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Original Paper

Comparison Between the Oncologic Outcome of Laparoscopic Surgery and Open Surgery for T1 and T2 Rectosigmoidal and Rectal Carcinoma: Matched Case-control Study

Takatoshi Nakamura[1], Yukihito Kokuba[1], Hiroyuki Mitomi[2], Wataru Onozato[1]
Kazuhiko Hatate[1], Takerou Satoh[1], Heita Ozawa[1], Atusi Ihara[1], Masahiko Watanabe[1]
[1]Department of Surgery Kitasato University Hospital, [2]Department of Pathology
National Sagamihara Hospital, Kanagawa, Japan
Corresponding Author: Masahiko Watanabe, Department of Surgery, Kitasato University Hospital
1-15-1 Kitasato, Sagamihara, Kanagawa 228-8520, Japan
Tel: +81 42 748 9111, Fax: +81 42 748 5120, E-mail: n-toshi@Kitasato-u.ac.jp

KEY WORDS:
Laparoscopic surgery; Rectal cancer; Matched case-control study

ABBREVIATIONS:
Laparoscopic Resection (Lap-R); Open Surgery (O-R); Randomized Controlled Trials (RCT)

ABSTRACT

Background/Aims: The long-term outcome of laparoscopic resection (Lap-R) of rectal cancer is still unclear. The purpose of this study was to elucidate the validity of Lap-R by comparing the short-term and mid-term outcome of Lap-R performed in our hospital to treat T1 and T2 rectal cancer patients with that of patients with the same clinicopathological background treated for rectal cancer by open surgery (O-R).

Methodology: We conducted a matched case-control study of the oncologic outcome of T1 and T2 rectal cancer patients who had undergone Lap-R between 1996 and 2002 by matching them for sex, age, location, and TNM classification with patients who underwent O-R during the same period, and the total number of subjects in both groups combined was 76.

Results: The median follow-up period in the Lap-R group was 36 months, as opposed to 58 months in the O-R group. There were no operative deaths in either group. Comparison of the postoperative complications showed that intraoperative blood loss was significantly less in the Lap-R group than in the O-R group ($P<0.0001$), and there were fewer cases of intestinal obstruction ($p=0.0312$). The number of postoperative hospital days was also significantly shorter ($p=0.00046$).

The overall survival rate was 91.6% in the Lap-R group and 92.7% in the O-R groups, and the difference was not significant ($p=0.5306$). The recurrence-free survival rate was 96.7% in the Lap-R group and 82.4% in the O-R group, and the difference was not significant ($p=0.4587$). The difference in recurrence rate between the groups was not significant ($p=0.446$), and there were no differences in modes of recurrence, but local recurrence was the most common mode in both groups. No recurrences were observed at the site of the port in the Lap-R group.

Conclusions: When we performed our matched case-control study of Lap-R and O-R as surgical procedures for T1 and T2 rectal cancer, Lap-R was less invasive based on the short-term outcome. Moreover, there were no significant differences in mode of recurrence or recurrence rate, and no significant difference between the two groups was observed in oncologic outcome. It will be necessary to await the results of both Japanese and international randomized controlled trials (RCT). However, short- and mid-term follow-up of identical patients at a single institution as in the present study also appeared to have sufficient significance.

INTRODUCTION

It has been more than 10 years since laparoscopic surgery (Lap-R) became a choice of treatment for colorectal cancer. The advantages of Lap-R for colon cancer have been reported to be that it enables less postoperative pain, decreased postoperative intestinal obstruction, a shorter postoperative hospital stay, an earlier return to a normal life, and even better postoperative quality of life (1-4). RCT in regard to long-term outcome have been performed in various countries, and the long-term outcome of Lap-R has been reported to be equivalent to that of open surgery (O-R) (5,6). However, Lap-R for rectal cancer is definitely a difficult operation from a technical standpoint, and in many clinical studies it has been described as not being indicated for rectal cancer (5,6). As a result, the safety and low invasiveness of Lap-R are unclear. Furthermore, there have been no large-scale RCT on the short-term outcome or long-term outcome, and they are also still unclear.

The present study was a matched case-control study in which we compared the safety, low invasive-

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ness, and short-term outcome of Lap-R with O-R in T1 and T2 rectal cancer patients, excluding T3 and T4 rectal cancers, which require neoadjuvant chemotherapy, and assessed the validity of Lap-R as a procedure for T1 and T2 rectal cancer.

METHODOLOGY

Lap-R was performed on 71 rectal cancer patients during the period from April 1996 to December 2003, and we adopted the patients with depth of invasion T1 and T2 who did not have any obvious preoperative lymph node metastases or distant metastases as potential subjects of the study. Patients with intestinal obstruction or who did not consent to Lap-R were excluded. Before surgery all patients underwent contrast enema fluoroscopy, colorectal endoscopy, abdominal ultrasonography, and abdominal and pelvic CT examinations. The location of the rectal cancers was determined by colorectal endoscopy. The cancers were classified according to their distance from the anal verge as under rectum (0cm to 7cm), upper rectum (7.1cm to 12cm), and rectosigmoid (12.1cm to 17cm). We matched 38 patients each who underwent Lap-R and O-R for pathologic TNM category, sex, age (±5 y), location, and day of surgery (between 1990 and 2003) and adopted them as the subject group **(Table 1)**.

The surgical technique of Lap-R consisted of inserting the initial port in the upper portion of the umbilicus and insufflating the abdomen with CO_2 at a mean pressure of 8 mmHg/hr. There were no conversions from Lap-R to O-R. In addition to outpatient clinic visits, postoperative follow-up consisted of CEA measurements (every 3 to 12 months), contrast enema examinations, abdominal ultrasound examinations, and thoracic and abdominal CT examination (6 months), and recurrence was judged on the basis of the imaging findings and the histopathological findings considered as a whole. Postoperative adjuvant chemotherapy, principally with fluorouracil (5-FU), was performed in a total of 8 patients, 4 stage III patients each in the Lap-R group and the O-R group, and the significant difference in number of patients to whom it was administered was the same in both groups.

The Mann-Whitney U test was used to statistically analyze the non-parametric data. Overall survival rates were calculated by the Kaplan-Meier method, and group comparisons were made by the log-rank test.

TABLE 1 Demographic characteristics of the Patients

		Laparoscopic surgery group	Open surgery group
Number of patients		38	38
Sex ratio (Male:Female)		27:11	27:11
Age (yr; Mean [range])		61 (30-77)	62.5 (49-85)
Location	Rectosigmoid	10	10
	Upper Rectum	12	12
	Under Rectum	16	16
TNM stage	pT1N0	25	25
	pT2N0	9	9
	pT2N1	3	3
	pT2N2	1	1
Period [mo; median/range/]		36 (8-90)	58 (15-120)

pTNM stage: pathological TNM stage.

TABLE 2 Operative and Postoperative Results

	Laparoscopic surgery Group	Open surgery Group	*p*-value
Mean Operation Time (min)	240 (145-560)	225 (115-415)	NS
Bleeding (mL)	50 (10-460)	205 (60-1580)	$p<0.0001$
Mean time to oral intake (days)	3 (2-8)	4 (2-14)	NS
Mean number days of parenteral opiates	1 (0-5)	1 (0-5)	NS
Mean length of stay (days)	14 (7-64)	19.5 (9-66)	$p=0.00046$

TABLE 3 Number of Patients with Postoperative Complications

Complication	Laparoscopic surgery Group (n=38)	Open surgery Group (n=38)	*p*-value
Anastomotic leak	1	2	NS
Anastomotic stenosis	0	1	NS
Bleeding	2	1	NS
Wound infection	2	4	NS
Prolonged ileus	2	10	$p=0.0312$

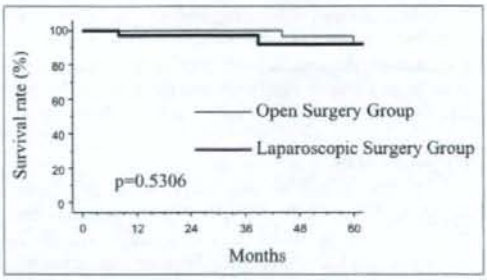

FIGURE 1 Comparison between the overall curves of the laparoscopic surgery group and the open surgery group.

RESULTS

Comparison between the Lap-R group and O-R group showed an intraoperative blood loss of 50mL in the Lap-R group and 205mL in the O-R group, and there was significantly less bleeding in the Lap-R group ($P<0.0001$). The length of the postoperative hospital stay was 12 days in the Lap-R group and 16.5 days in the O-R group, and significantly shorter in the Lap-R group ($p=0.00096$, **Table 2**). On the other hand, there were no significant differences between the groups in operation time, time until resumption of meals, or number of times analgesics were used **(Table 2)**. Comparison of the postoperative complications showed significantly fewer cases of intestinal obstruction in the Lap-R group ($p=0.0312$). There were no significant differences between the groups in suture failure, anastomotic stenosis, postoperative bleeding, or wound infection **(Table 3)**. The cumulative 5-year survival rate was 91.6% in the Lap-R group and 92.7% in the O-R group, and the difference was not significant ($p=0.5306$, **Figure 1**). The recurrence-

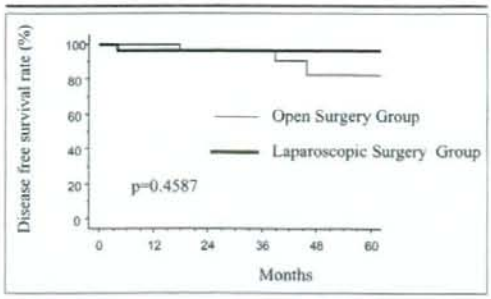

FIGURE 2 Comparison between the disease-free survival curve of the laparoscopic surgery group and the open surgery group.

TABLE 4 Cases of Tumor Recurrence after Laparoscopic Colectomy and Open Colectomy

Location	Method	pTNM	Time of recurrence (mo)	Site of recurrence*	Outcome (mo)
1 Under R	laparoscopic	pT1N0	31	Lung	39, dead
2 Upper R	laparoscopic	pT2N0	6	local	8, dead
3 Under R	open	pT1N0	46	local	60, dead
4 Rectosig	open	pT1N0	39	local	44, dead
5 Under R	open	pT2N1	68	Liver	79, dead

*Site where recurrence was first noticed.

free survival rate was 96.7% in the Lap-R group and 82.4% in the O-R group, and the difference was not significant (p=0.458, **Figure 2**).

There were 2 cases (5%) of postoperative recurrence in the Lap-R group. In 1 case it consisted of pulmonary metastasis, and in the other case there was local recurrence. In the O-R group, on the other hand, there were 3 cases (7%) of recurrence. In 2 cases it was local recurrence, and in the other case it was liver metastasis. As a result, there was no significant difference in recurrence rate between the groups. No port-site recurrence was observed in the Lap-R group.

DISCUSSION

The results of the matched case-control study of Lap-R and O-R for T1 and T2 rectal cancer revealed a more favorable short-term outcome after Lap-R than after O-R and no difference between the groups in long-term outcome. In terms of the short-term outcome, there was significantly less blood loss and intestinal obstruction with Lap-R, and the postoperative length of stay was also significantly shorter than after O-R. Among the postoperative complications there was only 1 case of suture failure in the Lap-R group. It has been reported in 5.7% to 21% of patients in whom Lap-R was performed, and some institutions routinely recommend a colostomy for low rectal cancer (7-11). When the intestine is sectioned on the distal side of the rectum, it appears to become a cause of suture failure due to the choice of device, difficulty of the maneuvers, etc. Presumably that is why there are differences among institutions in the safety of the anastomoses.

In regard to short-term outcome, there is less postoperative pain with Lap-R, early ambulation is possible, and peristalsis resumes sooner. As a result, oral intake starts earlier after Lap-R than after O-R, and the hospital stay is shorter, and earlier return to the patient's normal life has also been demonstrated. Thus, there have been many reports that Lap-R is less invasive and that postoperative QOL is better (10-15). However, Yamamoto *et al.* compared the invasiveness markers CRP and WBC count, as well as IL-6 and NK activity and found no significant differences between the two groups in any of the markers (16). In the future we should also probably monitor invasion markers in relation to the short-term outcome and assess the low invasiveness of Lap-R more objectively.

In regard to the long-term outcome, Anthuber *et al.* assessed 101 rectal cancer patients in a report from a single institution, and the results showed that significantly fewer postoperative complications occurred after Lap-R than after O-R. They also reported that the long-term outcome was almost the same in both groups (17). However, patients with T3 and T4 rectal cancer that had been treated by neoadjuvant chemotherapy were included among the subjects, and it cannot be said to have been adequate as evidence for Lap-R. In our own study we found no significant differences between the two groups in regard to the long-term outcome of T1 and T2 rectal cancer in terms of mode of recurrence, recurrence rate, overall survival rate, or recurrence-free survival rate. However, no large-scale RCT in regard to Lap-R have been conducted in Japan or abroad, and the present study was a retrospective comparison between Lap-R and O-R. The results showed 1 case of local recurrence after Lap-R and 2 cases of recurrence after O-R. The difference was not statistically significant, but because maneuvers within the narrow pelvis are considered necessary for rectal cancer, maneuvers that might cause damage at the tumor site increase the risk of tumor cell dissemination in the peritoneal cavity during surgery (18). Thus, it appears particularly necessary to perform maneuvers with forceps cautiously during Lap-R. However, the magnifying visual effect of the endoscope is exploited in the narrow pelvis, and by maintaining a good field of vision, it may also be able to increase the safety of the intraoperative maneuvers (19). First, it seems necessary to conduct an RCT in which T1 and T2 rectal cancer patients are the subjects and confirm the long-term outcome of Lap-R. The next step would be to add various preoperative chemotherapy methods and radiotherapy methods to surgical treatment, which is currently the method of treatment for T3 and T4 rectal cancer patients. As a result, there is a strong possibility that differences in the short-term and long-term outcome of rectal cancer will occur as a result of preoperative therapy. Thus, it will be necessary to conduct the assessments by standardizing treatment methods prospectively without creating any preoperative or postoperative bias. As a result of advances in laparo-

scopic surgery technology and accumulation of experience, in the future Lap-R will probably become one of the choices for the treatment of rectal cancer. The validity of Lap-R should be demonstrated based on the results of many multi-center RCT.

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Operatoin

低位前方切除時の安全な消化管器械吻合

前田耕太郎　花井　恒一　佐藤　美信
升森　宏次　小出　欽和　船橋　益夫

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低位前方切除時の安全な消化管器械吻合

前田耕太郎* 花井 恒一*1 佐藤 美信*2
升森 宏次*2 小出 欽和*2 船橋 益夫*2

はじめに

進行下部直腸癌に対する低位前方切除時の吻合は，器械吻合法の開発により安定した手技となった。さらに double stapling technique (DST) の登場により[1]，直腸を牽引しながら切離と縫合を同時に行い，経肛門的な吻合を行うために，より低位での吻合が，より確実で容易となってきた。

しかしながら，従来のリニアステイプラーを用いた吻合法では，男性の狭骨盤例ではリニアステイプラーの挿入が困難な症例があったり，リニアステイプラーのヘッドがある程度のボリュームを占めるため，切除肛門側の臓器の噛みこみや縫合部の確認ができないなどの問題があった。これらの問題を解決するために，我々はリニアステイプラーの代わりにエンドステイプラーを使用し，直腸を水平方向に切離する代わりに垂直方向に切離し，サーキューラーステイプラーで吻合する方法を IO-DST[2][3] と称して行っているので，その手技と成績について述べる。

* Kotaro MAEDA 藤田保健衛生大学消化器外科 教授
*1 Tsunekazu HANAI et al. 同外科

key words：直腸癌，低位前方切除術，器械吻合

I. IO-DST の手術

吻合の手技をより安全に確実に行う場合には，定型的な手技が必須である（**表 1**）。

1. 剝離と直腸内洗浄

腹側より直腸を total mesenteric excision (TME) の層で肛門挙筋まで十分剝離したのち，腫瘍肛門側の直腸に直角鉗子を掛ける（**図 1**）。

次に，残存直腸内の遊離癌細胞を除去し吻合部局所再発を防止するために，I 式直腸内洗浄用肛門鏡（ユフ精器社）を用いて経肛門的な洗浄を蒸留水で行う。洗浄量は，腹膜翻転部以上の腫瘍では 2,000 m*l*，以下の癌では 1,500 m*l* とする[4]。

2. 直腸の切離

直腸の切離には，エンドステイプラーを使用する。切離の際には，左手で直角鉗子ごと直腸を口側に牽引しつつ，AW の距離を勘案して

表 1 IO 吻合の手順

1	TME による直腸剝離
2	腫瘍肛門側への直角鉗子装着
3	I 式洗浄器による直腸洗浄
4	エンドステイプラーによる直腸切離
5	サーキュラーステイプラーによる吻合
6	肛門鏡による出血の確認
7	リークテスト

肛門側切離線の直腸に垂直方向にエンドステイプラーを挿入する（**図1**）。直腸の牽引の方向は，骨盤内で単に頭側に牽引すると**図2**のように直腸が斜めに切離されてしまうため，頭側背側に牽引しつつ切離を行う（**図3**）。このように牽引することにより，エンドステイプラーが体に対して垂直方向に設置されなくても，切離の方向は直腸と直角になる。これは，肛門が体幹の背側よりやや腹側に位置しているために，考慮しなければならない手技の注意点である。

直腸切離の際の体位は，従来の砕石位を用いると下部直腸がより肛門側に位置するようになるため，大腿開脚水平位を用いる[5]。この体位が困難な場合には，砕石位の脚の角度をより水平にすると，下部直腸がより口側に位置して吻合が行いやすい。

3. 吻　合

エンドステイプラーによる切離で，直腸の縫合線はIの字になっている。吻合には，サーキュラーステイプラーを用いて行うが，サーキュラーステイプラーの挿入にはK式開肛器（ユフ精器社）を使用する[6]。K式開肛器を使用することにより，肛門の損傷も少なく，どの吻合器も容易に挿入が可能である。ただし，K式開肛器挿入の際には，術者が直腸切離断端をガーゼで押さえておくほうが，余計な直腸の損傷もなく，より安全である。

サーキュラーステイプラーで打ち抜く部位は（**表2**），エンドステイプラーで切離した切離線の側方で後壁側を原則としている。エンドステ

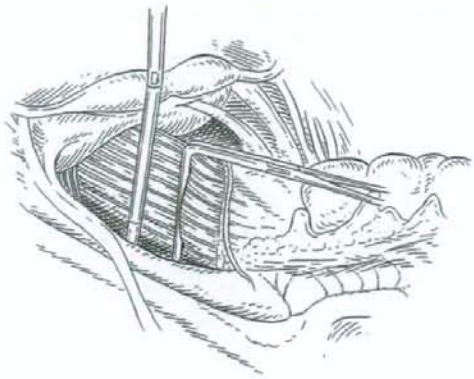

図1　IO-DSTの直腸切離
直角鉗子を掛け，直腸を洗浄後エンドステイプラーによる直腸の切離を行う。

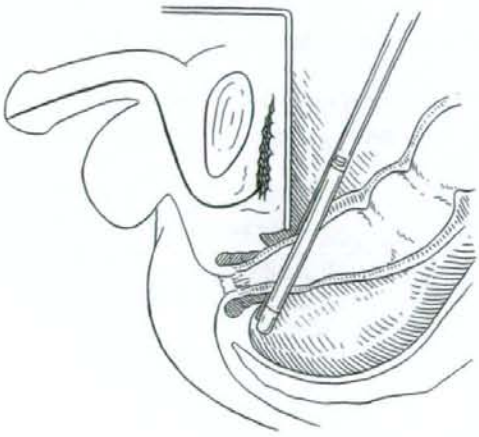

図2　エンドステイプラーの不適切な装着法

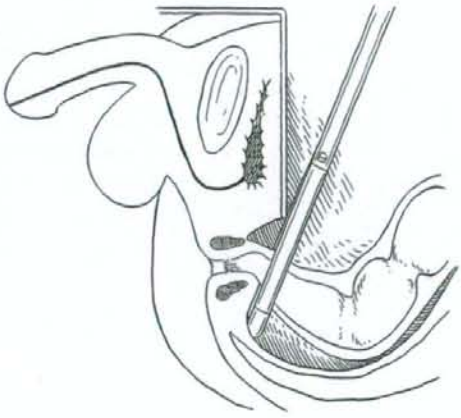

図3　エンドステイプラーの適切な装着法

表 2　IO 吻合の原則

- Staple on staple 部を打ち抜く
- できれば直腸切離部の背側を打ち抜く
- 腟壁などの巻き込みがないことを確認
- サーキュラーステイプラーはエンドステイプラーによる切離部の側方に打ち出す

イプラーを 2 回使用して直腸を切離した場合には，staple on staple の部位はサーキュラーステイプラーで打ち抜くようにする。

4. 吻合後のチェック

吻合後のチェックは，とくに重要である。器械は常に万能であると考えるのでなく，そのでき具合を確認する操作を怠らない注意が必要である。

吻合後には，肛門鏡を用いて吻合部に出血のないことを確認する。その後に，腹側から骨盤内に生理食塩液を満たし，ネラトンを肛門より挿入し，ネラトンに接続した注射器より空気を注入しリークテストを行う。エアーリークがみられた場合には，腹側より追加縫合を行い，再度リークテストでエアーリークのないことを確認して，手術を終了する。

II. single stapling と double stapling，経肛門吻合法の比較

低位直腸癌に対する低位前方切除術を施行した際に，single stapling technique（SST）による吻合を行った 47 例と IO-DST により吻合を行った 34 例，経肛門吻合（PAA）を施行した 9 例を retrospective に比較検討した[7]。

肛門縁から腫瘍下縁までの距離と吻合後の肛門縁からの距離は，SST に比し IO-DST を行った症例で有意に短く（7.0，5.0 対 5.8，4.0 cm），低位での吻合がなされていた。経肛門吻合（5.0，4.0 cm）と IO-DST 間では差がなかった。

出血量は，SST（578 ml）および PAA（950 ml）に比べて IO-DST（400 ml）で有意に少なく，手術時間は PAA（327 分）に比し IO-DST（281 分）で有意に短かった。

肛門側の腫瘍より切離断端までの距離は，3 術式で差はなかった。

術後 1 カ月目の排便回数は，IO-DST（1 日 2.5 回）では SST（1 日 4.0 回）に比べて有意に少なく，術後 1 年以上経過後は IO-DST（1 日 2.0 回）は PAA（1 日 3.5 回）に比べて有意に少なかった。

術後合併症や局所再発の頻度には，これらの 3 吻合術式間で差はなかった。

III. IO-DST の成績

1. 対象症例

IO-DST を施行した 105 例（男性 76，女性 29 例）の成績を示す。年齢の中央値は 59 歳（range 36～86）で，77 例には covering loop stoma を作製した。68 例には，側方のリンパ節郭清を施行した。Dukes A が 30 例，B が 29 例，C が 36 例，D が 10 例であった。

肛門縁より腫瘍までの距離は，T1 腫瘍では 5 cm（range 4.0～10.0）で，T2-4 腫瘍では 6.5 cm（range 3.0～15.0）であった。

腫瘍より肛門側切離縁までの距離は，T1 腫瘍では 2 cm（range 1.0～4.0）で，T2-4 腫瘍では 2.5 cm（range 1.0～6.0）であった。

術後の肛門縁より吻合部までの距離は，T1 腫瘍では 4.2 cm（range 3.0～6.0）で，T2-4 腫瘍では 4.0 cm（range 2.5～7.0）であった。

2. 術後の合併症

術後の合併症は，ストーマを作製した症例で合計 12 例（15.6%），作製しなかった症例で 4 例（14.3%）とほぼ同等であった（**表 3**）。

ストーマを作製した症例での縫合不全は 3 例（3.9%）で，作製しなかった症例では 2 例（7.1%）であった（**表 3**）。ストーマを作製した症例では，狭窄，直腸腟瘻，術後イレウス，術後腸炎がおのおの 1 例（各 1.3%）みられ，創感染も 5 例（6.5%）みられた。ストーマを作製しなかった

表3　IO-DST術後の合併症

	ストーマあり (n＝77)	ストーマなし (n＝28)
縫合不全	3 (3.9%)	2 (7.1%)
狭窄	1 (1.3%)	0 (0%)
直腸膣瘻	1 (1.3%)	0 (0%)
イレウス	1 (1.3%)	0 (0%)
腸炎	1 (1.3%)	1 (3.6%)
創感染	5 (6.5%)	1 (3.6%)
計	12 (15.6%)	4 (14.3%)

表4　IO-DST術後の再発

治癒切除	92 (100%)
計	12 (13.0%)
肝臓	7 (7.6%)
肺	6 (6.5%)
骨盤内	4 (4.3%)
リンパ節	1 (1.1%)
脳	1 (1.1%)
骨	1 (1.1%)

＊吻合部再発はなし

症例では，術後腸炎が1例（3.6%），創感染が1例みられている。

3. 術後再発

治癒切除例92例では，再発は合計12例（13.0%）みられた（**表4**）。遠隔転移が主にみられ，骨盤内の局所再発は4例（4.3%）にみられたが，吻合部再発はみられなかった。

4. 術後排便機能

IO-DST術後の術後1カ月目の排便機能は，ストーマのなかった症例で1日3.5回（range 1〜10），ストーマ造設例では閉鎖術後1カ月目で4.0回（range 1〜10）と早期より良好であった（**表5**）。

術後1年目には，ストーマのなかった症例で1日2.0回（range 1〜4），ストーマ造設例では3.0回（range 0.5〜5）であった。

表5　IO-DST術後の排便機能

	ストーマあり (n＝77)	ストーマなし (n＝28)
n	69	27
排便回数（日）（術後1カ月）	4.0 (1〜10)	3.5 (1〜10)
n	67	21
排便回数（日）（術後1年）	3.0 (0.5〜5)	2.0 (1〜4)

n：症例数　　（　）内はrange

おわりに

エンドステイプラーを使用して直腸を垂直方向に切離（I字形）したのち，サーキュラーステイプラーを使用して吻合（O字形）するIO-DSTの手術手技と成績について概説した。本吻合法では，最終的に垂直方向に長い楕円形の吻合口が形成されることになる。術後早期より良好な排便機能が得られるのは，本吻合法によって形成された吻合口が肛門管と同様の垂直方向に長い楕円形の形状をしているためと考えている。

より安全な吻合を行う際にもっとも重要であるのは，安定した手技を確実に行い，その結果を逐次確認する操作を行うことであることを最後に申し述べたい。

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ORIGINAL ARTICLE

Morphological characteristics of lateral pelvic lymph nodes in rectal carcinoma

Hiroyoshi Matsuoka · Tadahiko Masaki · Masanori Sugiyama · Yutaka Atomi · Yasuo Ohkura · Atsuhiko Sakamoto

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Abstract
Aim Macroscopic and imaging indicators for lymph node metastasis have been documented not in lateral pelvic lymph nodes but in mesorectal lymph nodes in patients with rectal carcinoma. We conducted this study to uncover morphological characteristics of lateral pelvic lymph nodes in patients with rectal carcinoma.
Materials and methods Fifty-eight patients with locally advanced rectal carcinoma who had total mesorectal excision and lateral pelvic lymph node dissection were studied. Total number of lateral pelvic lymph nodes evaluated was 462, with 538 mesorectal lymph nodes being used for comparison. Factors of lymph nodes evaluated were size (long- and short-axes diameters), shape (ovoid and irregular), and heterogeneity of internal structure. Receiver operating characteristic (ROC) curve analysis was used to compare the diagnostic accuracy of each factor.
Results Lateral pelvic lymph node at non-metastatic status appeared to be longer (4.5 vs 3.5 mm) and thinner (2.2 vs 2.6 mm) than mesorectal lymph nodes. ROC curve analysis, for discriminating non-metastatic and metastatic lateral pelvic lymph nodes, revealed that a short-axis diameter appeared to be the most prominent factor with highest area under curve (0.907) and was more reliable than either long-axis diameter (0.811) or shape (0.527) other than internal structure (1.00). A short-axis diameter was an independent risk factor for metastasis by multivariate analysis with an odds ratio of 1.29 ($p<0.0001$, 95% confident interval, 1.22–1.36). The most reliable cut-off value was 4 mm with 96% of sensitivity, 68% of specificity, and 82% of overall accuracy.
Conclusion Lateral pelvic lymph nodes tended to be longer and thinner than mesorectal lymph nodes at non-metastatic status. A short-axis diameter of 4 mm or larger was the prominent indicator of metastasis in lateral pelvic lymph nodes.

Keywords Lateral pelvic lymph node · Lateral pelvic lymph node dissection · Rectal cancer · Mesorectal excision

Introduction

As the characteristics of mesorectal lymph nodes have been closed up following the introduction of total mesorectal excision [1], pathological characteristics of these lymph nodes were already clarified [2–6]. Furthermore, optimal criteria for preoperative imaging diagnosis of mesorectal lymph nodes have already been demonstrated [7–9]. In terms of lateral pelvic lymph nodes metastasis, it is an important factor for local recurrence and survival, and dissection is needed, if metastasis is detected [10–12].

Although it has recently been reported that accuracy of preoperative diagnosis of lateral pelvic lymph nodes was higher than that of mesorectal lymph nodes, the optimal diagnostic criteria are still controversial [13].

When clarifying optimal preoperative diagnostic criteria, pathologic exploration would be needed beforehand. However, there has been no paper describing the pathological characteristics of lateral pelvic lymph nodes. Therefore, we conducted this study to clarify morphological character-

H. Matsuoka (✉) · T. Masaki · M. Sugiyama · Y. Atomi
Department of Surgery, Kyorin University, School of Medicine, Tokyo, Japan
e-mail: hiroelvis@aol.com

Y. Ohkura · A. Sakamoto
Department of Pathology, Kyorin University, School of Medicine, Tokyo, Japan

Table 1 Comparison between non-metastatic mesorectal and lateral pelvic lymph nodes

		Non-metastatic LPLNs (440)	Non-metastatic MRLNs (420)	*p*
Long-axis diameter (mm)	Mean	4.5	3.5	$p<0.01$
	Range	0.3–22.0	0.1–12.0	
Short-axis diameter (mm)	Mean	2.2	2.6	$p<0.0001$
	Range	0.3–10.0	0.1–8.0	
Shape (number of lymph nodes)	Ovoid	257 (59%)	374 (89%)	$p<0.00001$
	Irregular	183 (41%)	46 (11%)	

MRLN Mesorectal lymph nodes, *LPLN* lateral pelvic lymph nodes

istics of lateral pelvic lymph nodes by comparing them with those of mesorectal lymph nodes as counterpart.

Materials and methods

Fifty-eight patients with locally advanced rectal carcinoma (tumor, node and distant metastasis, T3 or T4 stage) who had total mesorectal excision and lateral pelvic lymph node dissection between July 1997 and June 2006 were studied. We performed lateral pelvic lymph node dissection similarly as reported in the previous literatures [10–12]. Unilateral dissection was performed when the tumor was located in the right or left side. Bilateral dissection was performed when the tumor occupied more than half of the rectal circumference or was situated at the anterior or posterior parts of the rectum. All visible and palpable lateral pelvic lymph nodes were harvested, fixed in 10% formalin, embedded in paraffin blocks, and sectioned along the greatest dimension.

Hematoxylin and eosin staining was performed, and histological findings were recorded in the computer database. Total number of lateral pelvic lymph nodes evaluated was 462 (positive for metastasis, 22; negative for metastasis, 440), with 420 non-metastatic mesorectal lymph nodes being used for comparison. Factors of lymph nodes evaluated were size, shape, and internal structure. Long- and short-axes diameters were measured on the pathologic slides. Shape was categorized into ovoid (round or ellipse) and irregular (other than round and ellipse). Heterogeneity of internal structure was categorized into negative or positive. Heterogeneity was defined as positive if the tumor deposit destroyed lymph follicle. Therefore, this was the gold standard of metastasis.

Statistical analysis was performed using SPSS version 6.1 for Windows (SPSS Japan, Tokyo, Japan). Univariate analysis was obtained with Mann–Whitney *U* test for numeric data and Fisher's exact test for categorized data. Difference was considered significant when a *p* value was less than 0.05. Multivariate analysis was performed by logistic regression analysis.

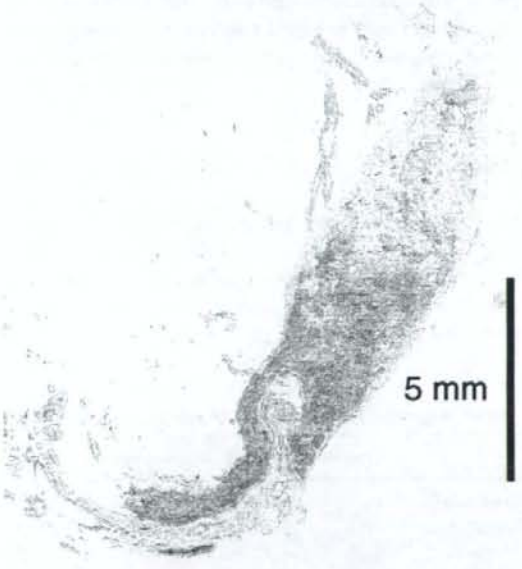

Fig. 1 A non-metastatic lateral pelvic lymph node, 14 mm in a long axis diameter with irregular shape and no tumor involvement. A *black line* indicates 5 mm (hematoxylin and eosin stain)

Fig. 2 Non-metastatic mesorectal lymph nodes. Long-axis diameter, 5 mm or less, with ovoid shape and homogenous internal structure. A *black line* indicates 5 mm (hematoxylin and eosin stain)

Table 2 Comparison between non-metastatic and metastatic lateral pelvic lymph nodes

		Non-metastatic LPLNs (440)	Metastatic LPLNs (22)	*p*
Long-axis diameter (mm)	Mean	4.5	10.0	$p<$
	Range	0.3–22.0	3.0–25.0	0.00001
Short-axis diameter (mm)	Mean	2.2	6.9	$p<$
	Range	0.3–10.0	2.0–16.0	0.00001
Shape (number of lymph nodes)	Ovoid	257 (59%)	14 (64%)	ns
	Irregular	183 (41%)	8 (36%)	

LPLN Lateral pelvic lymph nodes, *ns* not significant

Receiver operating characteristic (ROC) curve analysis was used to compare the diagnostic accuracy of each factor. It represents that, when a ROC curve approaches nearest to the point (0,1), both sensitivity and specificity are highest. Area under ROC curve was used for the evaluation of an optimal criterion. When both sensitivity and specificity are 100%, area under ROC curve indicates value 1, whereas when both sensitivity and specificity are 0%, area under ROC curve indicates value 0 [14–16]. In the ROC curve analysis, areas under curves were represented to clarify diagnostic accuracy of each factor. Long- and short-axes diameters were analyzed as numeric data. Ovoid shape was chosen as metastatic criteria because the majority of metastatic nodes were ovoid (64% in metastatic lateral pelvic lymph nodes). Presence of heterogeneity in internal structure was used as a gold standard as metastasis because all of metastatic nodes were heterogeneous due to tumor involvement.

Fig. 3 A metastatic lateral pelvic lymph node, 15 mm in a long axis diameter with irregular shape and half heterogenous change in internal structure by tumor involvement (hematoxylin and eosin stain)

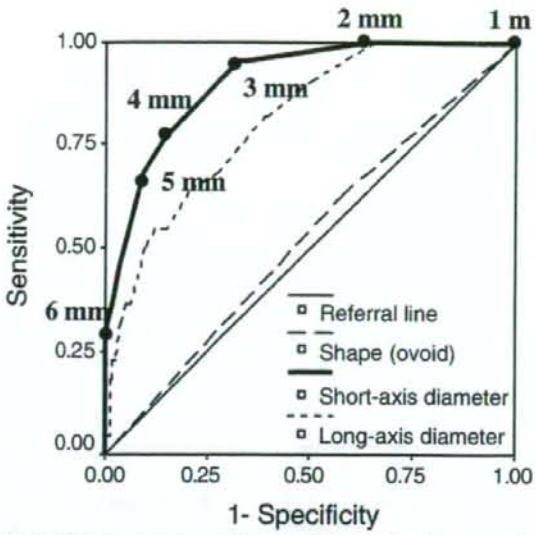

Fig. 4 ROC curves in terms of lateral pelvic lymph nodes metastasis

Results

Mean number of lateral pelvic lymph nodes harvested in each case was 12 (range 1–38). Of these, mean number of metastatic lateral pelvic lymph nodes was 1 (range 0–8) per case. The number of mesorectal lymph nodes harvested in each case ranged from 4 to 22, with a mean of 14. Of these,

Table 3 Logistic regression analysis for risk factor of metastasis

	Odds ratio	95% Confidence interval	*p*
Long-axis diameter	x	x	ns
Short-axis diameter	1.29	1.22–1.36	<0.0001
Shape (ovoid)	x	x	ns

ns Not significant

mean number of metastatic mesorectal lymph nodes was 1 (range 0–9) per case.

As shown in Table 1, in the non-metastatic lymph node groups, lateral pelvic lymph nodes appeared to be longer than mesorectal lymph nodes in a long-axis diameter (mean 4.5 vs 3.5 mm, $p<0.01$), and shorter in a short-axis diameter (mean 2.2 vs 2.6 mm, $p<0.0001$). Non-metastatic lateral pelvic lymph nodes appeared to be long and irregular in shape, whereas mesorectal lymph nodes were likely to be ovoid (Figs. 1 and 2).

As shown in Table 2, although there was no significant difference in terms of shape between metastatic and non-metastatic lateral pelvic lymph nodes, long (mean 10.0 vs 4.5 mm, $p<0.00001$) and short-axis diameter (mean 6.9 vs 2.2 mm, $p<0.00001$) were significantly increased (Fig. 3). As shown in Fig. 4, a short-axis diameter showed the highest area under curve and was more reliable than either a long-axis diameter or shape other than internal structure in the evaluation of lymph node metastasis. By multivariate analysis, a short-axis diameter was the independent risk factor for metastasis with an odds ratio of 1.29 ($p<0.0001$, 95% confident interval, 1.22–1.36; Table 3). A cut-off value of lymph node metastasis was 4 mm in a short-axis diameter (Fig. 4). Sensitivity was 96%, specificity was 68%, and overall accuracy was 82%, respectively.

Discussion

The characteristics of lymph nodes are different by the location of nodes [17, 18]. It has already been reported in the mediastinal lymph nodes in lung carcinoma [19, 20]. These reports suggested that distinguished cut-off value is needed in each location of lymph nodes. However, in the pelvic lymph nodes, such observation has not yet been reported.

Although mesorectal lymph nodes have been well discussed in terms of their characteristics [2–6], lateral pelvic lymph nodes have seldom been discussed so far. There was only one report from Canessa et al. [21] describing size of lateral pelvic lymph nodes in disease-free cadavers. However, they did not evaluate tumor-bearing lateral pelvic lymph nodes. In the present study, we found that the significant morphologic indicator of metastasis was a short-axis diameter. There have been some reports showing that a short-axis diameter was a more reliable indicator of a metastatic lymph node than a long-axis diameter due to its less oriented bias [22, 23]. A similar finding was noted also in the present study. Clinical utility of a short-axis diameter should be examined in the preoperative imaging diagnosis of lymph node metastasis.

There are a lot of imaging tools to date such as ultrasonography, magnetic resonance imaging (MRI), multi-detector or multislice computed tomography, sentinel lymph node mapping, and positron emission tomography (PET). However, preoperative diagnosis of lymph node metastasis is still a challenge because of fatal drawbacks such as micrometastasis or existence of slice intervals. Some authors stated that sentinel lymph node biopsy for lymph node metastasis was a useless procedure [24, 25]. Although PET scan is helpful to detect distant metastasis, diagnostic ability in lymph node staging is still unsatisfactory with approximately 50% of accuracy [26, 27]. In terms of detection of lateral pelvic lymph node metastasis, Arii et al. [13] has recently described that MRI is superior to CT scan due to its high resolution. Hopefully, we would like to address on this issue by using MRI in the next step.

Conclusions

Lateral pelvic lymph nodes tended to be longer and thinner than mesorectal lymph nodes. A short-axis diameter was a significant indicator for metastasis. A cut-off value of metastatic lateral pelvic lymph node was 4 mm in a short-axis diameter.

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特集

腹腔鏡下大腸癌手術の現状と問題点

大腸癌に対する腹腔鏡下手術の現状と問題点

奥田準二[*1]　田中慶太朗[*1]　近藤圭策[*1]　加藤哲也[*1]
茅野　新[*1]　田代圭太郎[*1]　谷川允彦[*1]

Current Status of Laparoscopic Surgery for Colorectal Cancer: Okuda J[*1], Tanaka K[*1], Kondo K[*1], Kato T[*1], Kayano S[*1], Tashiro K[*1] and Tanigawa N[*1] ([*1]Department of General and Gastroenterological Surgery, Osaka Medical College)

Early colorectal cancer excluded from endoscopic resection is a good indication for laparoscopic surgery, although the technical difficulty depends on the tumor location. In case the tumor located in cecum, ascending colon, sigmoid colon or rectosigmoid, laparoscopic oncologic surgery could be optimal in terms of minimally invasive surgery without compromising radicality. Recently, several randomized trial mainly from western countries showed no significant difference of oncologic outcome between laparoscopic and open surgery, especially in case of right and left colon cancer. However, if the tumor is located in transverse colon, descending colon or rectum, laparoscopic oncologic surgery might be technically and oncologically difficult. Regarding the indication and result of laparoscopic colorectal cancer surgery, there is some difference among institutions. Therefore, proper informed consent should be mandatory based on the demonstration of technical feasibility and oncological data in each institution.

Key words: Laparoscopic surgery, Colorectal cancer, Current status
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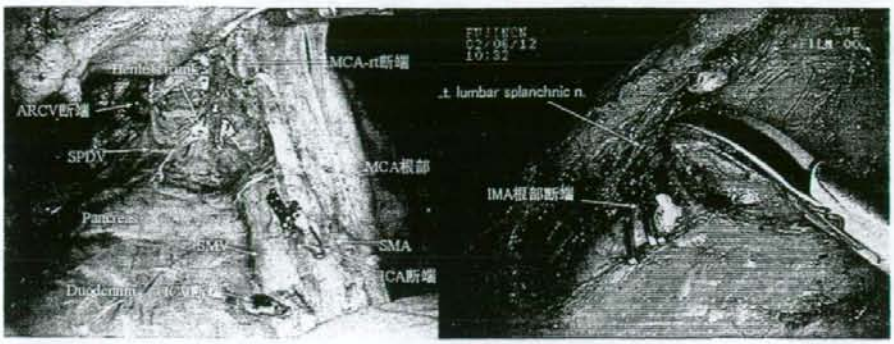
はじめに

筆者らは，癌手術の原則を遵守した適切な手技のもとに適応を段階的に拡大し，現在までに1,150例を越える腹腔鏡下大腸癌手術を行ってきた．本稿では，大腸癌に対する腹腔鏡下手術の現状と問題点について述べる．

1. 腹腔鏡下大腸癌手術の適応と注意点

内視鏡的切除や経肛門的局所切除などの適応外の早期大腸癌は腹腔鏡下手術の良い適応であり，盲腸から下部直腸までの全大腸で施行可能である[1]．ただし，病変部位によって難易度が異なる．盲腸・上行結腸やS状結腸・直腸S状部に対する腹腔鏡下手術では，sm癌に対するD2郭清のみならず，進行癌に対する系統的D3リンパ節郭清を伴う適切な腹腔鏡下手術手技も確立されてきた（図1）．世界的にみても，盲腸・上行結腸やS状結腸・直腸S状部に対する腹腔鏡下手術は，欧米を中心とした複数のランダム比較試験（RCT）で短期～中期成績において（一部では長期成績においても）再発や予後に悪影響がないと報告され[2～8]，本邦でも系統的D3リンパ節郭清を伴う適切な腹腔鏡下手術手技を確立した施設を中心に同部の進行癌に対するRCT（JCOG0404）が進行中である[9]（表1）．なお，第8回日本内視鏡外科学会のアンケート調査によれば，2005年度の腹腔鏡下大腸癌手術数は5,196件で，進行癌

*1 大阪医科大学一般・消化器外科



a | b

図1　上行結腸・S状結腸進行癌に対する腹腔鏡下手術
a：上行結腸進行癌に対する surgical trunk 郭清（D3）.
b：S状結腸進行癌に対する腰内臓神経温存 IMA 根部郭清（D3）.

表1　大腸癌に対する開腹手術と腹腔鏡下手術のランダム比較試験

Lacy AM, et al. Lancet 2002	再発や予後に悪影響なし -Stage Ⅲでは腹腔鏡群の方が予後良好-
Leung KL, et al. Lancet 2004	再発や予後に悪影響なし
COST Group N Engl J Med 2004	再発や予後に悪影響なし
COLOR Grorp Lancet Oncol 2005	再発や予後に悪影響なし
CLASSIC Trial Group Lancet 2005	再発や予後に悪影響なし
JCOG 0404 2004～on going	689例(予定登録数818例)

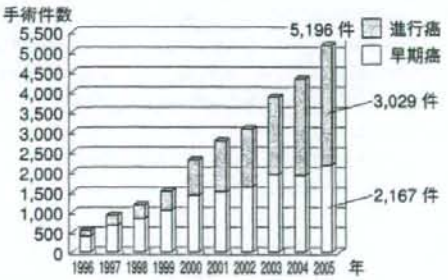
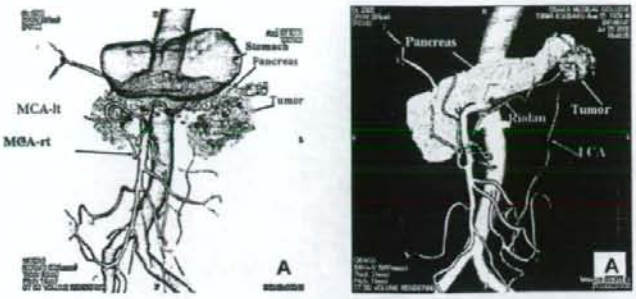


図2　腹腔鏡下大腸癌手術数（第8回日本内視鏡外科学会アンケート調査2006年）

症例が3029件と約6割を占めていた[10]（図2）．ただし，大腸癌に対する腹腔鏡下手術の適応と実績には施設間格差が大きいため，各施設（手術チーム）の熟練度やデータを説明した上で十分なインフォームド・コンセントのもとに適用することが望まれる．とくに，横行結腸・下行結腸や直腸（Ra/Rb）癌に対する腹腔鏡下手術では的確なリンパ節郭清と血管処理，適切な腸管の剥離授動と切除の面で難易度が高い．

筆者らは，癌手術の原則を遵守した適切な手技のもとに適応を段階的に拡大し，現在までに1,150例を越える腹腔鏡下大腸癌手術を行ってきた．とくに血管分岐のバリエーションが多い横行結腸の病変には国内外で初めて3D-CT画像を応用した術前シミュレーションと術中ナビゲーションの有用性を報告し，活用している[11,12]（図3）．また，直腸（Ra/Rb）の病変に対する腹腔鏡下手術には高度の技術と豊富な経験が要求されるため，手術チームの熟練度やデータをもとにインフォームド・コンセントを得て段階的に適応を拡大してきた[13]．したがって，筆者らは減圧不能の腸閉塞・高度他臓器浸潤や巨大腫瘍などの症例を除き，盲腸から上部直腸（Ra）では漿膜浸潤癌まで，下部直腸（Rb）では適切な剥離操作や側方郭清の困難性から病変が腸壁内に確実にとどまり，リンパ節に明らかな転移のないMP, N(－)までを主な適応としている（図4）．これにより，腹腔鏡下低位前方切除では自律神経完全温存のTotal mesorectal excision（TME）の層での直腸



a | b

図3　横行結腸癌に対する Integrated 3D-CT の有用性
a：病変支配血管が独立分岐の中結腸動脈左枝の症例.
b：病変支配血管が副中結腸動脈と左結腸動脈の症例.

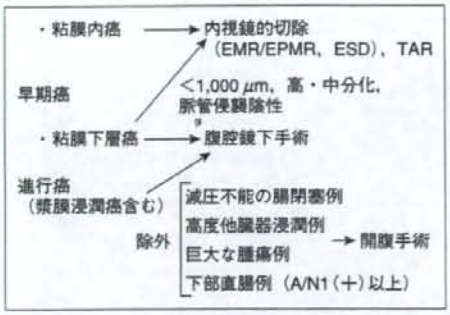
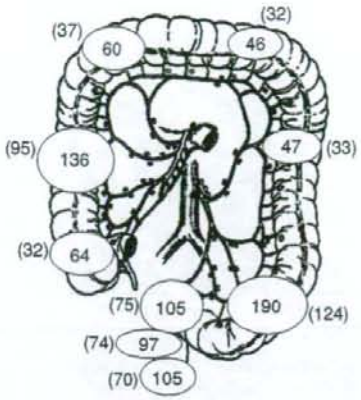


図4　大腸癌に対する治療方針

の剥離授動と肛門側切離予定線が歯状線までであれば括約筋温存術が基本で，低侵襲機能温存手術としてのメリットが活かされる．ただし，手技の向上と経験の蓄積により，症例を選択して腹腔鏡下の自律神経温存側方郭清も行い，直腸 Rb 癌への適応を拡大しつつある[14]．なお，高齢者や肥満者も適応外とはせず，開腹手術既往者も腹腔内癒着に注意しつつ腹腔鏡下手術を行っている．さらに，全身状態（心・肺・肝・腎機能）不良者でも activity があって全身麻酔に耐えられれば適応としている．

2.　手術成績からの考察

図5に示すごとく，2006年4月までに850例の大腸癌（Stage 0 72例，Ⅰ276例，Ⅱ178例，Ⅲa 194例，Ⅲb 91例，Ⅳ 39例）に腹腔鏡下手術（D0～1 郭清 69例，D2 郭清 202例，D3 郭清 579例）を施行した．このうち進行大腸癌は572例であった．上記症例以外に，適応外以外の理由で開腹移行した症例は48例（開腹移行率 5.3%：48/898）であった．開腹移行の理由は，高度癒着が19例，低位前方切除で直腸切離時のステイプリングトラブルが16例，出血が4例，肝硬変で著明に肥厚した腸間膜の剥離困難が4例，その他5例であった．術後合併症は，完遂例850例中，創部感染35例，縫合不全20例，腸閉塞14例，吻合部狭窄5例，吻合部出血5例，感染性腸炎5例，リンパ漏（乳糜漏）4例，腹腔内出血3例，仙骨前面膿瘍3例，肺塞栓2例，ポート部ヘルニア1例，その他5例であった．このうち，縫合不全はほとんどが低位前方切除（DST）例で，発生率は7.4%であった．すなわち，開腹移行例や術後合併症例からみても直腸癌に対する腹腔鏡下手術の難易度が最も高いことがわかる．しかし一方で，腹腔鏡下手術の利点である近接視・拡大視効果を活かして繊細な操作を行えば，図6のように骨盤内自律神経を完全温存した直腸の剥離授動が的確に行える．そこでDST例での縫合不全の詳細をみると，ほとんどが男性の狭骨盤例で，吻合部は肛門から4～5 cmの低位で多く，直腸切離時のステイプリング3回以上がほとんどであった．したがって，とくに男性の狭骨盤例では肛門管直上まで下部直腸を十



1993年9月～2006年4月

850人	(572人)
D0～1	69
D2	202
D3	579
Stage 0	72
Stage I	276
Stage II	278
Stage IIIa	194
Stage IIIb	91
Stage IV	39

図5　腹腔鏡下大腸癌切除例

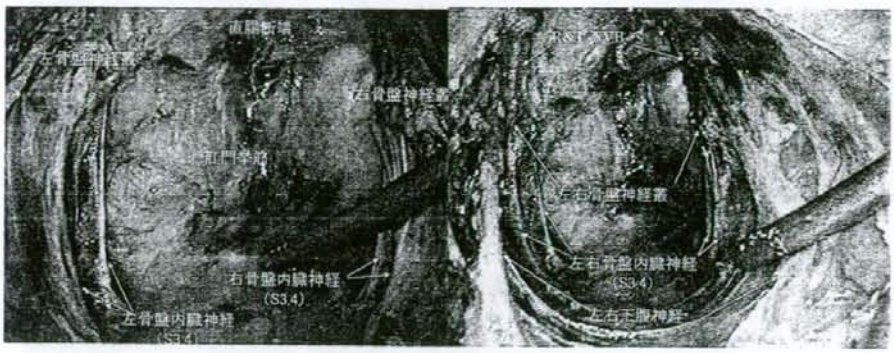


図6　直腸癌に対する腹腔鏡下手術
骨盤内自律神経の完全温存.

分に剥離授動して直腸間膜処理を的確に行うとともに着脱式腸鉗子で直腸を扁平になるように閉鎖して直腸洗浄後のステイプリングが1～2回で完了して適切な切離面が得られることと，2回のステイプリングで直腸切離を行った場合にはステイプラーのオーバーラップしたところからシャフトの槍を出して安全で確実な吻合を心がけている（図7）．なお，図8に示すように，近年，右下腹部のポートからのステイプリングが有用と見直すとともに，ストレートであるが確実な閉鎖が行えるEchelon 60を愛用しており，その後の縫合不全率は2.9%（3/103）と減少した．また，DST吻合例には，リークテストも兼ねて術中大腸内視鏡を行い，吻合部出血の有無やステイプリングの状態，吻合部前後の腸管の状態（色調など）もチェックするようにしている．

ところで，腹腔鏡下手術を効果的に用いれば，超低位直腸切除を開腹手術よりも的確に施行できる．その1つが，prolapsing法との併用である（図9）．すなわち，sm癌の内視鏡的切除後追加腸切除例や小さなMP癌の病変で第1ヒューストンバルブ付近（肛門縁から5 cm程度）と低位のために腹腔側からのステイプリングが困難な場合には，prolapsing法が有効である．もう1つは，経肛門的括約筋部分切除法（ISR）との併用である（図10）．すなわち，病変が肛門縁から3～4 cmの超低位で肛門側腸管切離予定部が歯状線から括約筋間溝になるような症例では，経肛門