PROTOCOL PAPER

Surgical manipulation related to the risk of postoperative complications in laparoscopic gastrectomy: A study protocol

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Abstract

Background: Few researches have reported the relationship between surgical skill and outcome on gastric cancer surgery. To prevent complication after gastrectomy, we need to identify specific manipulation or techniques that can increase the risk. In the present report, we attempt to identify techniques that directly cause intra-abdominal infectious complications (IAICs).

Methods: This is a study protocol. We planned the multicenter case-control study, where the cases are patients who developed IAICs and the controls were those who did not develop IAICs after gastrectomy. All of one-hundred patients diagnosed as clinical $\leq T4a$ and $\leq N1$, and underwent distal gastrectomy are extracted. Two raters blinded to the outcome evaluate each video after editing to remove personal information from the operating videos. We then identified items with significant difference between the two groups for consideration of whether or not they were risk factors for IAIC.

Keywords: Laparoscopic surgery, Surgical skill, infectious complication, gastrectomy

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Introduction

Surgeons are well aware that the surgical procedures and manipulation are strongly related to the incidence of postoperative complications. Indeed, Birkmeyer et al. previously reported that quality surgeons with higher scores of surgical skill assessment have lower incidences of postoperative complication¹⁾s. However, the methodology for assessing surgeons' techniques has not been established.

Some researchers use the objective structured assessment of technical skill (OSATS) scale developed by Martin et al. in 1995, which includes seven items for evaluating surgeons' basic skills: respect for tissue, time and motion, instrument handling, knowledge of instrument, use of assistants, flow of operation and forward planning, and knowledge of the specific procedure²⁾. Recently, Fecso et al. also reported that surgery with a higher score is related to a lower incidence of postoperative complications in laparoscopic gastrectomy (LG) for gastric cancer³⁾.

However, this OSATS can be used to assess many kinds of surgery and is not specific to a targeted surgery. Therefore, we cannot use it to identify a specific technique that directly causes complications. In gastrectomy, surgeons must endeavor to prevent pancreatic fistula or anastomotic leakage and intra-abdominal infectious complications (IAICs). To prevent such complications, we need to identify specific actions or techniques that can increase the risk of complications. If we were able to identify such factors, the information could prove quite relevant in training to perform LG.

We have been preserving videos of our surgeries with the spread of laparoscopic surgery and have therefore been able to evaluate our procedures objectively and retrospectively. In the present report, we focused on LG and attempted to identify specific techniques that directly cause IAICs.

Methods

Study design and methods

This was a case-control study, where the cases were patients who developed IAICs and the controls were those who did not develop IAICs after gastrectomy. Several Japanese hospitals were asked to participate based on the following criteria: performed LG from

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January 2008 through December 2018 and equipped with facilities for the electronic storage of clinical data, including medical records, images, and videos of operations. This study protocol was approved by the Institutional Review Board and conducted in accordance with the Declaration of Helsinki and national ethical regulations.

Participants

The patients enrolled in this study had histologically confirmed gastric adenocarcinoma, were diagnosed as clinical $\leq$ T4a and $\leq$ N1, and underwent distal gastrectomy, not total or other function-preserving procedures. The exclusion criteria were carcinoma in the gastric stump, the presence of another primary malignancy, other simultaneous operation, peritonitis, a poor general condition ($\geq$ 3ASA-PS or $\geq$ 2ECOG-PS), distant metastatic lesion (M1), and a history of chemotherapy or chemo-radiotherapy. Patients whose surgical videos had not been preserved were also excluded. Cancer staging was based on the 7th UICC/TNM classification.

Patients were divided into two groups: the IAIC group (case) and non-IAIC group (control). IAICs were defined as the incidence of grade $\geq$ 2 intra-abdominal infection, according to the Clavien-Dindo classification⁴⁾.

Video assessment and outcomes

We held consensus meeting involving several expert surgeons and decided on the assessment items for LG. According to the items, two raters who had been blinded to the group allocation evaluated each video after editing to remove personal information from the operating videos. We then identified items with significant difference between the two groups for consideration of whether or not they were risk factors for IAIC after LG.

The descriptive statistics were evaluated, and the score of each item was compared between the two groups using the Mann-Whitney U-test, while categorical variables were evaluated by Fisher's exact test. All statistical tests were one-sided, and p values of $\leq$ 0.05 were considered to indicate statistical significance. All of the analyses were performed with STATA software (version 14, U.S).

Data collection, case matching, and sample size estimation

To compare the surgeons' skill between the two groups, we had to adjust for potential confounding factors, such as the sex, body mass index, tumor location, size, TNM stage, and other surgical risks. To adjust for these factors, we applied propensity score matching to extract patients for the outcome comparison. Our study team clarified through consensus meetings the covariates related to the risk of pancreatic fistula or anastomotic leakage after LG. The score was estimated using a logistic regression model and greedy matching (ratio = 1:1

without replacement) with a caliper width of 0.2 standard deviations (SDs) of the logit of the estimated propensity score.

The design of this study is original and had not been reported previously, making it difficult to determine the sample size. When we used the five-point Lickert scale, the minimal important difference was estimated to be 1.0 point, and the SD was 2.0. The statistical power required was 80%, and the alpha level was one-side 0.05. The total sample size was thus estimated to be 100 cases. Assuming an incidence of Grade $\geq$ 2 IAICs at 8.0%, a total of 625 cases were considered required. Accounting for cases missing video or other clinical information, we estimated that 1000 patients would be needed for this study.

Discussion

When we conduct comparative studies among surgical procedures, the skill of surgeons is a confounding factor^{1, 3, 5-7)}. However, this important factor has often not been adjusted for in previous studies due to difficulties in measuring the surgical skill or performance in each case.

In the present study, we focused on laparoscopic distal gastrectomy for gastric cancer and investigated which techniques caused IAICs. Identifying high-risk surgical techniques is clinically relevant for surgeons treating gastric cancer patients. Furthermore, establishing methods for evaluating the surgical performance is useful for analyses of comparative studies.

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