

Prospective randomized controlled trial investigating the type of sutures used during hepatectomy

Norifumi Harimoto, Ken Shirabe, Tomoyuki Abe, Takafumi Yukaya, Eiji Tsujita, Tomonobu Gion, Kiyoshi Kajiyama, Takashi Nagaie

Norifumi Harimoto, Ken Shirabe, Tomoyuki Abe, Takafumi Yukaya, Eiji Tsujita, Tomonobu Gion, Kiyoshi Kajiyama, Takashi Nagaie, Department of Surgery, Iizuka Hospital, Fukuoka 820-8505, Japan

Author contributions: Harimoto N, Shirabe K, Kajiyama K and Nagaie T designed research; Harimoto N, Abe T, Yukaya T, Tsujita E, and Gion T performed research; Harimoto N, Shirabe K and Kajiyama K contributed analytic tools; Harimoto N and Shirabe K analyzed data; Harimoto N wrote the paper.

Correspondence to: Norifumi Harimoto, MD, PhD, Department of Surgery, Iizuka Hospital, 3-83 Yoshio-machi Iizuka-city, Fukuoka 820-8505, Japan. nharimotol@aih-net.com

Telephone: +81-948-223800 Fax: +81-948-295744

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Abstract

AIM: To determine whether absorbable sutures or non-absorbable sutures are better in preventing surgical site infection (SSI), in this paper we discuss the results of a randomized clinical trial which examined the type of sutures used during hepatectomy.

METHODS: All hepatic resections performed from January 2007 to November 2008 at the Department of Surgery at Iizuka Hospital in Japan were included in this study. There were 125 patients randomly assigned to an absorbable sutures (Vicryl) group or non-absorbable sutures (Silk) group.

RESULTS: SSI was observed in 13.6% (17/125) patients participating in this study, 11.3% in the Vicryl group and 15.8% in the Silk group. Incisional SSI including superficial and deep SSI, was observed in 8% of the Vicryl group and 9.5% of the Silk group. Organ/space SSI was observed in 3.2% of the Vicryl group and 6.0% of the Silk group. There were no significant differences, but among the patients with SSI, the pe-

riod for recovery was significantly shorter for the Vicryl group compared to the Silk group.

CONCLUSION: The incidence of SSI in patients receiving absorbable sutures and silk sutures is not significantly different in this randomized controlled study; however, the period for recovery in patients with SSI was significantly shorter for absorbable sutures.

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Key words: Hepatectomy; Absorbable suture; Surgical site infection

Peer reviewer: Eddie K Abdalla, MD, Professor, Department of Surgical Oncology, PO Box 301402, Houston, TX 77230-1402, United States

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INTRODUCTION

Despite recent developments in surgery and patient management during the perioperative period, critical complications still develop in a few patients who undergo hepatic resection^[1,2]. Surgical site infection (SSI) is one of the most important morbidities of surgery and leads to prolonged hospital stays. Previous studies revealed absorbable suture material in gastrointestinal surgical procedures to reduce the risk of SSI^[3,4] although most of those studies have been limited to skin closures. Absorbable sutures are used in most hospitals in the United States and Europe based on the available clinical studies. On the other hand, silk sutures are still used in most hospitals in Japan. A

study by Kobayashi *et al*^[5] revealed patients with intraoperative bowel injury, blood loss > 2000 mL, and age > 65 years are at risk of developing SSI after hepatectomy for liver cancers and then all blood vessels and bile ducts were ligated with silk or vessel clips during parenchymal resection. Absorbable sutures are now widely used for abdominal closure in Japan according to the CDC guidelines^[6]. During the resection of the liver, silk sutures are generally used for the vessels in Japan, because silk sutures are easier to handle and less expensive than absorbable sutures. However, foreign materials, especially silk, are known to accelerate infection^[6,7] and thus lead to a prolonged hospital stay. Togo *et al*^[8] reported the usefulness of absorbable sutures to prevent SSI with a historical control study using an animal model. There has been no known randomized clinical trial for suture material used in the ligation of the cut surface of the liver. In this paper the authors provide the outcome of a randomized clinical trial investigating the type of sutures used during hepatectomy to determine which is better in preventing SSI, absorbable sutures or non-absorbable sutures.

MATERIALS AND METHODS

Study design

All hepatic resections without biliary reconstruction performed from January 2007 to November 2008 at the Department of Surgery at Iizuka Hospital in Japan were included in this study. Only patients who met the following criteria were enrolled: (1) liver resection without biliary reconstruction; (2) without other malignancy; and (3) until compensated cirrhosis with Child-Pugh class A or B. At the author's department, the rate of SSI during hepatectomy was 25% according to previous data. The sample size required to detect a difference by chi-square test with 80% power at the 5% significance level was 124 patients. There were 130 patients enrolled in this study. One patient refused to participate in the study. The authors obtained approval from the local ethics committee and obtained informed consent from the other patients. Finally 125 patients were randomly assigned to an absorbable sutures (Vicryl, Johnson & Johnson Corp., Tokyo, Japan) or a non-absorbable sutures (Silk) group. Because the operative procedure used on 4 patients was either conversion to radiofrequency ablation or biliary reconstruction (Figure 1) they were not included in the study. Randomization was achieved by providing sealed envelopes to be opened by the operator before laparotomy. Data analysis was performed for 125 patients.

Liver function was evaluated preoperatively using Child classification and indocyanine green retention test at 15 min (ICGR15) in patients with underlying liver disease. The presence of ascites and ICGR15 test value of more than 40% were considered an absolute contraindication for resection. Hepatitis B surface antigen (HBs Ag) and hepatitis C antibody (HCV Ab) were routinely measured preoperatively.

Surgical technique and intra-operative care were stan-

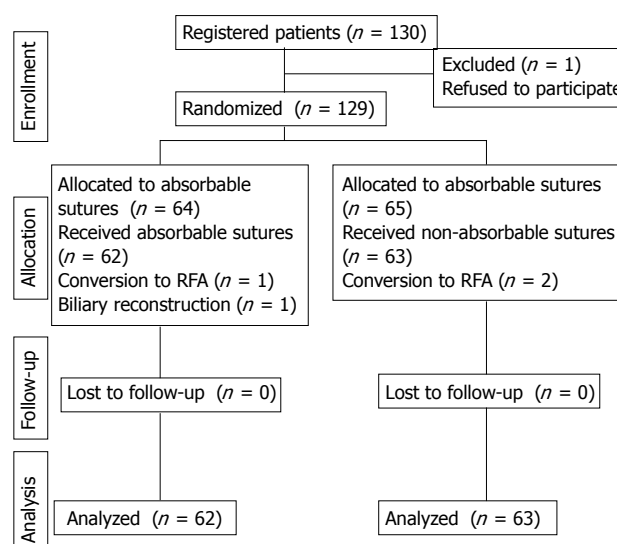


Figure 1 The trial profile of the patients in this study. RFA: Radiofrequency ablation.

dardized by the same team in this study. These included a J-shaped incision for routine abdominal access, a slow and gentle hepatic dissection using an ultrasonic dissector with coagulator (CUSA Excel, Integra Co., USA), with systematic ligation of all sizable vessels, and close ultrasonographic guidance along the transection line. Cholecystectomy was performed in all patients if the gallbladder was present. Intraoperative bile leakage test was routinely performed to identify bile leakage^[9]. With this procedure, we recognized small bile leakage sites on the cut liver surface and could repair these sites by Z-suturing using 6-0PDSII (Johnson & Johnson Corp., Tokyo, Japan). Intraoperative vascular control was achieved using the Pringle maneuver^[10]. In order to prevent backflow bleeding central venous pressure was decreased to as low as 5 mm Hg when possible with careful circulating volume and respiratory assistance. When central venous pressure control was insufficient, outflow control was achieved by selective vascular exclusion, or by clamping of the infrahepatic inferior vena cava^[11]. One or two closed drains were inserted close to the cut surface of liver parenchyma. Before the subcutaneous tissue was closed, the wound was washed with 1 L saline. Vicryl (Johnson & Johnson Corp., Tokyo, Japan), an absorbable suture material, was used during abdominal wound closure. Drains were removed when no bleeding or bile leakage were observed within 3 d. Bile leakage was defined as the drainage of macroscopic bile from the surgical drains for more than 7 d after surgery^[9]. If bile leakage is clinically suspected after the removal of drains, percutaneous drainage is performed. Intravenous ampicillin/sulbactam (ABPC/ SBT) 1.5 g was administered 30 min before surgery and additional ABPC/ SBT was administered every 3 h. Systemic antibiotics were used for only two days after surgery. During the operation gloves were changed every 3 h.

Postoperative infection

SSI was defined as a condition in which purulent dis-

Table 1 Comparison of clinicopathological data of the groups

Variables	Vicryl group (n = 62)	Silk group (n = 63)	P-value
Age	68 ± 10	67 ± 12	0.684
Male/female	37/25	41/22	0.720
Body mass index	22.6 ± 3.0	23.7 ± 12	0.159
Diabetes mellitus (%)	19.4	33.0	0.104
HBV (%)	17.7	20.6	0.560
HCV (%)	50.0	39.7	0.666
Albumin (g/dL)	3.6 ± 0.5	3.6 ± 0.5	0.694
Total bilirubin (mg/dL)	0.7 ± 0.4	0.7 ± 0.4	0.813
AST (IU/L)	46 ± 31	43 ± 27	0.592
Platelet count (x 10 ³ /μL)	21.0 ± 11.0	19.7 ± 10.1	0.460
ICGR15 (%)	15.4 ± 9.0	16.4 ± 11.9	0.589
Child-Pugh A/B	58/4	59/4	0.999
HCC/non-HCC	46/16	47/16	0.826
Liver cirrhosis (ch/lf/lc)	15/20/27	15/22/26	0.948
Anatomical/nonanatomical	20/42	20/43	0.618
Operation time (min)	273 ± 88	276 ± 105	0.876
Blood loss (g)	698 ± 894	763 ± 1329	0.749
Transfusion (%)	12.9	17.4	0.620
Bile leakage (%)	3.2	6.3	0.680
Total SSI (%)	11.3	15.8	0.603
Incisional SSI (%)	8.0	9.5	0.999
Organ/space SSI (%)	3.2	6.3	0.680
Remote infection (%)	3.2	1.6	0.546
Hospital stay (d)	16 ± 15	16 ± 14	0.880

SSI: Surgical site infection; HBV: Hepatitis B virus; HCV: Hepatitis C virus; HCC: Hepatocellular carcinoma; AST: Aspartate aminotransferase.

charge was observed from any incision or space that was manipulated during an operation with or without microbiological evidence as in the guideline issued by CDC^[6] and it was identified prospectively by direct observation of the surgical site. Patients were followed up 30 d after hospital discharge. SSI occurring after hospital discharge was included in this study. Remote infection was defined as a condition in which fever and leukocytosis were present with bacteria in sputum, urine, catheter-tip, blood, or other body fluid/space with or without microbiological evidence.

Statistical analysis

We analyzed associations between the continuous and categorical clinico-pathologic variables using the Student's *t* tests and χ^2 tests, respectively. Multivariate analysis was performed with a logistic regression test. A *P* value less than 0.05 was considered statistically significant.

RESULTS

Incidence of postoperative infection

The clinicopathological factors between the Vicryl and Silk groups were compared (Table 1). No significant differences were recognized during the evaluation of the host factors and the operative factors. SSI was observed in 13.6% (17/125) of patients in this study, 11.3% in the Vicryl group and 15.8% in the Silk group (*P* = 0.620). Incisional SSI including superficial and deep SSI, were observed in 8% of the Vicryl group and 9.5% of the Silk group (*P* =

Table 2 Comparison of clinicopathological data of the groups

Variables	SSI(+) (n = 17)	SSI(-) (n = 108)	P-value
Age	68 ± 10	67 ± 11	0.667
Male/female	13 / 4	65/43	0.287
Body mass index	24.3 ± 5.2	23.0 ± 3.9	0.208
Diabetes mellitus (%)	35.3	25.0	0.384
HBV (%)	23.5	18.5	0.703
HCV (%)	64.7	41.7	0.560
Albumin (g/dL)	3.6 ± 0.4	3.6 ± 0.5	0.977
Total bilirubin (mg/dL)	0.7 ± 0.3	0.7 ± 0.4	0.938
AST (IU/L)	56 ± 22	43 ± 29	0.070
Platelet count (x 10 ³ /μL)	20.7 ± 7.3	20.4 ± 11.0	0.904
ICGR15 (%)	19.9 ± 8.3	15.3 ± 10.7	0.101
Child-Pugh A/B	17/0	100/8	0.597
HCC/non-HCC	15/2	78/30	0.638
Liver cirrhosis (ch/lf/lc)	2/7/8	28/35/45	0.435
Anatomical/nonanatomical	8/9	32/76	0.228
Operation time			
> 265 min (%)	76.5	44.4	< 0.050
Blood loss			
> 1000 g (%)	41.2	18.5	< 0.050
Transfusion (%)	11.8	15.7	0.999
Bile leakage (%)	35.3	0	< 0.010
Vicryl/silk	7/10	55/53	0.603
Hospital stay (d)	29 ± 23	15 ± 12	< 0.010

SSI: Surgical site infection; HBV: Hepatitis B virus; HCV: Hepatitis C virus; HCC: Hepatocellular carcinoma; AST: Aspartate aminotransferase.

0.999). Organ/space SSI was observed in 3.2% of the Vicryl group and 6.0% of the Silk group (*P* = 0.680). Organ/space SSI was namely abdominal abscess and percutaneous drainage was needed. Remote infection was observed with an incidence of 3.2% in the Vicryl group and 1.6% in the Silk group (*P* = 0.546). Pneumonia and urinary tract infection were observed in the Vicryl group and pneumonia in the Silk group. There were no significant differences. There was no hospital mortality in this study.

Risk factor for SSI

In the univariate analyses, operation time > 265 min, blood loss > 1000 g, and bile leakage differed significantly as predictive factors of SSI (Table 2). The type of sutures was not significant. Five factors including operation time > 265 min, blood loss > 1000 g, bile leakage and the type of sutures were analyzed with multivariate logistic regression. Results are given in Table 3. Blood loss > 1000 g was the only independent variable among the five factors.

Comparison of duration to recovery in the patients with SSI

Among the patients with SSI, the period for recovery in the Vicryl group was significantly shorter compared to the Silk group (Table 4).

DISCUSSION

Togo *et al.*^[8] reported the usefulness of absorbable sutures to prevent SSI with a historical control study using an animal model. This is the only report that the use of

Table 3 Multivariate logistic stepwise regression analysis for predictive factors of surgical site infection

	Adjusted odds ratios (95% CI)	P value
Blood loss > 1000 g	7.598 (1.396-41.364)	< 0.01

Table 4 Comparison of the period for recovery in patients with surgical site infection

Vicryl	28 ± 11 d
Silk	54 ± 30 d

$P < 0.05$.

absorbable sutures contributed significantly to the prevention of development of SSI. In our prospective study, the incidence of SSI in the Vicryl group was lower compared to the Silk group for both incisional SSI and organ/space SSI, however there were no other significant differences. Watanabe *et al.*^[12] reported the use of absorbable sutures in seromuscular suturing or intra-abdominal ligation was associated with a significantly lower incidence of SSI than non-absorbable sutures in the lower alimentary tract procedure, but not in the upper. The incidence of SSI is low so any significant difference is difficult to observe. The duration for recovery from SSI was significantly shorter in the Vicryl group than in the Silk group. Since SSI increases treatment costs and diminishes patient satisfaction markedly, the use of an absorbable suture is recommended in view of the medical economy and patient's quality of life.

The incidence of SSI as a form of postoperative infection was previously reported to be 20%-25%^[8,13,14]. In our clinical experience, the incidence of SSI was observed to be 13.1% in this study and the rate of occurrence is decreasing every year because of SSI surveillance and development of surgical techniques such as closed suction drain and the prevention of bile leakage. Togo *et al.*^[8] reported the incidence of postoperative infection gradually decreased significantly with additional countermeasures. A larger sample size as well as a multi-institutional study is required for a randomized controlled study.

Intraoperative blood loss, long operation time and bile leakage were associated with SSI in our study. Both transfusion and operation time are reported to be risk factors of SSI in hepatectomy or other surgery^[5,15]. Transfusion could induce immunosuppression in postoperative patients by reduction of the natural killer cell and cytotoxic T-cell populations^[16,17]. Operation time could influence the concentration of systemic antibiotics, leading to the incidence of SSI. Bile leakage was observed at 4.8% (6/125) in this study. Generally the incidence of bile leakage was 4.0%-7.2% in recently reported large series^[9,18-20]. The presence of bile, blood, and devitalized tissues in the dead space after hepatectomy may provide the ideal environment for bacterial growth and development of organ/space SSI, which frequently results in liver failure. To reduce organ /space SSI, it is most impor-

tant to prevent bile leakage.

In conclusion, there were no significant differences between absorbable sutures and silk sutures on the incidence of SSI during the resection of the liver in this randomized control study; however, the period for recovery in patients with SSI was significantly shorter for absorbable sutures. Further study is needed to provide evidence on the use of absorbable or non-absorbable suture materials in a multi-institutional randomized clinical trial.

COMMENTS

Background

Surgical site infection (SSI) is one of the most important morbidities of surgery and leads to prolonged hospital stays. In this paper the authors provide the outcome of a randomized clinical trial investigating the type of sutures used during hepatectomy to determine which is better in preventing SSI, absorbable sutures or non-absorbable sutures.

Research frontiers

During the resection of the liver, silk sutures are generally used for the vessels in Japan, because silk sutures are easier to handle and less expensive than absorbable sutures.

Innovations and breakthroughs

This is a randomized clinical trial investigating the type of sutures used during hepatectomy.

Applications

The incidence of SSI was not significantly different between absorbable sutures and silk sutures in this randomized controlled study; however, the period for recovery in patients with SSI was significantly shorter for absorbable sutures.

Terminology

Vicryl is an absorbable suture material and silk is a non-absorbable suture material, which is widely used in Japan.

Peer review

Authors report prospective randomized study of surgical site infection comparing silk to vicryl ties in liver resection.

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