Other Laparoscopic Gastrectomies for EGC

Laparoscopic distal, proximal, and total gastrectomies are performed according to the location of the tumor, as with open surgery. Laparoscopic proximal and total gastrectomies are indicated for EGC located at the upper stomach [49–53]. In both of these procedures, how to make reconstruction laparoscopically is a problem. Furthermore, to preserve the function of the gastric remnant after gastrectomy, a laparoscopic pylorus-preserving gastrectomy without injuring vagal nerves such as the pyloric or hepatic branch was tried [54].

Advanced Gastric Cancer

D2 lymph node dissection in which the lymph nodes in the first (perigastric) and second (along the celiac artery and its branches) tiers are dissected is widely accepted in Japan for the treatment of advanced gastric cancer, A study of Japanese experience found that 30-40% of patients with metastasis in even second-tier lymph nodes who underwent D2 lymph node dissection have survived more than 5 years [55]. However, surgeons in the USA and other Western countries rarely perform extensive prophylactic lymphadenectomy, because two European randomized trials (RCT) showed no survival advantage of D2 over D1. Since these trials also compared D1 and D2 and showed high operative mortality in the latter - exceeding 10% - the British NHS Cancer Guidance officially discourages the use of D2 in clinical practice [56, 571.

According to the JSES survey, D1+α lymph node dissection was performed in 67% and D2 lymph node dissection in 23% of LADGs for gastric cancer in Japan. Several investigators reported low mortality and morbidity in laparoscopic D2 lymph node dissection [58–60]. More recently, RCT by Huscher et al. [48] demonstrated the feasibility and safety of laparoscopic subtotal gastrectomy with D2 lymph node dissection for advanced gastric cancer. However, laparoscopic D2 lymph node dissection requires a learning curve, as does conventional open surgery. To establish the acceptability of laparoscopic gastrectomy with D2 lymph node dissection against advanced gastric cancers, safe techniques and new instruments must be developed.

Future Aspects

To establish laparoscopic surgery as a standard treatment for gastric cancer, several issues must be resolved. The first is the prevalence of standard techniques, and the development of education and training systems is important. Recently, several training machines and animal training centers for getting better laparoscopic techniques have been developed. In addition, the JSES has started to design a Board Certification Examination for laparoscopic procedures. Thus, with the aim of popularizing laparoscopic surgery, education and training in standard laparoscopic techniques continue to develop.

The second issue is the evaluation of long-term outcome of laparoscopic gastrectomy for gastric cancer. Since laparoscopic gastrectomy for gastric cancer has been shown to be potentially superior in short-term outcome to open surgery, multicenter, large-scale randomized trials are required in order to establish laparoscopic gastrectomy not only for EGC but also for advanced gastric cancer.

Third, the oncological aspects of the influence of CO₂ pneumoperitoneum should be elucidated. So far, the effects of CO₂ pneumoperitoneum on cancer growth and progression, including lymph node metastasis and both hematogenous and peritoneal dissemination, have been reported in animal models [61–63]. CO₂ pneumoperitoneum in laparoscopic surgery has been reported to be inferior to laparotomy in open surgery regarding the activation of the spread of cancers except liver metastasis [64]. To better evaluate the oncological aspects of laparoscopic surgery, further examination of the effects of CO₂ pneumoperitoneum on cancer progression are needed.

Thus, laparoscopic surgeons have to design and implement education and training systems for standard laparoscopic procedures, evaluate clinical outcomes by multicentric RCT studies, and clarify the oncological aspects in basic studies. Laparoscopic surgeons expect that laparoscopic gastrectomy with minimal invasiveness will become a worldwide standard procedure for the treatment of gastric cancer.

116

Dig Dis 2005;23:113-118

Etoh/Shiraishi/Kitano

References

- 1 Matsukura A, Furusawa M, Tomoda H, et al: A clinicopathological study of asymptomatic gastric cancer. Br J Cancer 1996;74:1647– 1650.
- 2 Kubota H, Kotoh T, Masunaga R, et al: Impact of screening survey of gastric cancer of clinicopathological features and survival: retrospective study at a single institution. Surgery 2000; 128:41-47.
- 3 Adachi Y, Mori M, Maehara Y, et al: Prognostic factors of node-negative gastric carcinoma: univariate and multivariate analyses. J Am Coll Surg 1997;184:373-377.
- 4 Azagra JS, Goergen M, De Simone P, et al: The current role of laparoscopic surgery in the treatment of benign gastroduodenal diseases. Hepatogastroenterology 1999,46:1522-1526.
- 5 Yano H, Monden T, Kinuta M, et al: The usefulness of laparoscopy-assisted distal gastrectomy in comparison with that of open distal gastrectomy for early gastric cancer. Gastric Cancer 2001,4:93-97
- 6 Shimizu S, Noshiro H, Nagai E, et al: Laparoscopic gastric surgery in a Japanese institution: analysis of the initial 100 procedures. J Am Coll Surg 2003,197:372-378.
- 7 Adachi Y, Suematsu T, Shiraishi N, et al: Quality of life after laparoscopy-assisted Billroth I gastrectomy. Ann Surg 1999,229:49-54.
- 8 Maruyama K: The most important prognostic factors for gastric cancer patients: a study using univariate and multivariate analyses. Scand J Gastroenterol Suppl 1987;22:63-68.
- 9 Okajima K: Prognostic factors of gastric cancer patients: a study by univariate and multivariate analysis (in Japanese/English abstract). Jpn J Gastroenterol Surg 1997;30:700-711.
- 10 Kunisaki C, Shimada H, Takahashi M, et al: Prognostic factors in early gastric cancer. Hepatogastroenterology 2001;48:294-298.
- 11 Isozaki H, Tanaka N, Okajima K: General and specific prognostic factors of early gastric carcinoma treated with curative surgery. Hepatogastroenterology 1999;46:1800-1808.
- 12 Nakamura K, Morisaki T, Sugitani A, et al: An early gastric carcinoma treatment strategy based on analysis of lymph node metastasis. Cancer 1999;85;1500-1505.
- 13 Namieno T, Koito K, Higashi T, et al: Assessing the suitability of gastric carcinoma for limited resection: endoscopic prediction of lymph node metastases. World J Surg 1998;22:859-864
- 14 Gotoda T, Yanagisawa A, Sasako M, et al: Incidence of lymph node metastasis from early gastric cancer: estimation with a large number of cases at two large centers. Gastric Cancer 2000;3:219-225.
- 15 Kunisaki C, Shimada H, Nomura M, et al: Appropriate lymph node dissection for early gastric cancer based on lymph node metastases. Surgery 2001;129:153-157.

- 16 Korenaga D, Haraguchi M, Tsujitani S, et al: Clinicopathological features of mucosal carcinoma of the stomach with lymph node metastasis in eleven patients. Br J Surg 1986;73:431–433.
- 17 Iriyama K, Asakawa T, Koike H, et al: Is extensive lymphadenectomy necessary for surgical treatment of intramucosal carcinoma of the stomach? Arch Surg 1989;124:309-311.
- 18 The Japanese Gastric Cancer Association: Guidelines for the treatment of gastric cancer. Tokyo, Kanehara-Shuppann, 2001.
- 19 Ono H, Kondo H, Gotoda T, et al: Endoscopic mucosal resection for treatment of early gastric cancer. Gut 2001;48:225-229.
- Oyama T, Hotta Y, Hirasawa, et al: Endoscopic submucosal resection using a hook knife (abstract in Japanese). Gastrointest Endosc 2003; 45:1525.
- 21 Yahagi N, Fujishiro M, Kakushima N, et al: Endoscopic submucosal dissection for early gastric cancer using the tip of an electro-surg snare (thin type). Dis Endosc 2004;16:34–38.
- 22 Inoue H, Kudo S: A novel procedure of en bloc EMR using triangle-tipped knife (abstract). Gastrointest Endosc 2003;57:494.
- 23 Ohgami M, Otani Y, Kumai K, et al: Curative laparoscopic surgery for early gastric cancer: five years' experience. World J Surg 1999;23: 187-193.
- 24 Altorjay A, Szanto I, Garcia J, et al: Endoscope-assisted laparoscopic resection of the gastric wall. Orv Hetil 1996;137:2743-2745.
- 25 Ohashi S: Laparoscopic intraluminal (intragastric) surgery for early gastric cancer. A new concept in laparoscopic surgery. Surg Endosc 1995,9:169-171.
- 26 Kitano S, Iso Y, Moriyama M, et al: Laparoscopy-assisted Billroth I gastrectomy. Surg Laparosc Endosc 1994;4:146-148.
- 27 Japan Society for Endoscopic Survey: Nationwide survey on endoscopic surgery in Japan. J Jpn Soc Endosc Surg 2004;9:491-499.
- 28 Kitagawa Y, Fujii H, Mukai M, et al: Radioguided sentinel node detection for gastric cancer. Br J Surg 2002;89:604-608.
- 29 Miwa K, Kinami S, Taniguchi K, et al: Mapping sentinel nodes in patients with early-stage gastric carcinoma. Br J Surg 2003;90:178-182.
- 30 Reintgen D, Cruse CW, Wells K, et al: The ordinary progression of melanoma nodal metastases. Ann Surg 1994;220:759-767.
- 31 Veronesi U, Paganelli G, Galimberti V, et al: Sentinel-node biopsy to avoid axillary dissection in breast cancer with clinically negative lymph nodes. Lancet 1997;349:1864-1867.
- 32 Kitano S, Shiraishi N: Minimally invasive surgery for gastric tumors. Surg Clin N Am 2005; 85:151-164.
- 33 Mochiki E, Nakabayashi T, Kamimura H, et al: Gastrointestinal recovery and outcome after laparoscopy-assisted versus conventional open distal gastrectomy for early gastric cancer. World J Surg 2002;26:1145–1149.

- 34 Adachi Y, Shiraishi N, Shiromizu A, et al: Laparoscopy assisted Billroth I gastrectomy compared with conventional open gastrectomy. Arch Surg 2000;135:806-810.
- 35 Yasuda K, Inomata M, Shiraishi N, et al: Laparoscopy-assisted distal gastrectomy for early gastric cancer in obese and nonobese patients. Surg Endosc 2004,18:1253-1256.
- 36 Noshiro H, Shimizu S, Nagai E, et al: Laparoscopy-assisted distal gastrectomy for early gastric cancer: is it beneficial for patients of heavier weight? Ann Surg 2003;238:680-685.
- 37 Schwenk W, Bohm B, Muller JM: Postoperative pain and fatigue after laparoscopic or conventional colorectal resections. A prospective randomized trial. Surg Endosc 1998; 12:1131–1136.
- 38 Yasuda K, Sonoda H, Shiroshita M, et al: Laparoscopically assisted distal gastrectomy for early gastric cancer in the elderly. Br J Surg 2004,91:1061-1065.
- 39 Kitano S, Shiraishi N, Fujii K, et al: A randomized controlled trial comparing open vs. laparoscopy-assisted distal gastrectomy for the treatment of early gastric cancer: an interim report. Surgery 2002;131:S306-S311.
- 40 Adachi Y, Shiraishi N, Ikebe K, et al. Evaluation of the cost for laparoscopic-assisted Billroth I gastrectomy. Surg Endosc 2001;15:932–936.
- 41 Rosin D, Brasesco O, Rosenthal RJ: Laparoscopy for gastric tumors. Surg Oncol Clin N Am 2001;10:511-529.
- 42 Reyes CD, Weber KJ, Gagner M, et al: Laparoscopic vs. open gastrectomy. A retrospective review. Surg Endosc 2001;15:928-931.
- 43 Tanimura S, Higashino M, Fukunaga Y, et al: Laparoscopic gastrectomy with regional lymph node dissection for upper gastric cancer. Gastric Cancer 2003;6:64-68.
- 44 Azagra JS, Goergen M, De Simone P, et al: Minimally invasive surgery for gastric cancer. Surg Endosc 1999;13:351-357.
- 45 Huscher CG, Anastasi A, Crafa F, et al: Laparoscopic gastric resections. Semin Laparosc Surg 2000;7:26-54.
- 46 Ballesta Lopez C, Ruggiero R, Poves I, et al: The contribution of laparoscopy to the treatment of gastric cancer. Surg Endosc 2002;16: 616-619.
- 47 Kitano S, Shiraishi N, Kakisako K, et al: Laparoscopy-assisted Billroth-I gastrectomy (LADG) for cancer: our 10 years' experience. Surg Laparosc Endosc Percutan Tech 2002;12: 204–207.
- 48 Huscher CG, Mingoli A, Sgarzini G, et al: Laparoscopic versus open subtotal gastrectomy for distal gastric cancer: five-year results of a randomized prospective trial. Ann Surg 241:232– 237.
- 49 Asao T, Hosouchi Y, Nakabayashi T, et al: Laparoscopically assisted total or distal gastrectomy with lymph node dissection for early gastric cancer. Br J Surg 2001;88:128-132.

- 50 Ikeda Y, Sasaki Y, Niimi M, et al: Hand-assisted laparoscopic proximal gastrectomy with jejunal interposition and lymphadenectomy. J Am Coll Surg 2002;195:578-581.
- 51 Mochiki E, Nakabayashi T, Kamimura H, et al: Gastrointestinal recovery and outcome after laparoscopy-assisted versus conventional open distal gastrectomy for early gastric cancer. World J Surg 2002;26:1145-1149.
- 52 Tanimura S, Higashino M, Fukunaga Y, et al: Laparoscopic gastrectomy with regional lymph node dissection for upper gastric cancer. Gastric Cancer 2003;6:64-68.
- 53 Kim YW, Han HS, Fleischer GD: Hand-assisted laparoscopic total gastrectomy. Surg Laparosc Endosc Percutan Tech 2003;13:26-30.
- 54 Horiuchi T, Shimomatsuya T, Chiba Y: Laparoscopically assisted pylorus-preserving gastrectomy. Surg Endosc 2001;15:325-328.
- 55 Sasako M, McCulloch P, Kinoshita T, et al: New method to evaluate the therapeutic value of lymph node dissection for gastric cancer. Br J Surg 1995;82:346-351.

- 56 Bonenkamp JJ, Songun I, Hermans J, et al: Randomised comparison of morbidity after D1 and D2 dissection for gastric cancer in 996 Dutch patients. Lancet 1995;345:745-748.
- 57 Cuschieri A, Fayers P, Fielding J, et al: Postoperative morbidity and mortality after D1 and D2 resections for gastric cancer: preliminary results of the MRC randomised controlled surgical trial. The Surgical Cooperative Group. Lancet 1996;347:995-999.
- 58 Tanimura S, Higashino M, Fukunaga Y, et al: Hand-assisted laparoscopic distal gastrectomy with regional lymph node dissection for gastric cancer. Surg Laparosc Endosc Percutan Tech 2001;11:155-160.
- 59 Uyama I, Sugioka A, Matsui H, et al: Laparoscopic D2 lymph node dissection for advanced gastric cancer located in the middle or lower third portion of the stomach. Gastric Cancer 2000;3:50-55.

- 60 Goh PM, Khan AZ, So JB, et al: Early experience with laparoscopic radical gastrectomy for advanced gastric cancer. Surg Laparosc Endosc Percutan Tech 2001;11:83–87.
- 61 Canis M, Botchorishvili R, Wattiez A, et al: Tumor growth and dissemination after laparotomy and CO₂ pneumoperitoneum: a rat ovarian cancer model. Obstet Gynecol 1998; 92:104-108.
- 62 Gutt CN, Kim ZG, Schmandra T, et al: Carbon dioxide pneumoperitoneum is associated with increased liver metastases in a rat model. Surgery 2000;127:566-570.
- 63 Ishida H, Idezuki Y, Yokoyama M, et al: Liver metastasis following pneumoperitoneum with different gases in a mouse model. Surg Endosc 2001;15:189-192.
- 64 Shiromizu A, Suematsu T, Yamaguchi K, et al: Effect of laparotomy and laparoscopy on the establishment of lung metastasis in a murine model. Surgery 2000;128:799-805.

Pharma

The Review of Medicine and Pharmacology

Medica

Volume 23

別刷

メデカルレビュー社

〒541-0046 大阪市中央区平野町1-7-3 吉田ビル TEL 06-6223-1468 〒113-0034 東京都文京区湯島3-19-11イトーピア湯島ビル TEL 03-3835-3041

された治療としての下大腸癌手術

大分大学第1 外科 猪股 雅史,安田 一弘 白石 憲男,北野 正剛

はじめに

William Control of the French State

No. 2016年時代的DEEPER

KEY WORDS

s aproduction of the control of

Caperal squres as the same as

- - - Waspitomi (nomen)(新聞) - - - Wyelbino Yasuda (新聞)。

Augustanish (BRAS)

e en esta de la composita de l

1991年, Jacobsら¹⁾が世界ではじめ て腹腔鏡下大腸切除術を報告して以来, 腹腔鏡下手術は従来の開腹手術と比べ 低侵襲で整容性に優れており、低侵襲 治療としての位置づけを確立しながら. この10年余りで急速に普及してきた20。 一方、早期癌から進行癌へその適応拡 大がすすむにつれ, port site recurrenceなどの癌に対する腹腔鏡下手術の 影響が懸念されるようになり、1990年 半ばより各国で開腹手術と腹腔鏡下手 術のランダム化比較試験(RCT)が開始 され始めた。本稿では、大腸癌に対す る開腹手術と腹腔鏡下手術との国内外 で施行されているRCTに基づいたエビ デンスを示すとともに、標準治療とし ての腹腔鏡下手術の現時点での位置づ けと今後の展望について概説する。

I. 大腸癌に対する 腹腔鏡下手術の現況

1. 日本内視鏡外科学会アンケート 調査結果

わが国における大腸癌に対する腹腔 鏡下手術の現況は、日本内視鏡外科学 会の2年に1度行っている全国アン ケート調査結果がに基づくと、2003年 までに施行された腹腔鏡下手術の症例 数は年々増加しており、総手術症例数 は17,200例を超え、2003年の1年間で は4,000例に及び、そのなかで進行癌 の比率は55%を占めるに至っている (図1)。わが国のこのような普及の背 景には、2002年の腹腔鏡下手術の保険 適応拡大が主な要因の1つと考えられ る。

2. 厚生労働省多施設共同班研究報告

わが国の大腸癌に対する腹腔鏡下手 術の治療成績について、平成13~16年 度厚生労働省がん研究助成金[がんに

Pharma Medica Vol.23 No.12 2005 41

おける体腔鏡手術の適応拡大に関する 研究(北野班)」における多施設共同研 究 (retrospective multicenter study) の なかで報告されている⁴⁾⁵⁾。この班研 究は、わが国の腹腔鏡下手術の先進的 な17施設が参加し、1993年から2002年 8月までの大腸癌に対する腹腔鏡下手 術施行2,036症例を集計し、安全性と 根治性を解析している。これによると 登録症例の癌進行度の割合は, stage I ; 53%, stage II ; 16%, stage II ; 26%. stage IV; 5%である。開腹移 行(conversion)は、結腸癌の4.8%, 直腸癌の4.4%, 開腹移行理由は, 適 応を超えた癌の過進展が約半数、術中 の出血や他臓器損傷が約3割という内 訳である。結腸癌の治療成績では、術 中合併症は1.4%, 術後合併症は12.6% の頻度, 根治手術1,367例中61例 (4.5%) に再発を認め、その形式は、 肝が2.4%と最も多く,腹膜が0.4%, 肺が0.4%, リンパ節が0.3%, 局所が 0.2%という内訳である。5年生存率は, stage I, Ⅱ, Ⅲの順に, 95%, 86%, 74%を示している(図2-1)。直腸癌で は, 術中合併症が3.6%, 術後合併症 は14.1%の頻度で、根治手術476例中30 例(6.3%)に再発を認め、その形式は、 肝が2.7%と最も多く, 肺0.6%, 腹膜 1.1%, 局所0.8%, リンパ節0.7%と いう内訳であった。5年生存率は, stage I, II, IIの順に, 95%, 85%, 80%を示している(図 2-2)。このRetrospective multicenter studyの報告か ら、わが国の結腸癌および直腸癌の治 療成績は、合併症・再発率・再発形 式・5年生存率のいずれも従来の開腹 手術と比較してほぼ同等と考えられる。

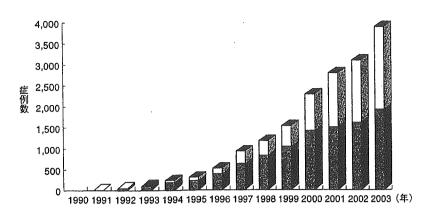


図1. 大腸癌に対する腹腔鏡下手術の動向 (第7回日本内視鏡外科学会全国アンケート調査) ■:早期大腸癌、□:進行大腸癌

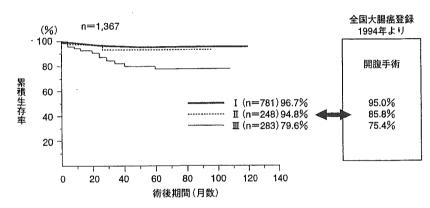


図 2-1. 結腸癌に対する腹腔鏡下手術の遠隔成績(TNM staging別) 追跡調査期間: 3~125ヵ月(中央値32ヵ月) (文献⁵引用改変)

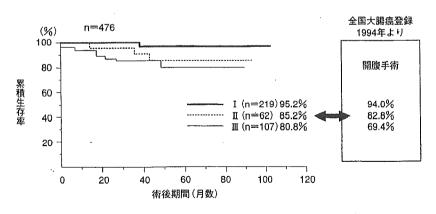


図 2-2:直腸癌に対する腹腔鏡下手術の遠隔成績(TNM staging別) 追跡調査期間: 3~120ヵ月(中央値28ヵ月)

(文献5)引用改変)

Ⅱ. 大腸癌に対する腹腔鏡下手術のエビデンス

1990年代半ばより海外ですすめられている大腸癌に対する腹腔鏡下手術と

開腹手術のRCTを表1に示す。また現在まで長期成績が報告された3つのTrialの概要と結果を表2,3にまとめた。2002年のスペインのLacyらの報告のでは、腹腔鏡下手術は再発率、

表1. 現在進行中の海外RCT(大腸癌に対する開腹手術vs腹腔鏡下手術)

国名	治験名	開始	Target accrual	
スペイン	— (Lacy AM)	1993	250	——— 完了
香港	— (Leung)	1993	1000	完了
米国	COST (Nelson H)	1994	1200	完了
ドイツ	LAPKON (Bohm B)	1995	1200	
イギリス	CLASSIC (Guillou PJ)	1996	1000	
ヨーロッパ	COLOR (Hazebroek EJ)	1997	1200	
ニュージーランド	— (Bagshaw)	1998	1260	

表 2. 長期成績が報告された海外RCTの試験概要 (大腸癌に対する開腹手術vs腹腔鏡下手術)

著者	雑誌	症例	第一次エンドポイント	第二次エンドポイント
Lacy (スペイン)	Lancet (2002)	OC 101 LAC 105	癌関連生存率	全生存率 無再発生存率
Leung (香港)	Lancet (2004)	OC 200 LAC 203	全生存率 無再発生存率	_
COST (米国)	N Engl J Med (2004)	OC 428 LAC 435	再発までの期間	無再発生存率 全生存率 合併症 クオリティ・オブ・ライフ
JCOG (日本)		OC 409 LAC 409	全生存率	無再発生存率 合併症 術後早期経過 腹腔鏡下手術完遂率

OC:開腹手術, LAC:腹腔鏡下手術

癌死率,全死亡率において独立した危険減少因子であり(p=0.04,0.02,0.006),その差はstage Ⅲの開腹手術の治療成績不良によるものと考察されている。2004年の米国ⁿ,香港[®]からの報告では,腹腔鏡下手術と開腹手術との間にどのstageにおいても再発率、全生存率に差は認めず同等との結果であった。しかし、これらのRCTは症例数が少なかったり、術後補助療法の規定がなかったり、あるいは開腹移行率や合併症発生率が高いなど、わが国の医療にそのまま受け入れることは妥当ではないと考えられる。

Ⅲ. わが国におけるエビデンスの確立

前述の背景を受けてわが国でも,厚 生労働省科学研究費補助金に基づき, Japan Clinical Oncology Group (JCOG) の臨床研究として,2004年10月より「進 行大腸がんに対する腹腔鏡下手術と開 腹手術との根治性に関するランダム化 比較試験(JCOG 0404)」(研究代表者: 北野正剛)"が開始されている。予定 登録症例数は818例,登録期間は3年, 追跡期間5年の非劣性試験である。腫 瘍深達度はT3・T4(他臓器浸潤を除 く),主占拠部位は盲腸・上行結腸・

表 3. 長期成績が報告された海外RCTの試験結果(大腸癌に対する開腹手術vs腹腔鏡下手術)

著者	開腹 合併症率 周術期3 移行率		周術期死亡率	全生存率	無再発生存率	
Lacy ' 11% (スペイン)		p=0.001	p=0.19	HR 0.39	p=0.006	
		(29% vs 11%)	(2.9% vs 0.9%)	95% CI 0.19~0.82	(StageⅢ症例)	
Leung	23%	NS	p=0.97	p=0.61	p=0.45	
(香港)		(24% vs 26%)	(0.6% vs 2.4%)	(73% vs 76%)	(78% vs 75%)	
COST (米国)	21%	p=0.64 (20% vs 21%)	p=0.40 (1.0% vs 0.5%)	p=0.51 (85% vs 86%)	NS	

S状結腸・直腸S状部の病変を対象と 1. ランダム化割付因子は登録施設と 腫瘍占拠部位(右側/左側)の2因子で ある。このRCTは海外で報告された RCTの問題点をovercomeすべく以下の ような特徴を有している。すなわち, ①対象は早期癌を除外し進行癌に限定, ②リンパ節郭清をD3と規定, ③補助 化学療法はstageⅢに対して5Fu/Lv静 注療法と規定、④試験への参加施設お よび手術を施行する手術担当責任医の 基準を設定, ⑤全施行症例の手術写真 を中央判定委員会にて審査、など臨床 試験の高い質の確保を目指している。 2005年11月現在, RCT開始後間もなく 1年を迎えようとしているが、登録総 数約200例の進捗状況である。

IV. 大腸癌に対する腹腔鏡下手術の位置づけ

本稿で示したわが国の多施設共同班研究と海外のRCT結果に基づくエビデンスから、現時点における腹腔鏡下手術の位置づけを結腸癌と直腸癌に分けて図3に示した。結腸癌に対しては、深達度T2までは腹腔鏡下手術が受け入れられており、T3/T4に関しては根治性に関する長期成績が十分に明らかにされていないため、わが国の大規模RCTの結果が期待されるところである。一方、直腸癌においては、現時点ではT1あるいはT2までが受け入れられつつあるが直腸の切離・吻合手技の安全性や側方郭清を踏まえた適応の問題点があり、現在、腹腔鏡下大腸切除研究

会(代表:渡邊昌彦教授)が中心となり 直腸癌に対するphase II study, いわ ゆるFeasible studyが開始されるとこ ろである。

V. 標準化への取り組み

わが国の大腸癌に対する腹腔鏡下手 術の標準化への取り組みとして、前述 のRCTによるEBMの確立とともに技 術面における標準化への努力も行われ ている。

1. 腹腔鏡下大腸切除研究会の取り組み

1998年に発足した本会(設立者/代表:小西文雄教授)は,標準術式の確立,講習会の開催やトレーニング法の検討,データ集積による治療成績の分析など,大腸癌研究会のプロジェクト研究としてすすめられてきた¹⁰。

2. 内視鏡外科学会技術認定制度の発足

昨年度より,日本内視鏡外科学会において,安全な手術手技の普及を目的に,指導的立場にある内視鏡外科医を認定する制度が発足した。提出された無修正ビデオの手術手技に対して,共通項目と臓器別項目に分けて各領域ごとに厳正に審査が行われている¹¹¹。本制度の推進により,腹腔鏡下手術の普及と手術手技の標準化がさらにすすむものと考えられる。

おわりに

大腸癌に対する外科治療は,大きく変貌しようとしている。これは「患者にやさしい低侵襲治療」を望む社会のニーズとそれを実践させうる腹腔鏡下手術の登場に帰するところが大きい。

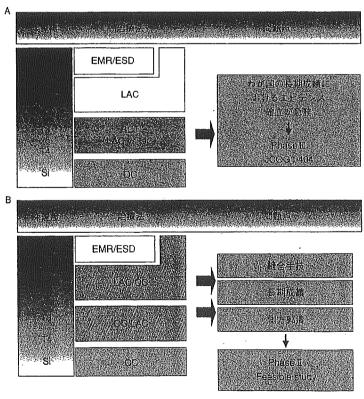


図3. 外科治療における腹腔鏡下手術の位置づけ A:結腸癌, B:直腸癌

地集 大腸癌をめぐる最近の話題|

現時点で腹腔鏡下手術は早期結腸癌において標準治療として受け入れられているが、進行結腸癌や直腸癌では、エビデンスの確立や安定した手技の点からまだ十分とはいえない状況である。今後は、わが国のRCTによるEBMの確立、講習会やアニマルラボによるトレーニングシステムの整備、学会レベルでの技術認定制度の取り組みが必要であり、さらに安全性、長期成績に加え医療経済も考慮した総合的な評価が腹腔鏡下手術の標準化に必要であろう。

文 献

 Jacobs M, Verdeja JC, Goldstein HS: Minimally invasive colon resection (Iaparoscopic colectomy). Surg Laparosc Endosc 1: 144-150, 1991

- 2) 猪股雅史,北野正剛,白石憲男:悪性腫瘍への腹腔鏡下手術の現況.外科治療 90:7-13,2004
- 3) 日本内視鏡外科学会学術委員会:内視 鏡外科手術に関するアンケート調査 - 第7回集計結果報告-. 日鏡外会誌 9: 475-569, 2004
- 4) 北野正剛, 北島政樹, 小西文雄, 他: 厚生労働省がん研究助成金「がんにお ける体腔鏡手術の適応拡大に関する研 究」第2.回アンケート調査結果報告; 大腸がん.29-59, 2002
- 5) Kitano S, Kitajima M, Konishi F, et al:
 A multicenter study on laparoscopic surgery for colorectal cancer in Japan:
 Surg Endosc, 2005 (in press)
- 6) Lacy AM, Garcia-Valdecasas JC, Delgado S, et al: Laparoscopy-assisted colectomy versus open colectomy for treatment of non-metastatic colon cancer; a randomised trial. Lancet 359: 2224-2229, 2002
- 7) The Clinical Outcomes of Surgical Therapy (COST) Study Group: A

- comparison of laparoscopically assisted and open colectomy for colon cancer. N Engl J Med 350: 2050-2059, 2004
- Leung KL, Kwok SPY, Lam SCW, et al: Laparoscopic resection of rectosigmoid carcinoma: prospective randomised trial. Lancet 363: 1187 – 1192, 2004
- 9) Kitano S, Inomata M, Sato A, et al: Randomized controlled trial to evaluate laparoscopic surgery for colorectal cancer: Japan clinical oncology group study JCOG 0404. Jpn J Clin Oncol 35: 475-477, 2005
- 10) 小西文雄:腹腔鏡下大腸切除-術式の 発展・展開と課題.腹腔鏡下大腸手術. 腹腔鏡下大腸切除研究会 編,アプロー チとスタンダードテクニック.東京, 医学書院, 2-14, 2002
- 山川達郎:日本内視鏡外科学会技術認 定制度。日鏡外会誌 10:253-260, 2005

Safety of Laparoscopic Intracorporeal Rectal Transection With Double-Stapling Technique Anastomosis

Seiichiro Yamamoto, MD, PhD, Shin Fujita, MD, PhD, Takayuki Akasu, MD, PhD, and Yoshihiro Moriya, MD, PhD

Abstract: To assess the feasibility and analyze the short-term outcomes of laparoscopic intracorporeal rectal transection with doublestapling technique anastomosis, a review was performed of a prospective registry of 67 patients who underwent laparoscopic sigmoidectomy and anterior resection with intracorporeal rectal transection and doublestapling technique anastomosis between July 2001 and January 2004. Patients were divided into 3 groups: sigmoid colon/rectosigmoid carcinoma, upper rectal carcinoma, and middle/lower rectal carcinoma. A comparison was made of the short-term outcomes among the groups. The number of cartridges required in bowel transection was significantly increased in patients with middle/lower rectal carcinoma, and significant differences were observed in the length of the first stapler cartridge fired for rectal transection. Furthermore, mean operative time and blood loss were also significantly greater in the middle/lower rectum group; however, complication rates and postoperative course were similar among the 3 groups. No anastomotic leakage was observed. Laparoscopic intracorporeal rectal transection with double-stapling technique anastomosis can be performed safely without increased morbidity or mortality.

Key Words: laparoscopic low anterior resection, rectal transection, double-stapling technique, complication, colorectal carcinoma

(Surg Laparosc Endosc Percutan Tech 2005;15:70-74)

ore than 10 years have passed since the first report of laparoscopic colectomy by Jacobs et al¹ in 1991. With regard to long-term oncological safety, which is the most important concern for laparoscopic surgery (LS) for malignancies, there have been no reports indicating that LS is inferior to conventional open surgery (OS).²⁻⁵ On the other hand, because LS requires surgical techniques that are different from those of OS, even a surgeon with considerable experience in OS cannot readily perform LS.

In particular, LS for rectal carcinoma is very difficult surgery from a technical standpoint, and consequently many randomized, controlled trials have excluded patients with middle/lower rectal carcinoma. This is because of concerns over the safety of the procedure, ie, the risk of complications associated with the laparoscopic procedure and the risk of tumor cell spillage because of traumatic manipulation of the tumor. Previous studies have reported an anastomotic leakage rate of 5.7% to 21% in patients who underwent laparoscopic low anterior resection (Lap-LAR), and some authors have recommended a covering ileostomy as a routine in Lap-LAR cases. 6-12 It remains uncertain which cases of rectal carcinoma are appropriate for laparoscopic surgery.

Since our first laparoscopic colectomy for colorectal carcinoma in 1993, approximately 280 laparoscopic resections for colorectal malignancies have been carried out at our institution. Most of our early experience was confined to early (Tis or T1) colorectal cancer located at the cecum, ascending colon, sigmoid colon, or rectosigmoid due to technical problems and concerns regarding port site and peritoneal recurrences. In June 2001, we unified our surgical and postoperative management procedures and expanded our indications for laparoscopic colectomy to include advanced colorectal cancers (ie, T2 lesions and beyond) located anywhere in the colon and/or rectum.

In 1980, Knight and Griffen¹³ described the double-stapling technique (DST), which offered great advantages in that it permitted low rectal anastomoses to be performed with great ease. The aim of the present study was to assess the feasibility and analyze the short-term outcomes of laparoscopic intracorporeal rectal transection with DST anastomosis, one of the most demanding and stressful techniques in laparoscopic colorectal surgery, in selected patients with sigmoid colon and rectal carcinoma, who all underwent LS at our hospital after June 2001.

PATIENTS AND METHODS

Patients

At the Division of Colorectal Surgery of the National Cancer Center Hospital in Japan, 156 nonrandomized consecutive patients underwent laparoscopic colorectal resections between July 2001 and January 2004. During this period, 67 patients were treated by laparoscopic sigmoidectomy and anterior resection with DST anastomosis. Because the safety of LS in cancer patients remains to be established, candidates for laparoscopic surgery were patients who were preoperatively diagnosed with T1 or T2. Additionally, LS cases also included patients with sigmoid colon or upper rectal carcinoma who were preoperatively diagnosed with T3 but wished to undergo LS, as well as those for which palliative resection was

Copyright © 2005 by Lippincott Williams & Wilkins

Received for publication March 25, 2004; accepted November 26, 2004. From the Division of Colorectal Surgery, National Cancer Center Hospital, Tokyo, Japan.

Reprints: Seiichiro Yamamoto, MD, PhD, Division of Colorectal Surgery, National Cancer Center Hospital 5-1-1, Tsukiji, Chuo-ku, Tokyo, 104-0045, Japan (e-mail: seyamamo@ncc.go.jp).

considered necessary. Exclusion criteria for LS were tumors larger than 6 cm, a history of extensive adhesions, severe obesity (body mass index >32 kg/m²), intestinal obstruction, and refusal to undergo LS. The preoperative workup consisted of a clinical investigation, barium enema, total colonoscopy, chest x-ray, abdominal ultrasonography, and computed tomography.

LS was contraindicated for patients with preoperative diagnoses of T3 and T4 tumors in the middle and lower rectum because, with the current instrumentation, it was difficult to perform laparoscopic procedures without grasping and manipulating the bowel or mesorectum near the tumor; our concern was that this would result in accidental tumor spillage. Furthermore, lateral lymph node dissection combined with total mesorectal excision remains the standard surgical procedure for patients with T3 and T4 lower rectal carcinoma in Japan, and lateral lymph node dissection by laparoscopy is still an unexplored frontier. 14-16 As a result, some patients were found to have T3 cancer only after histopathological examination of the surgical specimens. Preoperative or postoperative radiation therapy was not performed in this series because of the low local recurrence rate in patients with T1-T3 lower rectal carcinoma without preoperative radiation. 14,16

Patients were divided into 3 groups: sigmoid colon/rectosigmoid carcinoma, upper rectal carcinoma, and middle/lower rectal carcinoma. For the patients with rectal carcinoma, a primary rectal carcinoma was defined according to its distance from the anal verge as determined by colonoscopy. The tumors were grouped into lower rectum (0-7 cm), middle rectum (7.1-12 cm), and upper rectum (12.1-17 cm). We combined patients with middle and lower rectal carcinoma as a group because laparoscopic techniques for rectal transection and DST anastomosis were almost same: anastomosis located below peritoneal reflection.⁷ Patients with lesions located within 2 cm of the dentate line who underwent laparoscopic intersphincteric rectal resection and hand-sewn coloanal anastomosis were excluded from the present study. This surgical technique has been described previously.¹⁷ Conversion to open surgery was defined as any incision greater than 7 cm, excluding cases in which the incision was enlarged due to a large specimen size that could not be removed with a 7-cm incision.

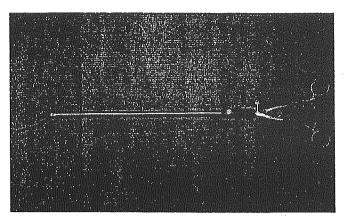
Laparoscopic Technique

Laparoscopic resection techniques have previously been described, with minor modifications. ^{7,17} Initial port placement was performed using the open technique, and pneumoperitoneum was induced using carbon dioxide. Two 5-mm ports were then inserted in the left lower midabdominal and the left lower quadrant regions, and 2 other 12-mm ports were inserted in the mid-lower and the right midabdominal regions under laparoscopic guidance.

The left colon was initially mobilized laterally to medially until the left ureter and superior hypogastric nerve plexus were identified. The mobilization of splenic flexure was performed if necessary. Usually, Japanese patients have a long sigmoid colon, and if the surgeon preserves 1 or 2 arcades of marginal vessels of sigmoid colon by division of sigmoidal arteries between superior rectal artery and marginal vessels, mobilization of splenic flexure becomes unnecessary; thus,

splenic mobilization was performed in only about 20% of our patients. Then, a window was made between the mesocolon containing the arch of the inferior mesenteric vessels and the superior hypogastric nerve plexus, starting at the bifurcation, with support from an assistant holding the sigmoid mesocolon ventrally under traction and to the left using a 5-mm bowel grasper through the left lower quadrant port. After the dissection, proceeding to the origin of inferior mesenteric artery. taking care not to injure the superior hypogastric nerve plexus and the roots of the sympathetic nerves, intracorporeal high ligation of the inferior mesenteric artery was performed. After cutting the inferior mesenteric vein and left colic artery, mobilization of the rectum and mesorectum was performed. The avascular plane between the intact mesorectum anteriorly and the superior hypogastric nerve plexus, right and left hypogastric nerves, and Waldeyer fascia posteriorly was entered by sharp dissection and extended down to the level of the levator muscle for middle and lower rectal carcinomas, taking care to protect the pelvic nerves. For proximal sigmoid colon carcinoma, the mesentery at the promontory was excised routinely using ultrasonic shears (laparoscopic coagulating shears [LCS], Ethicon Endo-Surgery Inc, Cincinnati, OH) or an endolinear stapler (Endo GIA Universal, Tyco Healthcare, Auto Suture Co, US Surgical Corp, Norwalk, CT). For rectosigmoidal and upper rectal lesions, mesorectal tissue extending down to 5 cm below the tumor was excised routinely using LCS. Middle and lower rectal tumors were treated by total mesorectal excision. Immediately before rectal transection, laparoscopic rectal clamping was performed just above the anticipated point of rectal transection, using a bowel clamping device (Fig. 1) introduced through the 12-mm mid-lower port. A distinct advantage of this device is that the bowel clamp at the head of the device can be easily bent intraabdominally without reducing the grasping strength. Rectal washout was performed routinely using 1000 mL of a 5% povidone-iodine solution. Rectal transection was then performed by a multiplefiring technique, using Endo GIA Universal staples, introduced through the 12-mm right midabdominal port. 18 If the rectal transection was not completed after the first cartridge. the stapler line for the second cartridge was carefully positioned on the anal side stapler line of the first cartridge. The third and fourth firings were performed in the same way. A 4- to 5-cm incision was then made over the mid-lower 12-mm port site, and the bowel was exteriorized under wound protection and divided with appropriate proximal clearance. After inserting the anvil head of the circular stapler into the end of the proximal colon, the proximal colon was internalized and the incision was closed. Intracorporeal anastomosis under a laparoscopic view was performed by means of the DST, using a circular stapler (ECS 29 or 33 mm, Ethicon Endo-Surgery Inc). After the insertion of the body of the circular stapler into the anus, the puncturing cone was pushed through the midpoint of the linear staple line. In patients in whom 2 or more linear stapler cartridges were used for rectal transection, the puncturing cone was pushed near the crossing point of the first and second stapler lines.

The anastomotic air leakage test was performed if the "doughnuts" were incomplete. Patients with a low anastomosis within 1 cm from the dentate line and incomplete doughnuts



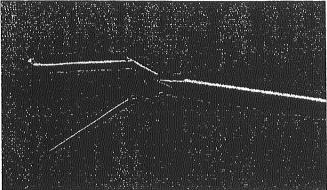


FIGURE 1. Bowel clamping device. A distinct advantage of this device is that the bowel clamp at the head of the device can be easily bent intraabdominally without reducing the grasping strength.

underwent a covering ileostomy. However, the decision to perform a protective ileostomy in this series was based on much looser criteria than those used in OS to avoid major anastomosis complications that could lead to a permanent stoma or a fatal outcome, especially in the early LS cases of lower rectal carcinoma.

Study Parameters

The parameters analyzed included gender, age, body mass index, prior abdominal surgery, operative time, operative blood loss, number of stapler cartridges fired and the length of the first stapler cartridge for rectal transection, conversion rate, days to resume diet, length of postoperative hospital stay, and both intraoperative and postoperative complications within 30 days of surgery. Pathologic staging was performed according to Duke's stage.

Statistical Analysis

Statistical analysis was performed using the χ^2 test, Kruskal-Wallis test with Bonferroni correction, and repeated-measure analysis of variance (ANOVA) with the Scheffe method when appropriate. A P value of < 0.05 was considered significant.

RESULTS

The patient demographics are summarized in Table 1. No significant differences were observed in baseline characteristics among the 3 groups. In the middle/lower rectum group, anastomosis was performed <3 cm from the dentate line in 7 patients and >3 cm but below the peritoneal reflection in 3 patients. We performed an anastomotic air leakage test in 2 patients with lower rectal carcinoma and did not find any sign of air leakage; however, both patients underwent a protective ileostomy, Overall, a protective ileostomy was required in 4 patients, and a transverse coloplasty pouch was created in 1 patient.

The number of patients in relation to the number of stapler cartridges used for rectal transection in each group is shown in Table 2. The number of cartridges required during bowel transection was significantly increased in patients with middle/lower rectal carcinomas compared with the other groups. Similarly, significant differences were observed in the length of the first stapler cartridge fired for rectal transection (Table 3). In patients with middle/lower rectal carcinomas, the length of the first stapler cartridge was 45 or 30 mm, and it was 45 or 60 mm for proximal lesions.

Operative and postoperative results are shown in Table 4. Mean operative time and blood loss were significantly greater in the middle/lower rectum group. All the operations were completed laparoscopically. We did not experience any accidental intestinal perforations at or near the tumor site. Liquid and solid food was started at a median of 1 and 3 postoperative days in all groups. The median length of postoperative hospitalization was 8–9 days. No significant differences were observed in the postoperative course among the 3 groups. All patients were discharged home.

The postoperative complications are listed in Table 5. There were no perioperative mortality and no anastomotic leakage. Reoperation of a laparoscopic division of an adhesive band for a postoperative small bowel obstruction was necessary in 1 patient with sigmoid colon carcinoma. No significant differences were observed in complication rates among the 3 groups.

TABLE 1. Patient's Characteristics*

	Sigmoid Colon/ Rectosigmoid	Upper Rectum	Middle/Lower Rectum
No. of patients	36	. 21	10
Sex ratio (male:female)	22:14	10:11	8:2
Age (y)	59 (30-79)	59 (37–73)	60 (47–76)
Body mass index (kg/m²)	23.5 (18.9–29.0)	24.1 (17.5–32.4)	23.8 (19.5–26.4)
Prior abdominal surgery (%)	6 (17)	5 (24)	5 (50)
Duke's stage			
Α	27	16	7
В	1	0	0
C	. 7	3	3
D	1	2	0

*Values are means (range), P > 0.05.

TABLE 2. Number of Patients in Relation to the Number of Stapler Cartridges Fired for Rectal Transection*

No. of Stapler Cartridges Fired	Sigmoid Colon/Rectosigmoid†	Upper Rectum†	Middle/Lower Rectum	
1	25	8	0	
2	9	12	2	
3	2	1	6	
4	0	0	2	
*P < 0.01 between †P < 0.01 versus n	groups, Kruskal-Wallis test. iddle, lower rectum/Bonefen	oni test.		

DISCUSSION

In the present study, short-term outcomes were compared among different tumor sites in patients who underwent laparoscopic intracorporeal rectal transection with doublestapling technique anastomosis. The closer the tumor site was to the anus, the more the number of stapler cartridges needed for rectal transection increased and the use of a longer Endo GIA Universal stapler cartridge was significantly restricted. suggesting that rectal transection for Lap-LAR in patients with middle/lower rectal carcinomas may be a difficult and stressful procedure. In the present study, however, the complication rate did not increase despite lower anastomotic sites. With thorough and careful intracorporeal rectal transection and DST anastomosis, the safety of Lap-LAR may be established.

Minimum invasiveness is often noted as one of the merits of LS in comparison with OS for colorectal cancer. 19-23 But even recently, some studies have reported that minimal or no short-term benefits were found with LS compared with standard OS. ^{24–26} Reviewing these reports raises a question about the conversion rate. Even granting that LS has a lower surgical invasiveness than OS, there is a possibility that the treatment outcomes of LS will be contaminated by the treatment outcomes of OS, when the conversion cases are included in the LS group, based on the intention-to-treat principle. In the study by Weeks et al,26 who reported a conversion rate of 25%, LS showed only minimal short-term quality-of-life benefits compared with OS in an intention-to-treat analysis, probably due to the high conversion rate. Moreover, they pointed out that patients assigned to laparoscopy-assisted colectomy who required intraoperative conversion to open colectomy had slightly poorer quality-of-life outcomes than patients who

TABLE 3. Length of the First Stapler Cartridge Fired for Rectal Transection*

Length of the First Stapler Cartridge (mm)	Sigmoid Colon/Rectosigmoid†	Upper Rectum†	Middle/Lower Rectum	
60	34	16	0	
45	2	5	7	
30	0	0	3	

^{*}P < 0.01 between groups, Kruskal-Wallis test.

TABLE 4. Operative and Postoperative Results

	Sigmoid Colon/Rectosigmoid	Upper Rectum	Middle/Lower Rectum
Operative time,* min (range)	221 (135–348)†	244 (190–328)‡	315 (190–392)
Blood loss,* mL (range)	29 (6–161)†	24 (10–198)†	124 (17–265)
Conversion	0	0	0
Liquid intake, d (range)	1 (1–4)	1 (1–3)	1 (1)
Solid food, d (range)	3 (2-5)	3 (3-4)	3 (2-4)
Hospital stay, d (range)	8 (7–12)	8 (7–11)	9 (7–17)

^{*}P < 0.01 between groups, repeated-measure analysis of variance.

successfully underwent minimally invasive resection, and that the length of postoperative hospital stay in the LS group requiring conversion was longer than that in patients assigned to OS (7.4 vs. 6.4 days), although statistical analysis was not performed regarding these points. If the conversion patients did not show a worse outcome than those undergoing OS, patients who might benefit from LS should be considered as candidates for LS. Further studies are necessary to evaluate postoperative and oncological outcomes of patients assigned to laparoscopy-assisted colectomy who then require intraoperative conversion.

The results of the current study suggested that laparoscopic approaches to middle/lower rectal carcinoma do not compromise early postoperative recovery, such as days to oral feeding and length of hospitalization. Previous studies reported an anastomotic leakage rate of 5.7% to 21% in patients undergoing Lap-LAR. 6-12 Some authors have recommended a covering ileostomy as a routine step in Lap-LAR. 6,10,2 At present, patients with a preoperative diagnosis of T1-T2, middle/lower rectal carcinoma are required to decide whether they prefer to undergo OS or LS, after being given full information at our institution.

TABLE 5. Morbidity and Mortality*

	Sigmoid Colon/ Rectosigmoid	Upper- Rectum	Middle/Lower Rectum
Mortality	0	0	0
Morbidity			
Wound sepsis	2	1	0
Bowel obstruction	1	0	1
Urinary tract infection	1	0	0
Abscess	0	0	1
Neurogenic bladder	0	1	0
Anastomotic leakage	0	0	0
Total	4	. 2	2

 $[\]dagger P < 0.01$ versus middle/lower rectum, Boneferroni test.

 $[\]dagger P < 0.01$ versus middle/lower rectum, Scheffe test.

 $[\]ddagger P < 0.05$ middle/lower rectum, Scheffe test.

In this study, the authors evaluated the safety of laparoscopic rectal transection using an endolinear stapler, which is one of the most technically difficult procedures in Lap-LAR. To date, we have not observed serious complications, such as anastomotic leakage. However, this surgical procedure remains technically difficult. We consider that this method should not be attempted if it is not performed by a laparoscopic surgical team with sufficient experience in LS. Regarding a surgical procedure that can be placed between OS and Lap-LAR, Vithiananthan et al²⁸ reported a hybrid method. In their procedure, they mobilized the left-sided colon and completed high ligation of the inferior mesenteric vessels with the use of the pneumoperitoneum, and then, from the inferior midline incision measuring 8 cm or longer, they performed rectal mobilization, mesorectal division, rectal transection, and anastomosis by DST using the OS tools. They noted that the mean incision length was 11.1 cm, which is longer than in Lap-LAR but shorter than in OS and that the patients treated with this method showed a significantly faster postoperative recovery than those treated with OS. Hand-assisted laparoscopic surgery may also be another treatment option.29 However, compared with the standard Lap-LAR technique evaluated in this study, both of these methods may need a larger incision. With the surgeon's proficiency in the surgical procedure and the improvement in and development of instruments, the safety of standard Lap-LAR will probably be established; however, it is important to remember that this surgical technique cannot be employed at an early stage of the learning curve of laparoscopic surgery.

In conclusion, the findings of the present study demonstrate that laparoscopic intracorporeal rectal transection with DST anastomosis can be performed safely without increased morbidity or mortality. Even at present, there are few prospective, randomized trials investigating the short-term and oncological outcomes in patients with middle/lower rectal carcinoma, perhaps mainly because Lap-LAR has not been widely performed compared with LS for colon/upper rectal carcinoma due to the technical difficulties. The radical resection of middle/lower rectal cancers is a procedure that requires advanced technical skills in OS, to say nothing of Lap-LAR; however, we believe that use of Lap-LAR for middle/lower rectal carcinoma will expand with improvements in technology and surgeons' experience in the near future.

REFERENCES

- 1. Jacobs M, Verdeja JC, Goldstein HS. Minimally invasive colon resection
- (laparoscopic colectomy). Surg Laparosc Endosc. 1991;1:144–150.
 2. Leung KL, Kwok SPY, Lam SCW, et al. Laparoscopic resection of rectosigmoid carcinoma: prospective randomized trial. Lancet. 2004;363: 1187–1192.
- The clinical outcomes of surgical therapy study group. A comparison of laparoscopically assisted and open colectomy for colon cancer. N Engl J Med. 2004;350:2050-2059.
- Lacy AM, García-Valdecasas JC, Delgado S, et al. Laparoscopic-assisted colectomy versus open colectomy for treatment of non-metastatic colon cancer: a randomized trial. *Lancet*. 2002;359:2224–2229.

- Scheidbach H, Schneider C, Hügel O, et al. Oncological quality and preliminary long-term results in laparoscopic colorectal surgery. Surg Endosc. 2003;17:903-910.
- Hartley JE, Mehigan BJ, Qureshi AE, et al. Total mesorectal excision: assessment of the laparoscopic approach. Dis Colon Rectum. 2001;44: 315-321.
- Yamamoto S, Watanabe M, Hasegawa H, et al. Prospective evaluation of laparoscopic surgery for rectosigmoidal and rectal carcinoma. Dis Colon Rectum. 2002;45:1648–1654.
- Poulin EC, Schlachta CM, Grégoire R, et al. Local recurrence and survival after laparoscopic mesorectal resection for rectal adenocarcinoma. Surg Endosc. 2002;16:989-995.
- Morino M, Parini U, Giraudo G, et al. Laparoscopic total mesorectal excision: a consecutive series of 100 patients. Ann Surg. 2003;237: 335-342.
- Anthuber M, Fuerst A, Elser F, et al. Outcome of laparoscopic surgery for rectal cancer in 101 patients. Dis Colon Rectum. 2003;46:1047–1053.
- Feliciotti F, Guerrieri M, Paganini AM, et al. Long-term results of laparoscopic vs open resections for rectal cancer for 124 unselected patients. Surg Endosc. 2003;17:1530-1535.
- Köckerling F, Rose J, Schneider C, et al. Laparoscopic colorectal anastomosis: risk of postoperative leakage: results of a multicenter study. Surg Endosc. 1999;13:639-644.
- 13. Knight CD, Griffen FD. An improved technique for low anterior resection of the rectum using the EEA stapler. Surgery. 1980;88:710-714.
- Moriya Y, Sugihara K, Akasu T, et al. Importance of extended lymphadenectomy with lateral node dissection for advanced lower rectal cancer. World J Surg. 1997;21:728-732.
- Takahashi T, Ueno M, Azekura K, et al. Lateral node dissection and total mesorectal excision for rectal cancer. Dis Colon Rectum. 2000;43(suppl): S59-S68.
- Fujita S, Yamamoto S, Akasu T, et al. Lateral pelvic lymph node dissection for advanced lower rectal cancer. Br J Surg. 2003;90:1580-1585.
- Watanabe M, Teramoto T, Hasegawa H, et al. Laparoscopic ultralow anterior resection combined with per anum intersphincteric rectal dissection for lower rectal cancer. Dis Colon Rectum. 2000;43:S94—S97.
- Franklin ME Jr. Laparoscopic low anterior resection and abdominoperineal resections. Semin Colon Rectal Surg. 1994;5:258–266.
- Lacy AM, García-Valdecasas JC, Piqué JM, et al. Short-term outcome analysis of a randomized study comparing laparoscopic vs open colectomy for colon cancer. Surg Endosc. 1995;9:1101-1105.
- Milsom JW, Böhm B, Hammerhofer KA, et al. A prospective, randomized trial comparing laparoscopic versus conventional techniques in colorectal cancer surgery: a preliminary report. J Am Coll Surg. 1998;187:46-57.
- Psaila J, Bulley SH, Ewings P, et al. Outcome following laparoscopic resection for colorectal cancer. Br J Surg. 1998;85:662–664.
- Schwenk W, Böhm B, Müller JM. Postoperative pain and fatigue after laparoscopic or conventional colorectal resections: a prospective randomized trial. Surg Endosc. 1998;12:1131–1136.
- Hasegawa H, Kabeshima Y, Watanabe M, et al. Randomized controlled trial of laparoscopic versus open colectomy for advanced colorectal cancer. Surg Endosc. 2003;17:636-640.
- Bokey EL, Moore JWE, Keating JP, et al. Laparoscopic resection of the colon and rectum for cancer. Br J Surg. 1997;84:822-825.
- Khalili TM, Fleshner PR, Hiatt JR, et al. Colorectal cancer: comparison of laparoscopic with open approaches. Dis Colon Rectum. 1998;41:832–838.
- Weeks JC, Nelson H, Gelber S, et al. Short-term quality-of-life outcomes following laparoscopic-assisted colectomy vs open colectomy for colon cancer. JAMA. 2002;287:321–328.
- Köckerling F, Rose J, Schneider C, et al. Laparoscopic colorectal anastomosis: risk of postoperative leakage: results of a multicenter study. Surg Endosc. 1999;13:639-644.
- Vithiananthan S, Cooper Z, Betten K, et al. Hybrid laparoscopic flexure takedown and open procedure for rectal resection is associated with significantly shorter length of stay than equivalent open resection. *Dis Colon Rectum.* 2001;44:927–935.
- Pietrabissa A, Moretto C, Carobbi A, et al. Hand-assisted laparoscopic low anterior resection: initial experience with a new procedure. Surg Endosc. 2002;16:431-435.

外科治療 Vol. 92 (2005: 增刊)

一般外科におけるクリニカルパス

クリニカルパスの実際 - われわれはこうしている - 食道・胃・大腸外科 腹腔鏡補助下大腸切除術のクリニカルパス

榎本 雅之 杉原 健一

永 井 書 店

一般外科におけるクリニカルパス

§ 1 クリニカルパスの実際一われわれはこうしているー

食道・胃・大腸外科

腹腔鏡補助下大腸切除術のクリニカルパス

Clinical pathways for laparoscopic assisted colorectal surgery

榎本雅之杉原健一*
ENOMOTO Masayuki SUGIHARA Kenichi

東京医科歯科大学大学院医歯学総合研究科腫瘍外科学 講師 *教授

Key word 腹腔鏡補助下大腸切除術/クリニカルパス/包括医療/バリアンス

大腸癌待機手術は、術式や経過が定型的であり、クリニカルパスによる患者 管理を行いやすい、当科では、術後回復の若干早い腹腔鏡補助下手術と開腹手 術を分けてクリニカルパスを作成している。腹腔鏡補助下手術に対しては、腹 会陰式直腸切断術とそれ以外の術式の2種類のクリニカルパスを作成して患者 管理を行っているので、そのクリニカルパスについて概説する。

はじめに

クリニカルパスは疾患に対する治療計画のこと である. 医療スタッフだけではなく患者にもクリ ニカルパスを提示することにより、その内容を共 有することが重要である。 クリニカルパスの導入 により、各医療スタッフがそれまでの経験にもと 基づく独自の計画にて患者を管理するのではな く、患者管理を標準化させ質の高い医療水準を維 持できるようにするということが主目的である. 一方,患者側にとっても,一連の治療の流れを把 握することができるため、治療に対する不安がな くなり、積極的に治療に参加することができる. しかし、提示されたクリニカルパス通りに治療が 進まないと、一層、不安が増す結果となることも あり、バリアンスが生じた場合には、不安を取り 除くために、詳細な説明を行わなければならない。 また, 主目的ではないが, クリニカルパスは医療 経営上の問題点を明確にできるため、入院医療包 括化への対策として導入する施設が増えている.

●クリニカルパスの導入

クリニカルパスの導入にあたっては、他施設の クリニカルパスを最初からそのまま流用するのは 望ましくない。成書に掲載されているクリニカル パスは、その施設において何回かの改定を経て完 成に近いものが掲載されていることが多い、最初 からそのようなクリニカルパスを導入しようとし ても、医療スタッフ全員のコンセンサスおよび協 力がなければ成り立たないからである。他施設の クリニカルパスを提示しても, 自施設における今 までの計画との間に大きな隔たりがあることや, 地域や社会環境の違いもあることから, 医療スタ ッフは不安が先立ち受け入れることができないと 考えるのは当然のことである。最初は、他施設の クリニカルパスは参考程度として, 実際に行われ ている治療経過を考慮して医療スタッフ全員が受 け入れることができる独自のクリニカルパスを作 成するべきである.

0433-2644/05/¥50/頁/ICLS

負のバリアンスが生じる原因は、 指示を出し忘 れた、あるいは、故意に出さなかったといった医 療スタッフ側の原因と,バリアンスが生じて指示 を中止したために起こる場合があるが、医療スタ ッフ全員が受け入れていないと, 医療スタッフ間 の相互チェック機能も働かず、前者が原因となっ て負のバリアンスが生じることが多くなる。大事 なことは、負のバリアンスがなるべく出ないクリ ニカルパスを作成することである。 負のバリアン スが多いと医療スタッフから不信感や不満が出 て、作成したクリニカルパスが形骸化してしまう 可能性がある。また、クリニカルパスは患者にも 提示するため、 負のバリアンスが多いと患者側も 不安や不信感を持つ可能性がある。 さらに、負の バリアンスが発生した場合、患者および家族に対 してその原因などの説明を行わなければならず, 医療スタッフの精神的負担も増大する結果とな る。最初から完璧なクリニカルパスを作成するこ とは困難で、定期的に正および負のバリアンスの 原因を検討して修正を加え,施設に合わせたより よいクリニカルパスを作成してゆけばよい。

●患者用クリニカルパスと医療スタッフ用クリニカルパス

患者用クリニカルパスと医療スタッフ用クリニカルパスの2種類を作成して運用している.患者用も医療スタッフ用と内容は同じであるが,患者は高齢者が多いことや医学用語を正確に理解できないことが多いため,患者用では文字を大きくし,絵などを交えて平易な文章で作成している.具体的には,A3用紙にフォント12のゴシック体を用いて,高齢者でも見やすいようにしている.医療スタッフ用は,指示もれがないか,あるいはクリニカルパス通りに診療が進んでいるかを毎日チェックできるように,チェックリスト形式のクリニカルパスを使用している。また,項目ごとの表形式にして時系列で記載すると理解しやすい.

●クリニカルパスの種類

待機的大腸癌手術は、 術式や経過が定型的であ り,クリニカルパスによる患者管理を行いやすい。 しかし、術式によっては経過および管理に違いが あるので、一種類だけのクリニカルパスだけでは 管理しにくい。結腸癌と直腸癌、さらに、直腸癌 では自律神経系の温存状態(排尿機能障害の可能 性の有無)やストマの有無による分類が必要であ る。また、術後回復の若干早い腹腔鏡補助下手術 と開腹手術を分けてクリニカルパスを作成してい る. 当科の腹腔鏡補助下手術は、結腸癌と直腸 S 状部は進行癌も適応としているが、上部、下部直 腸癌は早期癌しか適応としていない. したがって、 基本的に自律神経系を全温存しているため、腹会 陰式直腸切断術とそれ以外の術式の2種類のクリ ニカルパスを作成して腹腔鏡補助下大腸切除術の 患者管理を行っている(表1~6)。

●クリニカルパスの内容

1. 術前検査

術前検査はすべて外来で行っている。これは, 入院日数や検査項目が限られている入院医療包括 化への対策として行っている。

2. 入 院 日

入院医療包括化は入院日数が一定期間以上長くなると1日入院単価が下がるため、術前入院期間はなるべく短くする。手術2日前から術前腸管処置を開始するため、この日に入院とし、入院日には、手術の説明と同時に、患者用のクリニカルパスを提示しながらその説明も行う。患者および家族の中には、術後1週間後から食事が取れる、術後1ヵ月ぐらい入院するといった従来の経過を想定している人たちもいるので、創の消毒、食事の開始時期、退院日などについてもよく説明し、この時点で患者の不安を取り除き十分な理解を得ておくことがもっとも大切である。この時に了解を

表1-1 医療スタッフ用 腹腔鏡下大腸手術 [APR 症例を除く]

	入院 / 手術前々日	手術前日	手術当日(術前)	(術後)	第1病日
1. 点滴・注射	□点滴1500 ml	□点滴1500 ml	□点滴100 ml/hr	□点滴80 ml/hr	□点滴1500 ml
			□第2世代抗生物 □3時間後 . 1	ற質 1 g(手術開始時) g 追加投与	
				□疼痛時指示 □発熱時指示 □嘔気時指示 □不眠時指示 □不眠時指示	
2. 内服薬	□内服薬確認 (内服継続の必要性を判断)	□不眠時指示			□内服薬再開 (必要に応じて中止した内服の再開
	□術前腸管処置開始 □11時ニフレック1P □21時プルゼニド4T	□11時ラキソベロン2.5 ml			
3. 一般指示		□清拭,除毛	□ 6 時半 GE 110 ml	□ネブライザー □酸素投与	□ネブライザー □酸素中止
4. 外科的処置	□パッチテスト			□包交	□包交
			·		□胃管抜去 □導尿カテ抜去
5. 食事	□入院後は禁食 (水分は可)	□禁食 (21 時まで水分可)	□禁飲食	□禁飲食	□飲水可
6. 検査	□胸腹 X-P(/) □ ECG(/) □ スパイロ(/) □ 算, 生 血型(/) □ 極線症 ーカー(/) □ 接尿(/) □ BE(/) □ CS(/) □ EUS(/) □ EUS(/) □ EUS(/) □ CT(/) □ MRI(/)			□採血□Χ線	□採血□Χ線
7. 説明・指導	□入院時診療計画書 □病歴聴取 □手術説明/関連書類の承諾書	□麻酔科ラウンド		□手術結果説明	
バリアンス	□なし	□なし	□なし	□なし	□なし
バリアンスの理由					

得ておかないと、処置や退院の当日になってトラ 3. 予防的抗生物質投与 ブルの原因になることもあるので注意が必要であ 当科では、術中の第2世代セフェム系抗生物質 る.

投与しか行っていない。 閉腹前に小切開創を 1,000 ml の生食で洗浄することで、術後の創感染

表 1-2 医療スタッフ用 腹腔鏡下大腸手術 [APR 症例を除く]

診断

手術術式

第2病日	第3病日	第4病日	第5病日	第6病日	第7病日	第5~10病日/退院
□点滴1500 ml	□点滴1000 ml	□点滴なし				
二消化剤内服開始(便)	 					
□包交	□縫合創の包交なし	ノ(ガーゼも不要)			□全抜糸	
□硬膜外カテ抜去	□ドレーン抜去 (挿入の場合のみ)				早期退院の場合は	外来抜糸
□水分	□低残渣食 全粥	□同左	□一般食 常食	□同左	□同左	□同左
			(希望あれば全粥は	sよびパン食も可) 		Τ
						退院日:第病日 □退院処方確認・説明 □外来予約 <病理の結果が出る頃に> (月日)
口なし	□なし	□なし	□なし	□なし	□なし	□なし

は約7%である。一般的にみても、術後1~3日間の予防的投与を行えば十分である。入院医療包括化では、手術当日以外の薬剤の請求ができないため、術後には使用しないほうが得策である。し

かし、使用しないことにより術後の SSI が増加 すれば、入院日数が長くなり、1日入院単価が下 がってしまう。この点についてどうするかは、各 施設の考え方や経験から決定すればよい。

表 2 - 1 医療スタッフ用 腹腔鏡下大腸手術 [APR 症例]

患者名

診断

	入院/手術前々日	手術前日	手術当日(術前)	(術後)	第1病日	第2病日	第3病日
1. 点滴・注射	□点滴1,500 ml	□点滴1,500 ml	□点滴 100 ml/hr	□点滴80 ml/hr	□点滴1500 ml	□点滴 1500ml	□点滴 1000ml
			□第2世代抗生物 □3時間後,1	質 1 g(手術開始時) g 追加投与			
				□疼痛時指示 □発熱時指示 □嘔気時指示 □嘔気時指示 □不眠時指示 □硬膜外指示			
2. 内服薬	□内服薬確認 (内服継続の必要性を判断)	□不眠時指示			□内服薬再開 (必要に応じて中」	Lした内服の再開)	
	□術前腸管処置開始 □11時ニフレック1P □21時プルゼニド4T	□11時 ラキソベロン2.5 m					更の性状により適宜増減)
3. 一般指示			□ 6 時半 GE110 ml	□ネブライザー □酸素投与	□ネブライザー □酸素中止		
4. 外科的処置	□パッチテスト			□包交	□包交	□包交	□縫合創の包交なし (ガーゼも不要)
					□胃管抜去	□硬膜外カテ抜去	ドレーン抜去
5. 食事	□入院後は禁食 (水分は可)	□禁食 (21時まで水分可)	□禁飲食	□禁飲食	□飲水可	□水分	□低残渣食 全粥
6. 検査	□胸腹 X-P(/) □ ECG(/) □ Z バイロ(/) □ 血算、生化学(/) □ 感染症・血型(/) □ 操療(/) □ BE(/) □ CS(/) □ EUS(/) □ DEUS(/) □			□採血□Χ線	□採血□Χ線		
7. 説明・指導	□入院時診療計画書 □病歴聴取 □手術説明 関連書類の承諾書	□麻酔科ラウンド		□手術結果説明			
バリアンス	□なし	□なし	□なし	□なし	□なし	□なし	□なし
バリアンスの理由							

4. 食事の開始時期および上げ方

時期は、開腹手術と腹腔鏡補助下手術では差があ

るというのが実感である.手術を午前に行ったか 吻合部の強度よりも術後の消化管の蠕動運動の 午後に行ったかによって違うという考えもある 有無が重要であると考えている。蠕動運動の再開 が、当科ではいずれの場合でも、腹腔鏡下手術で は1病日目から水分摂取を開始している。食事の