

Intersphincteric resection for very low rectal cancer (Lecture). 3. Surgical treatment for local recurrence (Lecture). 4. Intersphincteric resection: Surgical Treatment for Local Recurrence (Videos). The X Congress of the Brazilian Society of Surgical Oncology, Brazil (Rio de Janeiro) 13-14, October 2011

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#### IV. 研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
木下平, 木下敬弘, 斎浦明夫, 江碓実, 坂本裕彦, 伊藤誠二	【胃癌肝転移に対する治療戦略】胃癌肝転移切除例に関する多施設共同研究.	癌の臨床	59	485-489	2013
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伊藤誠二, 伊藤友一, 三澤一成, 清水泰博, 木下平	【胃癌治療の過去と未来】胃癌の集学的治療の近未来.	癌の臨床	59	307-313	2013
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Yano T, Muto M, Minashi K, Onozawa M, Nihei K, Ishikura S, Kaneko K, Ohtsu A.	Long-term results of salvage photodynamic therapy for patients with local failure after chemoradiotherapy for esophageal squamous cell carcinoma.	Endoscopy	43(8)	657-663	2011
Kato K, Muro K, Minashi K, Ohtsu A, Ishikura S, Boku N, Takiuchi H, Komatsu Y, Miyata Y, Fukuda H	Gastrointestinal Oncology Study Group of the Japan Clinical Oncology Group (JCOG). Phase II Study of Chemoradiotherapy with 5-Fluorouracil and Cisplatin for Stage II-III Esophageal Squamous Cell Carcinoma: JCOG Trial (JCOG 9906).	Int J Radiat Oncol Biol Phys	81(3)	684-90	2011
Tahara M, Araki K, Okano S, Kiyota N, Fuse N, Minashi K, Yoshino T, Doi T, Zenda, Kawashima M, Ogino T, Hayashi R, Minami H, and Ohtsu A.	Phase I trial of combination chemotherapy with docetaxel, cisplatin and S-1 (TPS) in patients with locally advanced or recurrent/metastatic head and neck cancer.	Ann Oncol	22(1)	175-80	2011
Muto M, Satake H, Yano T, Minashi K, Hayashi R, Fujii S, Ochiai A, Ohtsu A, Morita S, Horimatsu T, Ezoe Y, Miyamoto S, Asato R, Tateya I, Yoshizawa A, Chiba T.	Long-term outcome of transoral organ-preserving pharyngeal endoscopic resection for superficial pharyngeal cancer.	Gastrointest Endosc.	74(3)	477-84	2011

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Kaneko K, <u>Yano T</u> , Minashi K, Kojima T, Ito M, Satake H, Yajima Y, Yoda Y, Ikematsu H, Oono Y, Hayashi R, Onozawa M, Ohtsu A.	Treatment strategy for superficial pharyngeal squamous cell carcinoma synchronously combined with esophageal cancer.	Oncology.	84(1)	57-64	2013
矢野友規, 金子和弘, 三梨桂子, 大津敦.	手技の解説 上部消化管内視鏡検査における頭頸部腫瘍の早期診断法.	Gastroenterological Endoscopy.	52(5)	1440-50	2010

## V. 研究成果の刊行物・別刷

特

..... 特集1 胃癌肝転移に対する治療戦略 .....

集

## 胃癌肝転移切除例に関する多施設共同研究

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**Multi-Institutional Retrospective Study for Resection of the Hepatic Metastases from Gastric Cancer:** Kinoshita T\*1, Kinoshita T\*2, Saiura A\*3, Ezaki M\*4, Sakamoto H\*5 and Itoh S\*1 (\*1Department of Gastroenterological Surgery, Aichi Cancer Center, \*2Department of Gastric Surgery, National Cancer Center Hospital East, \*3Department of Gastroenterological Surgery, Cancer Institute Ariake Hospital, Hepatobiliary and Pancreatic Surgery, \*4National Cancer Center Hospital, \*5Department of Gastroenterological Surgery, Saitama Cancer Center)

Significance of surgical resection of the liver metastasis from gastric cancer is still controversial without evidence. However, existence of the long survivors without any adjuvant chemotherapy may prove the potential for cure by the surgical resections. In many papers the results of the prognostic factors by multivariate analysis were different from each other because of the small number of the cases.

To solve this problem a retrospective study collecting the cases from 5 institutions is designed to find true prognostic factors by performing reliable multivariate analysis.

This study can offer best available indication at present for resection of the liver metastases from gastric cancer.

**Key words:** Gastric cancer, Hepatic metastases, Resection

*Jpn J Cancer Clin* 59 (5): 485~489, 2013

### はじめに

胃癌の肝転移の多くは多発性で、切除を考える場合は少ない。胃癌の肝転移の外科的な切除が生存に寄与し、有用であるというエビデンスは無い。これまでの胃癌肝転移の切除に関する英文論文で、予後因子に言及しているものをまとめ、表1に示す<sup>1~11)</sup>。長期生存例の症例報告は数多く存在するが、適応を選んで行われた単施設からの切

除経験の報告では、切除例の5年生存率は10.3~42%で、長期生存例も数多く存在し、切除が有効な可能性とその対象が存在する可能性を示唆させる。しかし、まとまった症例報告と言っても50症例に満たない症例数であり、切除が有効な対象を絞り込むため、多変量解析を行い優位な予後因子を求めても、解析の都度結果が変わるといふ経験を筆者自身もしている。実際に表1の3施設でそれぞれ2編の論文が出されているが、多変量解析による予後良好因子は、時期により異なっている。このように症例数が少なく多変量解析の信頼度が低いのである。従って現時点での手術の適応はこれらの多変量解析を行った論文の不安定な予後因子を利用するか、長期生存例の背景因子から推測して適応を考えているのが現状である。

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表1 胃癌肝転移切除に関する主な英文論文

著者	雑誌	施設	症例数	5生率	予後良好因子
Ochiai	<i>Br J Surg</i> 1994	NCC	21	19%	胃漿膜浸潤なし 脈管侵襲なし
Miyazaki	<i>Am J Gastroenterol</i> 1997	Chiba U	21	20%	単発, 断端距離 10 mm 以上
Ambiru	<i>Am J Surg</i> 2001	Chiba U	40	18%	異時性
Okano	<i>Ann Surg</i> 2002	Kagawa U	21	34%	単発, 異時性, 肝転移被膜あり, 高分化
Saiura	<i>Hepatogastro-enterology</i> 2002	Bokutoh H	10	20%	リンパ節転移なし
Zacherl	<i>J Gastrointest Surg</i> 2002	Wien U	15		片葉, 胃 Distal 病変
Skamoto	<i>Surgery</i> 2003	CIH	22	38%	単発, 5 cm 以下
Shirabe	<i>Hepatogastro-enterology</i> 2003	Kyushu U	36	26%	脈管侵襲なし 2個以下
Koga	<i>Jpn J Clin Oncol</i> 2007	CIH	42	42%	胃漿膜浸潤なし 単発
Sakamoto	<i>J Surg Oncol</i> 2007	NCC	37	11%	片葉, 4 cm 以下
Makino	<i>Anticancer Res</i> 2010	Yokohama City U	16	10.3%	片葉
Tsujimoto	<i>Hepatol Int</i> 2010	Defence Med- ical U	17	31.5%	胃原発 6 cm 以下 胃 D2 郭清

NCC：国立がん研究センター，CIH：癌研病院，H：病院，U：大学

胃癌の肝転移の切除の有用性を検証するためには、本来はある一定の適応での切除+補助化学療法対化学療法の比較試験が必要であるが、症例の多い施設でも年間2~3例程度で、症例の集積を考えると、比較試験を行うのは困難である。

そこで、多施設で集積した多変量解析に耐える十分な症例数で、予後因子を解析し、それを参考に、より信頼性の高い手術適応を考えるための共同研究を計画した。

## 1 ● 国立がん研究センター東病院の長期生存例

国立がん研究センター東病院の同時性21例、異時性35例の胃癌肝転移切除例のうち長期生存例の概要を表2, 3に示す。同時性、異時性それぞれ6症例ずつの5年以上生存例があるが、この12例中7症例は肝切除後の補助化学療法を受けていない症例である。少なくとも外科切除は単独でも胃癌肝転移を治癒せしめる効果があるという証明である。

異時性の長期生存例の原発巣の深達度はすべてSSで、同時性のそれは、1例のSSと残る5例

はすべてSEであることは特徴的で、異時性の場合には主病巣の深達度SEは予後不良因子になるかも知れないと考えるが、主病巣の深達度の予後に与える影響は、同時性、異時性で異なっており、同時、異時を一緒に解析すべきでない因子の存在を示唆している。

この時点で同時性21例、異時性35例を別々に多変量解析した結果、同時性では有意な予後因子は無く、異時性で、深達度SE以深 ( $p=0.042$ )、肝転移巣の最大径5.0 cm以上 ( $p=0.038$ ) が有意な予後不良因子であった。しかし表3の第1例目の肝転移の最大径は62 mmであり、もし、肝転移の最大径5.0 cm未満で切除適応を絞ったら、この症例の長期生存は幻になってしまう。このように多変量解析で得られた予後因子はあくまで一つの指標であって、それがそのまま適応基準になるわけではないが、切除にあまり積極的でなかった外科医に、こういう状況の症例では是非、外科切除を考慮すべきというメッセージとなり得る。



表2 長期生存例(同時肝転移切除)

個数/Size	肝切除術式	胃病変	生存期間	状態	
59 y M	1/40 mm	外側区域切除	tub2/se/n3	15 y 2 m	生存
53 y M	2/32 mm	S3, S6 部分切除	tub2/se/n1	9 y 3 m	生存
76 y M	1/60 mm	外側区域切除	tub2/se/n2	8 y 4 m	他病変
74 y F	2/45 mm	S2, S5 部分切除	tub2/se/n1	7 y 9 m	生存
79 y M	1/30 mm	S6 部分切除	pro1/se/n1	7 y 0 m	生存
55 y F	1/ 7 mm	部分切除	pap/ss/n1	5 y 6 m	生存

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表3 長期生存例(異時性肝転移切除)

個数/Size	肝切除術式	胃病変	生存期間	状態	
65 y F	1/69 mm	中央二区域切除	tub1/ss/n1	5 y 4 m	生存
75 y M	3/24 mm	S3 垂区域切除 S4, S7 部分切除	tub1/ss/n2	5 y 7 m	生存
67 y M	1/15 mm	S4/5 部分切除	tub2/ss/n1	5 y 4 m	生存
69 y M	1/30 mm	S3/4 部分切除	pap/ss/n1	8 y 6 m	他病死
54 y F	1/30 mm	S5 部分切除	NE/ss/n1	8 y 4 m	生存
65 y F	1/33 mm	右葉切除	tub2/ss/n1	16 y 2 m	生存

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## 2 研究計画

平成23年度のがん研究開発費「拠点病院の日常診療データベースから新しい臨床仮説を創出するための研究(23-A-14)」の小班を立ち上げ、「胃がん肝転移の外科的切除に関する多施設共同レトロスペクティブ研究」として研究を開始した。まず、比較的切除例の多い東京近郊のがん診療連携拠点病院である、国立がん研究センター中央病院、東病院、がん研有明病院、埼玉県立がんセンターの4施設で班員を構成し、各施設での症例の概要と成績を班会議で発表していただき、合計200症例を超えるデータベースを作成し、多変量解析を中心とする予後因子などを解析し、切除適応のガイドラインを作成するという趣旨に合意した。その後小班長であった筆者が愛知県がんセンターに移動となったため、愛知県がんセンター中央病院も研究に参加し、計5施設で小班を構成することになった。

データベースを作成するにあたり、その項目についての検討を行い、図に記したデータ入力フ

ォーマットを作成した。

データを施設外に持ち出すためには倫理審査委員会の承認が必要なため、「胃がん肝転移の外科的切除に関する多施設共同レトロスペクティブ研究計画書」を作成した。

計画書の概要を以下に示す。

### 概要

#### 目的

胃がん肝転移に対する外科切除症例の臨床データを後ろ向きに解析し予後との関連を検討する。

#### 研究対象

- 1) 1990年から2011年12月までの期間に、胃がん肝転移に対して根治目的に外科切除を行った症例
- 2) 同時性切除、異時性切除ともに含める
- 3) 肝切除前後に化学療法を併用した症例も含める
- 4) 各施設に臨床情報、病理組織学的情報が保管されている症例

The screenshot shows a complex data entry form with multiple sections:

- 入力画面 (Input Screen):** Contains the title '胃癌肝転移切除症例データベース (Ver 2.0)' and a sub-header '異時性の場合・胃切除/手術年月日'.
- 患者情報:** Fields for '症例番号', '生年月日', '性別', '生存', '死因', '栄養状態の評価(Alb値)', and '最終生存確認日'.
- 手術情報:** Includes '同時or異時', '肝切除/手術年月日', '肝切除時' (with sub-fields for '術中輸血/MAP', '術中輸血/FFP', '在院死(30日以内)', '合併症(gradeⅢ以上)', '合併症種類(記述)', 'ICG %', and '出血量 ml'), and '肝切除後の...' (with sub-fields for '再発の有無', '再発年月日', '主な再発形式(記述:改行はCtrl+Ent)'), and '再発に対する治療' (with sub-fields for '治療法(記述)', '化学療法の有無', '化療の薬剤(記述)', '局所投与', and 'TACE').
- 肝転移 (Liver Metastasis):** Fields for '最大径 mm', '個数', '肝切除術式(記述:改行はCtrl+Ent)', '断端', '断端距離 mm', '組織型', '治療効果(Gradeなど記述)', and 'AFP免疫染色'.
- 肝転移確認後/術前化学療法 (Post-confirmation/Pre-operative chemotherapy):** Fields for '有無', '化療開始日', '化療の薬剤(記述)', '局所投与', and '治療判定効果'.
- 肝切除後補助化学療法 (Post-resection adjuvant chemotherapy):** Fields for '有無', '薬剤(記述)', and '局所投与'.
- 胃原発巣 (Gastric Primary Tumor):** Fields for '切除施設', '胃癌原発術式', '胃切除部/清範囲', '深達度', '胃原発巣リンパ節転移分類(18歳以前)', 'リンパ節転移 個', '組織型', 'AFP産生等(記述)', 'リンパ管侵襲', and '静脈侵襲'.
- 胃切除補助化学療法 (Adjuvant chemotherapy for gastric resection):** Fields for '有無 (異時性)', '薬剤(記述)', and '経路'.
- 肝切除術前 (Pre-hepatectomy):** Fields for 'CEA', 'CA19-9', and 'AFP'.
- Buttons:** '入力OK' and 'キャンセル'.

図 データ集計のためのフォーマット

研究デザイン

本研究は多施設共同後向き観察研究である。日常診療のデータベースを用いて胃がん肝転移切除症例の臨床評価項目と予後との関連を検討する。

評価項目

診療録より研究対象となる患者の臨床情報・病理組織学的情報を収集する。全生存期間、無再発生存期間に関して評価する。

目標登録数

250例

研究期間

研究期間：倫理審査委員会承認日～2014年3月31日

目標症例数は250例とした。

参加施設からのデータ集積は終了し、計257例の集積症例で解析中である。

まもなく学会発表、論文発表で結果が公表される予定である。

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## Pulmonary metastasectomy for gastric cancer: a 13-year single-institution experience

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Received: 3 July 2012 / Accepted: 6 September 2012 / Published online: 27 November 2012  
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### Abstract

**Purpose** Pulmonary metastases from gastric cancer are rare, and the role of surgery is unclear. The purpose of this study was to determine which patients with metachronous metastatic gastric cancer (MGC) might benefit from pulmonary resection.

**Methods** Between 1998 and 2011, 12 patients underwent 14 pulmonary resections for MGC. We reviewed their clinical courses and evaluated their radiological findings.

**Results** Solitary pulmonary lesions were identified for 11 metastases, and the remaining three showed multiple pulmonary lesions. Six patients received treatment for the metastases before pulmonary resection. Lobectomy was performed for five lesions and wedge resection was performed for the remaining nine lesions. At the median

follow-up time of 23.0 months, four patients were alive without disease, and the median DFS following pulmonary resection was 6.6 months. The overall 5-year survival rate following pulmonary resection was 58.4 %. In a univariate analysis, the number of lesions and the tumor doubling time (TDT) were significant predictors of the DFS, although prior treatment was not a significant predictor of the DFS.

**Conclusion** Pulmonary resection for MGC might be an effective therapeutic option when there is a solitary metastatic lesion that has a long TDT, even if the patient has been previously treated for metastases.

**Keywords** Metastatic lung tumor · Pulmonary resection · Metastatic gastric cancer · Tumor doubling time · Tumor disappearance rate

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### Introduction

Worldwide, gastric cancer ranks second of all causes of deaths from cancer, with approximately 700,000 confirmed deaths annually. The gastric cancer incidence and death rates vary considerably among racial and ethnic groups, with higher rates in Asian countries than in Western countries [1]. In Japan, approximately 50,000 people die from gastric cancer annually [2].

After a curative resection for gastric cancer, recurrence can develop in a variety of forms: distant, peritoneal or local. The most common site of distant recurrence is the liver, followed by the lungs, brain and bones [3]. Most cases with lung metastases are also associated with metastasis to other organs. In addition, most pulmonary metastases are associated with carcinomatous lymphangitis and malignant pleural effusion [4]. Therefore, the