB No. : DSMC 2022-05-083)

2.2. Clinical evaluation and Treatment

All of the patients underwent a colonoscopy, biopsy, and staging imaging studies including computed tomography of the chest, abdomen, and pelvis, and magnetic resonance imaging of the pelvis. In addition, positron emission tomography scans was carried out in selected patients. Following the original description (12), we applied the general principles of complete mesocolic or mesorectal excision and central vascular ligation for CRC. The primary tumor was resected by sharp dissection of the visceral plane from the parietal fascia layer along with the entire regional mesocolon in an intact package. For right-sided colon cancer, radical lymphadenectomy was performed along the primary feeding vessels following a vertical line to expose the superior mesenteric vein. For left-sided colon or rectal cancer, high or selective ligation of the inferior mesenteric artery along with the lymph node dissection was performed based on the tumor location. The post-operative follow-up and adjuvant treatment were performed according to NCCN guidelines and individual indication.

In this study, energy devices were selected by surgeon’s preference, defined as the device used in lymph node dissection and vessel control in MIS of CRC. The conventional monopolar electrosurgery device was used in monopolar group. Ultrasonic shears

(Harmonic ACE, Ethicon Endo-surgery, Cincinnati, OH, USA) or integrated bipolar and ultrasonic device (Thunderbeat, Olympus Medical Systems Corp. Tokyo, Japan) was used in energy device group.

2.3. Evaluation of parameters

The tumors located in ascending or transverse colon were classified as a right-sided tumor, and the tumors located in descending, sigmoid or rectum were classified as a left-sided tumor. The conversion was defined if the surgical technique was interrupted during surgery; minimally invasive techniques to open approach. Surgical complications were classified by the Clavien-Dindo classification, and if patient had multiple surgical complications, the most severe of them was counted as morbidity.

Tumor stages were classified according to the American Joint Committee on Cancer (AJCC) staging system, 7th edition. Overall survival (OS) time was defined as the time between the date of surgery and the date of death or last follow-up visit, and disease-free survival (DFS) time was defined as the time elapsed between the date of surgery and tumor progression. Patients who died from other causes or were alive without progression or recurrence at the most recent follow-up were treated as censored in the analysis of DFS time. Recurrence was defined as the presence of a radiologically- and/or histologically-confirmed tumor, and the location of recurrence was defined as the first site of recurrence after a complete resection. If cancer recurrence occurred in the surgical field, it was defined as local recurrence. Conversely, if cancer recurred outside the surgical field, it was defined as systemic recurrence.

2.4. Statistical analyses

Data were expressed as mean with standard deviation or figure with percent. Statistical analyses were performed using SPSS software 25 (IBM, New York, NY, USA) and SAS 9.4 (SAS Institute Inc., Cary, NC, USA). Categorical variables were analyzed using the Chi-squared or Fisher's exact test, and continuous variables were analyzed using the independent t test or Mann-Whitney U rank test. Survival curves and disease-free intervals were obtained using the Kaplan-Meier method. The differences in OS and DFS rate were assessed using the log-rank test. The significance level of the statistical test was set to 5%. P-values of less than 0.05 were considered to indicate of statistical significance.

We estimated propensity scores with logistic regression to mitigate the confounding influence of the following covariates: tumor's lesion, pre-operative level of CEA and operation technique, because these variables were significantly different between conventional monopolar group and advanced energy device group in patient’s baseline characteristics. P-value for the Hosmer and Lemeshow Goodness-of-Fit Test of propensity-score matching model was 0.382. After matching, no significant differences in the baseline characteristics were shown.

3. Results

3.1. Patients' characteristics

Demographic characteristics were similar between the two study groups such as age, sex, body mass index, tumor's location, pre-operative existence of obstruction, pre-operative CEA, ASA score and operation technique after the propensity-score matching was performed.

3.2. Operative outcomes

The median operation time was equivalent between the monopolar group and the energy device group (212.2 min vs. 214.0 min, p=0.908). The amount of blood loss (72 ml vs. 54 ml, p=0.123), conversion cases to open surgery (11.1% vs. 4.8%, p=0.187), and intraoperative complications (9.5% vs. 4.8%, p=0.299) were higher in the monopolar group, but the differences were not statistically significant. In the monopolar group, a majority cause of conversion was severe adhesion (4 cases, 6.3%), and most of intraoperative complication was injury to adjacent organs (5 cases, 7.9%).

3.3. Postoperative outcomes

There were no apparent differences in the tolerance of diet and length of hospital stay between the two groups. The morbidity rates within 30 days (34.9% in the monopolar group, 27.0% in the energy device group. p=0.335) and its severity according to Clavien-Dindo classification (p=0.620) were comparable between the groups. Anastomotic site leakage was occurred in four patients (three patients in monopolar group and one patient in energy device group) received re-operation as primary repair or diverting stoma. On the other hand, anastomotic site stenosis was occurred in one monopolar group patient, received surgical dilatation of stricture. No mortalities occurred within 30 days in both study groups. Same proportion of patient (39.7%) from each group received postoperative adjuvant chemotherapy.

3.4. Pathologic outcomes

There were no significant differences in pathologic outcome of resected tumor, such as mass size, tumor’s differentiation, pathologic T or N stage, lymphovascular invasion, tumor budding and perineural invasion. The median numbers of harvested lymph nodes (monopolar: 19.2 vs. energy device: 20.1, p=0.662) and the numbers of tumor-positive lymph node (monopolar: 0.6 vs. energy device: 0.7, p=0.714) were similar in two groups.

3.5. Oncologic outcomes

In our study, median lengths of follow-up periods were 52.0 months for the whole study population, 52.9 months in the monopolar group and 51.1 months in the energy device group. Overall, 16 patients had recurrence of the tumor (11 in the monopolar group, 5 in the energy device group), and 14 patients died (9 in the monopolar group, 5 in the energy device group). During the follow-up periods, the 5-year overall survival rates of the monopolar and energy device groups were 84.6% and 91.6% (p=0.276), and the 5-year disease-free survival rates were 78.0% and 84.6% (p=0.328), respectively. Recurrence rate (17.5% vs. 7.9%) was higher in the monopolar group than the energy device group, and more systemic recurrences were occurred in the monopolar group (8 cases, 12.7% vs. 4 cases, 6.3%), But these distributions of recurrence were not significantly differed between the two groups (p=0.108, 0.332, respectively).

4. Discussions

The current study showed that short-term outcomes such as operation time, amount of blood loss, length of hospital stay, and complication rates did not differ between the groups used conventional monopolar device and advanced surgical energy device. Also, this study revealed that the advanced energy device did not affect long-term oncologic outcomes, such as 5-year overall survival rate and disease-free survival rate. As we know, this study is the first study on the long-term oncologic outcome of advanced energy device in surgery of CRC. Furthermore, among previous studies, our study may have several strengths of propensity-score matching to minimize selection bias.

The advanced surgical energy devices were designed to be multi-functioning: as grasper, dissector, cutter, or coagulator in a single device (5, 6). Some studies from randomized clinical trials show intraoperative advantages, including lower intraoperative blood loss and shorter operative time in patients undergoing MIS of CRC with ultrasonic shears or advanced bipolar vessel sealers than conventional monopolar devices (6, 9). In ex-vivo study using human pulmonary artery branches, vascular sealing by advanced energy devices was effective and able to sustain high intraluminal bursting pressures (13).

So, surgeons may think that the advanced energy device can be superior in operation time and amount of blood loss, because it produces higher burst pressure of dissected arteries as well as a significantly faster tissue dissection time (5, 14, 15). However, in our study, there was no significant difference in operative outcomes between two study groups. Previous retrospective study, included patients who underwent colorectal resection, reported similar result to ours that no significant differences were observed in operative time, conversion to open surgery rates, incidence of device-related injury to intra-abdominal organs, and postoperative morbidity between conventional monopolar group and advanced energy device group (11).

The numbers of dissected lymph nodes and the ratio of involved versus dissected lymph nodes have been used as markers for quality of surgery and histopathological evaluation (16). Recent studies suggested that advanced energy device may have superiority in radical lymphadenectomy because of its higher bursting pressure and versatility in hemostasis, sealing/coagulation, cutting, dissection and tissue manipulation at various ex-vivo model using porcine vessels (5, 17). In the current study, the number of total harvested lymph nodes and cancer-positive lymph nodes were not different between two study groups. We believe that the oncologic principle of radical lymphadenectomy with training in dedicated surgical skills is more important for quality of cancer surgery than the surgical instrument itself, although innovative instruments have been developed.

The optimal technique for curative resection of colon cancer includes high ligation of the mesenteric vessels, wide excision of the colonic mesentery and prevention of tumor cell spillage (18). Especially, during lymph node dissection in CRC, surgeons should avoid spillage of residual tumor cells from lymphatic leakage, because it can cause tumor recurrence and produce poor prognosis (19, 20). It can be said that advanced surgical energy is more advantageous in the treatment of microscopic tumor cells around lymphovascular structure. We hypothesized that advanced surgical energy could allow less microscopic cancer cell spillage and more tumoricidal effect during lymph node dissection, and impact on oncological outcomes. However, there was no significant difference in post-operative chyle leakage rate and long-term oncologic outcomes between monopolar group and energy device group. Additional pre-clinical studies and clinical studies using larger sample sizes on this issue are needed in the future.

The current study has several limitations, including its retrospective nature, small sample size, lack of multicenter data, and selection bias resulting from surgeon's individual preference-based selection of the surgical energy devices. Thus, further large long-term randomized prospective study and objective selection criteria for each device should be set up to demonstrate the significant benefit of using the advanced surgical energy devices in MIS for CRC.

5. Summary

The aim of this study is to investigate the impact of surgical energy device on operative and oncologic outcomes of minimally invasive colorectal cancer surgery. The study group included 63 matched pairs who underwent a minimally invasive colorectal cancer surgery with conventional monopolar device and advanced surgical energy devices between August 2015 and December 2017. In this study, the operative outcomes and the short-term clinical outcomes were not significantly different. During the median follow-up periods of 52.0 months, the 5-year overall survival rates and the 5-year disease-free survival rates of the conventional monopolar and advanced energy device groups were comparable. The use of advanced surgical energy device did not show the significant impact on operative and long-term outcomes compared with conventional monopolar device in minimally invasive colorectal cancer surgery. Further large long-term randomized prospective study and objective selection criteria for each device should be set up to demonstrate the significant benefit of using the advanced surgical energy devices in minimally invasive surgery for colorectal cancer.

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(Abstract)

The safety, efficiency and versatility of novel surgical energy devices have been proved by recent studies. The aim of this study is to investigate the impact of surgical energy device on operative and oncologic outcomes of minimally invasive colorectal cancer surgery. The study group included 80 patients who underwent a minimally invasive colorectal cancer surgery with conventional monopolar device and 217 patients with advanced surgical energy devices between August 2015 and December 2017. The propensity score-matching for tumor’s lesion, pre-operative level of CEA and operation technique produced 63 matched pairs. After matching, there was no significant difference in the patients’ baseline characteristics. The amount of blood loss, conversion cases to another surgery, operation time and intraoperative complications were not significantly different. The short-term clinical

outcomes and pathologic outcomes was comparable between two groups. During the median follow-up periods of 52.0 months, the 5-year overall survival rates of the monopolar and energy device groups were 84.6% and 91.6%, and the 5-year disease-free survival rates were 78.0% and 84.6%, respectively. The use of surgical energy device based on surgeons' preference did not show the significant impact on operative and long-term outcomes compared with conventional monopolar device in minimally invasive colorectal cancer surgery.

대장, 직장암의 최소침습 수술에서 기존의 단일극 수술기구와 최근의 에너지 기반 수술기구가 임상적, 종양학적 결과에 미치는 영향 : 성향점수 매칭 방법을 이용하여 분석한 연구

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(초록)

최근의 새로운 에너지 기반 수술 기구의 안전성, 효율성, 다재다능성은 기존의 여러 연구에서 증명된 바 있다. 본 연구의 목적은 에너지 기반 수술 기구가 대장, 직장암의 최소침습 수술에서 수술 결과 및 종양학적 예후에 미치는 영향을 분석하기 위함이다. 2015년 8월부터 2017년 12월까지 대장, 직장암으로 최소침습 수술을 시행 받은 환자 중 기존의 단일극 수술기구를 사용한 80명과 에너지 기반 수술 기구를 사용한 217명의 환자가 연구에 포함되었다. 종양의 위치, 수술 전 CEA 수치, 수술 방법을 성향 점수 매칭하였고, 최종적으로 63쌍을 분석하였다. 환자의 특성에서 두 군 간에 통계적으로 유의한 차이는 없었다. 출혈량, 개복 수술로의 전환 수, 수술 시간, 수술 중 합병증은 통계적으로 유의한 차이

가 없었다. 단기 합병증 비율과 병리학적 결과는 두 군 간에 비슷한 분포를 보였다. 평균 52.0 개월의 추적 관찰 기간 사이에, 5년 생존률은 단일극 수술 기구 군에서 84.6%, 에너지 기반 수술 기구 군에서 91.6% 였고, 5년 무병생존률은 각각 78.0% 와 84.6% 였다. 외과 의사의 선호도에 따른 에너지 기반 수술 기구의 사용은 기존의 단일극 수술 기구와 비교할 때 대장, 직장암의 최소침습 수술에서 수술 결과와 장기간의 종양학적 예후에 통계적으로 유의한 영향을 주지는 못하였다.

Table 1. Patient Characteristics

Characteristics	Before matching			Propensity-Score Matched		
	Monopolar (n=80)	Energy device (n=217)	p-value	Monopolar (n=63)	Energy device (n=63)	p-value
Age	66.7±9.8	66.7 ±11.9	0.989	66.4±10.0	65.5±11.6	0.634
Sex			0.672			0.716
Male	49 (61.3)	127 (67.7)		37 (58.7)	39 (61.9)	
BMI (kg/m^2)	28.8±43.1	24.3±3.6	0.357	23.9±3.8	25.0±3.3	0.094
Past abdominal surgery	12 (15.0)	44 (20.3)	0.302	10 (15.9)	14 (22.2)	0.364
Lesion			0.007			0.473
Colon	39 (48.8)	143 (65.9)		30 (47.6)	26 (41.3)	
Rectum	41 (51.2)	74 (34.1)		33 (52.4)	37 (58.7)	
Obstruction	14 (17.5)	25 (11.5)	0.176	12 (19.0)	6 (9.5)	0.127
Pre-OP CEA (ng/ml)	3.5±3.5	5.4±11.3	0.031	3.54±3.82	2.65±2.14	0.109
Pre-OP CCRT	12 (15.0)	23 (10.6)	0.243	8 (12.7)	15 (23.8)	0.106
ASA score			0.404			0.714
1	26 (32.5)	64 (29.5)		22 (34.9)	18 (28.6)	
2	45 (56.3)	119 (54.8)		32 (50.8)	38 (60.3)	
3	9 (11.3)	34 (15.7)		9 (14.3)	7 (11.1)	
OP technique			<0.001			1.000
Laparoscope	30 (37.5)	179 (82.5)		28 (44.4)	28 (44.4)	
Robot	50 (62.5)	38 (17.5)		35 (55.6)	35 (55.6)	

Values are presented as mean ± standard deviation or number (%). ASA: American society of anesthesiologists; BMI: Body mass index; CCRT: Concomitant Chemoradiotherapy; CEA: Carcinoembryonic antigen

Table 2. Operative Outcomes

Operative Outcomes	Monopolar (n=63)	Energy device (n=63)	p-value
Operation time(minute)	212.2±72.4	214.0±95.4	0.908
Blood loss (ml)	72±69	54±63	0.123
Conversion to open surgery	7 (11.1)	3 (4.8)	0.187
Adhesion	4 (6.3)	1 (1.6)	
Body habitus	2 (3.2)	1 (1.6)	
Locally advanced cancer	1 (1.6)	1 (1.6)	
Intraoperative complications	6 (9.5)	3 (4.8)	0.299
Bleeding	1 (1.6)	2 (3.2)	
Injury to organs	5 (7.9)	1 (1.6)	

Values are presented as mean ± standard deviation or number (%).

Table 3. Postoperative Outcomes

Postoperative Outcomes	Monopolar (n=63)	Energy device (n=63)	p-value
Sips of water (days)	4.6±2.4	4.7±5.5	0.950
Soft diet (days)	7.7±4.2	7.0±5.5	0.417
Length of hospital stay (days)	9.8±3.3	10.4±6.2	0.472
Morbidity within 30 days	22 (34.9)	17 (27.0)	0.335
Prolonged postoperative ileus	5 (7.9)	2 (3.2)	
PMC	5 (7.9)	1 (1.6)	
Anastomotic leakage	3 (4.8)	1 (1.6)	
Intra-abdominal abscess	0 (0)	1 (1.6)	
Urinary retention	1 (1.6)	0 (0)	
Heart complication	2 (3.2)	0 (0)	
Wound complication	2 (3.2)	2 (3.2)	
Hematochezia/Melena	2 (3.2)	3 (4.8)	
Pneumonia	0 (0)	1 (1.6)	
Ischemic colitis	0 (0)	1 (1.6)	
Chyle leakage	2 (3.2)	5 (7.9)	0.440
Clavien-Dindo classification			0.620
0	41 (65.1)	46 (73.0)	
1	6 (9.5)	7 (11.1)	
2	11 (17.5)	8 (12.7)	
3a	1 (1.6)	1 (1.6)	
3b	4 (6.3)	1 (1.6)	
Reoperation	4 (6.3)	1 (1.6)	0.365
Mortality within 30 days	0 (0)	0 (0)	
Postoperative CEA (ng/ml)	1.57±1.21	1.29±0.91	0.152
Post-OP chemotherapy	25 (39.7)	25 (39.7)	1.000

Values are presented as mean ± standard deviation or number (%). CEA: Carcinoembryonic antigen; PMC: Pseudomembranous Colitis

Table 4. Pathologic Outcomes

Pathologic Outcomes	Monopolar (n=63)	Energy device (n=63)	p-value
Mass size (large diameter, cm)	3.8±2.7	3.6±2.8	0.708
Differentiation			0.395
Well	8 (12.7)	4 (6.6)	
Moderate	49 (77.8)	53 (86.9)	
Poorly, Mucinous	6 (9.5)	4 (6.6)	
pT stage			0.987
T0	2 (3.2)	3 (4.8)	
T1	19 (30.2)	20 (31.7)	
T2	12 (19.0)	12 (19.0)	
T3	24 (38.1)	23 (36.5)	
T4	6 (9.5)	5 (7.9)	
pN stage			0.217
N0	46 (73.0)	51 (81.0)	
N1	15 (23.8)	8 (12.7)	
N2	2 (3.2)	4 (6.3)	
Lymph node (Positive)	0.6±1.9	0.7±2.0	0.714
Lymph node (Total)	19.2±10.5	20.1±12.6	0.662
Lymphovascular invasion	12 (19.0)	8 (12.7)	0.329
Tumor budding	22 (34.9)	16 (25.4)	0.244
Perineural invasion	10 (15.9)	6 (9.5)	0.285

Values are presented as mean ± standard deviation or number (%).

Table 5. Oncologic Outcomes

Oncologic Outcomes	Monopolar (n=63)	Energy device (n=63)	p-value (Log Rank)
Mean follow-up period (month)	52.9±21.3	51.1±17.6	0.625
5-year overall survival rate (%)	84.6	91.6	0.276
5-year disease free survival rate (%)	78.0	84.6	0.328
Recurrence	11 (17.5)	5 (7.9)	0.108
Recurrence pattern			0.332
Systemic recurrence	8 (12.7)	4 (6.3)	
Local recurrence	1 (1.6)	1 (1.6)	
Systemic and local recurrence	2 (3.2)	0 (0)	

Values are presented as mean ± standard deviation or number (%).