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Comparison of laparoscopic and open inguinal hernia repair in adults: A retrospective cohort study using a medical claims database

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## **Abstract**

**Introduction:** This study aimed to investigate and compare the surgical complications following laparoscopic inguinal hernia repair (LIHR) with those following open inguinal hernia repair (OIHR).

**Methods:** This was a retrospective cohort study based on nationwide claims data. We extracted the data of patients aged  $\geq 20$  years who underwent inguinal hernia repair (IHR) between 2009 and 2020. The primary outcome was postoperative complications of IHR, and the secondary outcomes were recurrence of hernia and length of hospital stay. Patient characteristics were adjusted with propensity score (PS) matching, the annual proportion of LIHR versus OIHR were summarized, and the surgical outcomes of each IHR were analyzed.

**Results:** Of the 15,728 eligible patients, 6,512 underwent LIHR. The proportion of LIHR increased from 14.7% to 52.8% annually during the study period. From the analysis of 6,060 pairs created by PS matching, the risk of surgical site infection (odds ratio [OR] 0.70; 95% confidence interval [CI] 0.56-0.86;  $p=0.0007$ ), and acute postoperative pain (OR 0.69; 95% CI 0.60-0.79;  $p<0.0001$ ), and chronic postoperative pain (OR 0.83; 95% CI 0.70-0.98;  $p=0.0291$ ) was significantly lower with LIHR than with OIHR. The recurrent rate was not significantly different between the LIHR and OIHR groups (OR, 0.68; 95% CI 0.45-1.01;  $p=0.0558$ ). Furthermore, no significant difference was found in the length of hospital stay between the LIHR and OIHR groups ([2.91 $\pm$ 1.94 days] versus [2.97 $\pm$ 2.61 days], difference  $\pm$  SE: 0.06 $\pm$ 0.04,  $p=0.1307$ ).

**Conclusion:** LIHR might be superior to OIHR in terms of fewer surgical complications and might be preferred over OIHR in the future.

**Keywords:** Adult inguinal hernia, laparoscopic inguinal hernia repair, open inguinal hernia repair

## **Introduction**

Surgical repair is the primary treatment for inguinal hernia and is one of the most common procedures in general surgery<sup>1,2</sup>. Although open inguinal hernia repair (OIHR) was the standard surgery for inguinal hernia, laparoscopic inguinal hernia repair (LIHR), which was developed in 1990, has become more popular; a retrospective study in the US reported that the rate of LIHR increased from 24.2% to 34.8% between 2010 and 2015<sup>3-6</sup>. Various studies have reported the advantages of LIHR, such as reduced postoperative pain, fewer complications including hematoma and nerve damage, and a lesser rate of chronic pain, compared with the OIHR<sup>7-15</sup>. The postoperative recurrence rate following LIHR is reported to be nearly equivalent to that following OIHR<sup>16-18</sup>. Although LIHR takes longer to perform and is more expensive than OIHR, it is considered beneficial in terms of social health economics due to the quick recovery after surgery<sup>7,14,15</sup>. Based on these studies, several guidelines have conditionally recommended LIHR for the treatment of inguinal hernia<sup>19,20</sup>. The condition includes that a surgeon must have specific expertise in performing LIHR for primary unilateral in male or primary bilateral hernias<sup>19</sup>. In a multicenter, randomized trial comparing OIHR and LIHR, no difference was found in the recurrence rates when the procedures were performed by experienced surgeons<sup>21</sup>. Despite the recent increase in the adoption of laparoscopic surgery and number of experienced surgeons, there have been few recent randomized controlled trials (RCTs) or observational studies on LIHR with large sample sizes.

Therefore, observational studies using medical data of a large number of subjects are necessary to evaluate

the outcomes of laparoscopic surgery compared with open surgery for inguinal hernia repair (IHR). In this study, we aimed to compare the outcomes of LIHR and OIHR.

## **Materials and Methods**

The Ethics Committee of Kyoto University School of Medicine approved this study protocol (approval no. R2575; May 11, 2021). The study was conducted according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines<sup>22</sup> and performed in accordance with the ethical standards laid down in the Declaration of Helsinki. The requirement for informed consent was waived because patient information was anonymized.

## **Data sources**

A retrospective cohort study was conducted to compare the outcomes of LIHR and OIHR in adults, using a nationwide commercial medical database provided by JMDC Inc. (Tokyo, Japan). The JMDC claims database comprises inpatient, outpatient, and pharmacy data collected from over 400 health insurers throughout Japan from 2005 to 2020. The database has the data of 7.3 million people, including employees and their families, which covers approximately 9% of the Japanese population<sup>23,24</sup>. The data of each patient can be traced unless the employee withdraws from the health insurance. The database includes patient characteristics, hospital/pharmacy claims data, and diagnoses coded according to the Medical Information

System Development Center (MEDIS-DC, Tokyo, Japan); these codes correspond to the International Classification of Diseases 10th revision (ICD-10) codes<sup>25</sup>, World Health Organization Anatomical Therapeutic Chemical (ATC) codes as drug information, and Japanese standardized procedure codes (K code) as procedural information.

### **Study population**

Patients aged  $\geq 20$  years who underwent IHR for the first time (ICD-10 code: K402, K403, K404, K409) except for femoral hernia cases between January 2009 and September 2020 were identified from the JMDC database. We excluded the following patients: those who (1) underwent another surgery simultaneously, (2) underwent emergency surgery for strangulated hernia, (3) underwent IHR for recurrent hernia, which is defined as inguinal hernia that occurred after IHR (ICD-10 code; K409), (4) had a previous laparotomy or previous laparoscopic surgery, because laparoscopic surgery might be difficult in such patients, (5) had a history of retropubic or robot-assisted laparoscopic radical prostatectomy (K code: K843), we divided these to describe the number of cases that occurred after prostate surgery, known as the risk factor of inguinal hernia, and (6) had inadequate data<sup>26</sup>. The study population was divided into two groups: LIHR and OIHR.

### **Patient and institutional characteristics**

Patient characteristics included age, sex, hernia type (unilateral or bilateral), medication identified by the

ATC code, comorbidities, and Charlson comorbidity index score<sup>27, 28</sup>. To ascertain the presence of specific comorbidities such as myocardial infarction, chronic obstructive pulmonary disease, and other diseases listed in the Charlson comorbidity index score, we used the diagnostic ICD-10 codes from all claims records within 360 days before the day of the index surgery. For information about the medical facility, the JMDC's institutional code was used. We classified the number of hospital beds into 0-19, 20-199, 200-299, 300-499, and  $\geq 500$  beds. The hospital categories were divided into university hospitals and non-university hospitals.

## **Outcomes**

The primary outcome was the incidence of postoperative complications in the two groups (LIHR and OIHR). In a previous study, these complications were defined as surgical site infections (SSI), acute pain, bleeding, seroma, fever, pneumonia, urinary tract infection, bladder injury, vas deferens injury, intestinal injury, and bowel obstruction within 30 days postoperatively and identified by MEDIS-DC codes (Online Resource 1)<sup>29</sup>. In addition, chronic pain was defined as pain lasting at least 3 months, postoperatively, as identified by MEDIS-DS and ATC codes. The secondary outcome was the duration of anesthesia, recurrence rate, and length of hospital stay in the two groups. A recurrence hernia was defined as a hernia that occurred after the primary hernia. We also evaluated the outcomes in each year from 2009 to 2020.



## **Statistical analyses**

For each surgery, the number and percentage of the overall covariate were calculated, and descriptive statistics were used to summarize the patient- or hospital-level data. Categorical variables are presented as numbers and percentages (%). Continuous variables are presented as mean and standard deviation (SD) if the data were normally distributed or as the median and interquartile range (IQR) if the data were non-normally distributed. Student's t-test or Mann-Whitney U test was used for comparison of continuous variables, and the chi-square test was used for comparison of categorical variables.

To adjust for confounders, a propensity score (PS) was calculated using patient/hospital backgrounds, medications, and other covariates. A nearest-neighbor matching without replacement was performed in a ratio of 1:1. The caliper was set by multiplying the SD of the logit of PS by 0.2. A multivariable logistic regression model was used to estimate the PS, and adjusted odds ratio (OR) and 95% confidence interval (CI) was calculated<sup>30</sup>. Standardized differences were used to measure the balance of covariates. A covariate was considered balanced if the absolute value of the standardized difference was less than 10%.

Subgroup analysis was performed by dividing the cohort into two groups; pre-2016 and post-2016 because we hypothesized that post-2016 surgical cases might have been affected by the implementation of the Japanese guidelines, an increase in LIHR, and improved physician skills<sup>19,20</sup>.

In addition, two sensitivity analyses were performed for the robustness of the research. First, we analyzed whether the postoperative observation period affected the occurrence of complications by changing the

observation period for postoperative complications to 60 or 90 days. Moreover, chronic postoperative pain was analyzed by changing the observation period to 120 or 180 days. Second, we used a multilevel logistic regression model to account for the differences between hospitals. Hospital identification (ID) was included as a random effect, and other covariates including age, sex, comorbidities, and number of beds at the hospitals, were included as fixed effects. Statistical significance was set at  $p < 0.05$  due to the exploratory nature of this study. Data analyses were performed using SAS version 9.4 software (SAS Institute Inc., Cary, NC, USA).

## **Results**

### **Patient characteristics**

We identified 15,728 adults from 2,851 institutions (range: 1-342 patients per institution) who underwent IHR and met the eligibility criteria (Figure 1). The number of eligible patients was 6,512 and 9,216 in the LIHR and OIHR groups, respectively. Table 1 summarizes the patient characteristics. The proportion of male was significantly higher than that of female (LIHR, 92.2%; OIHR, 91.4%). The mean age (SD) was 52.6 (11.9) years in the LIHR group and 53.3 (12.3) years in the OIHR group. There were more bilateral cases with LIHR than OIHR (LIHR, 66.3% versus OIHR, 33.7%). The Charlson comorbidity index score was not significantly different between the groups (median 0 (IQR 0-1), respectively).

### **Annual number and percentage of each surgery**

We examined changes in the population who underwent LIHR through the 11.5 years included in this study.

Figure 2 shows the annual number of each IHR type from 2009 to 2020. The annual percentage of LIHR increased from 14.7% (15/102 in 2009) to 52.8% (731/1,385 in 2020) within the 11.5 years.

### **Outcomes and PS matching**

The outcomes of each type of inguinal hernia repair are shown in Online Resource 2. PS matching was used to form 6,060 pairs of patients. The logistic model for estimating PS had a C-statistic of 0.695. All confounders showed less than 10% standardized differences, and the balance of patients between groups was good after PS matching (Table 1). Table 2 reports the OR and 95% CI for postoperative complications and recurrence after adjusting for patient characteristics. We found that LIHR significantly reduced the risk of SSI (OR, 0.70; 95% CI, 0.56-0.86;  $p=0.0007$ ), acute postoperative pain (OR, 0.69; 95% CI, 0.60-0.79;  $p<0.0001$ ) and chronic postoperative pain (OR, 0.83; 95% CI, 0.70-0.98;  $p=0.0291$ ) compared with OIHR. No significant difference was found in the incidence of inguinal hernia recurrence (OR, 0.68; 95% CI 0.45-1.01;  $p=0.0558$ ). Moreover, no significant difference was noted between the LIHR and OIHR groups in terms of the length of hospital stay (LIHR [2.91±1.94 days] versus OIHR [2.97±2.61 days],  $p=0.1307$ ) (Table 2). In terms of anesthesia time, LIHR consumed more time than OIHR (LIHR [141±49.4 min] versus OIHR [51.4±54.9 min],  $p<0.0001$ ) (Online resource 2). However, due to a large amount of missing data,

anesthesia time was excluded from the analysis.

### **Subgroup analysis**

The outcomes before and after 2016 were examined to evaluate the influence of the time period on LIHR.

In addition to the primary analysis, we found that LIHR significantly decreased the incidence of SSI and acute postoperative pain regardless of the period (Online Resource 3). The risk of recurrence following laparoscopic surgery before 2016 was significantly lower (pre-2016: OR 0.50; 95% CI 0.26-0.98;  $p=0.0422$ ); the risk of recurrence after 2016 was not (post-2016: OR 0.91; 95% CI 0.57-1.45;  $p=0.6681$ ).

The hospital stay following LIHR pre-2016 was significantly shorter than that following OIHR (LIHR [2.96±1.87 days] versus OIHR [3.17±2.83 days],  $p=0.0240$ ) (Online Resource 3).

### **Sensitivity analysis**

When the observation period for the postoperative complications was adjusted, the sensitivity analyses showed that the estimated odds ratios for those complications did not change (Table 3). In addition, in the multilevel analysis that accounted for the differences between hospitals, the OR of acute postoperative pain was significantly different to that in the main analysis (OR 0.66; 95% CI 0.55-0.80;  $p<0.0001$ ), although no significant risk of SSI (OR 0.91; 95% CI 0.69-1.20;  $p=0.4795$ ) and chronic postoperative pain (OR 0.85; 95% CI 0.71-1.01;  $p=0.0577$ ) was observed between OIHR and LIHR (Online resource 4).

## **Discussion**

This study compared the surgical outcomes of LIHR, which has been widely adopted in recent years, with those of OIHR. In this study, we demonstrated that the use of LIHR has increased over the years and is associated with fewer events of SSI and acute/chronic postoperative pain compared with OIHR. To the best of our knowledge, this is one of the few large-scale studies that have analyzed the surgical outcomes of IHR in Japan.

Similar to the United States, a previous nationwide survey in Japan showed that the number of LIHRs increased from 19.0% to 45.9% between 2011 and 2018<sup>31</sup>. In this study, we also reported a similar trend in 2019 and beyond. As seen in our results, the number of LIHRs has increased over the years. This is possibly because of the increased adoption of LIHR due to the benefits such as lesser postoperative pain as reported in previous studies<sup>7-18</sup>. Thus, we expect that the number of LIHRs is likely to increase further in the future.

Several meta-analyses of RCTs have assessed the surgical outcomes of LIHR versus OIHR<sup>11, 12, 16, 32</sup>. They reported that LIHR reduced postoperative pain, seroma, and hematoma formation. However, the recent trend of surgical complications following IHR for inguinal hernia is unknown because most of these studies were conducted until 2015. Our analyses indicate that the risk of postoperative pain following LIHR is lower than that following OIHR, which is similar to that reported in previous studies.

The incidence of SSI following IHR ranges from 0.4% to 4.8% in countries other than Japan and from 0.46% to 2.4% in Japan<sup>20, 33</sup>. The incidence of SSI in this study (LIHR, 2.7%; OIHR, 3.7%) is comparable with those in previous studies. Many authors have also reported that the risk of SSIs following LIHR was

lower than that following OIHR<sup>11, 12, 32,34</sup>. In the present study, we found that the incident rate of SSI following LIHR was 2.7%, and the reduced SSI risk associated with LIHR was significant. A possible reason for the decrease in SSI is that LIHR involves lesser external exposure of the tissues than OIHR<sup>35</sup>. Laparoscopic gastrointestinal surgery is a known mitigating factor for SSI, which supports this explanation<sup>33</sup>.

A previous meta-analysis of LIHR versus OIHR showed that the risk of hernia recurrence was not significant in both procedures<sup>16-18</sup>. The secondary outcomes in our study, are in line with this result. Recurrence might be influenced by the constant advancement in technology, such as the development of surgical techniques and experience of surgeons<sup>16</sup>. For example, when LIHR was first introduced, the recurrence rate was high due to inferior technology and lack of surgical expertise<sup>37</sup>. Hence, we examined the recurrence of hernia in two groups: in the last 5 years and earlier period. In contrast with our expectations, in our subgroup analysis, the risk of recurrence for LIHR between 2009 and 2015 was significantly lower than of OIHR (adjusted OR 0.50, 95% CI 0.26-0.98,  $p=0.0240$ ). In our opinion, although there were fewer surgical cases in earlier stage, many of the procedures may have been performed by surgeons with sufficient experience in performing LIHR.

Initially, we presumed that hospital stay following LIHR was longer than that following the open procedure because OIHR is often performed under spinal or regional anesthesia allowing day surgery, unlike LIHR which is performed under general anesthesia in all cases. However, no significant difference

was found in the length of hospital stay between the groups. This might be because IHR is a low-risk surgery, with low incidence of morbidity and mortality, where the patients can be discharged early or depending on hospital policy (e.g., clinical pathway) or physician preference<sup>38</sup>. Interestingly, in the subgroup analysis, the length of hospital stay in LIHR was significantly shorter than that in OIHR in pre-2016; there was no significant difference post-2016. One possible explanation was that there might be factors specific to OIHR such as the type of surgery. One trial reported a significantly shorter postoperative stay after a mesh technique than no mesh<sup>39</sup>. Also, from the Japan Society for Endoscopic Surgery survey, OIHR performed without mesh, pre-2016, was more than one, post-2016<sup>31</sup>. OIHR without mesh (conventional method, i.e., Bassini, McVay, Shouldice, et al.) post-2016 might be performed more than in pre-2016 in our study<sup>31</sup>. The new database containing information on the number of cases by procedures in the LIHR and OIHR would be expected. In addition, LIHR under general anesthesia requires a longer duration of surgery than OIHR, which may cause anesthesia-related postoperative complications (e.g., pneumonia) and increased hospital stay<sup>11</sup>. Our results showed that, although the anesthesia time in LIHR was longer than in OIHR, there was no significant difference in the incidence of postoperative pneumonia between LIHR and OIHR. In other words, the association between anesthesia time and anesthesia-related postoperative complications may be low and be unlikely to affect the length of hospital stay. Thus, there may likely be other factors. However, we could not perform an accurate analysis in this study due to missing data on anesthesia time; therefore, future evaluation is needed using accumulated, detailed anesthesia and surgery time data (Online resource

2).

This study has some limitations. First, the JMDC database does not contain details of surgical procedures such as transabdominal preperitoneal approach (TAPP), totally extraperitoneal approach (TEP), Lichtenstein method (tension-free repair), or others. This information was necessary for IHR, because each type of surgery differs in the level of difficulty. For example, TEP is known for its complexity and relatively long learning curve<sup>16</sup>. Given the lack of data regarding these surgical techniques, a study cannot evaluate and thus compare the outcomes of these surgical procedures; comparing our results with those of previous studies using these procedures could increase the reliability of our study. Thus, these findings should be interpreted carefully. Second, the data used in this study did not include surgeons' information; hence, the details regarding their level of experience are not known. Learning adequate skills for IHR is essential for reducing surgical complications. An RCT in 2012 comparing open and TAPP demonstrated the effect of surgeons' experience on the recurrence rate in the TAPP group; an experience with 80–250 LIHR procedures is needed to significantly reduce the incidence of complications<sup>21, 36, 37</sup>. Assuming that learning effects for LIHR would accumulate over the years, we examined surgical outcomes in two groups: the 2009-2015 and 2016-2020 groups. As a result, we found that the direction of the OR for surgical complications in groups was unchanged. In the era when the number of laparoscopic cases was less, surgeons with more experience might have performed LIHRs; the number of years of experience alone might not be a risk factor in recent years due to the effectiveness of training using surgical simulators<sup>40, 41</sup>.



An update of the data, including information on training history, is necessary for future evaluation. Third, the database does not contain information about the hospitals, i.e., the number of doctors, paramedical staff, or patients visiting the hospital daily. Previous literature indicates that specialized centers with high patient volumes achieve better outcomes<sup>19</sup>. In this study, we conducted a sensitivity analysis by using a multilevel model with random effects as a hospital facility to determine whether the odds ratios of postoperative complications were different between LIHR and OIHR. The results for most of the complications were consistent with those of the main analysis, indicating robustness. However, the occurrence of SSI was not significant, although the trend (direction) of the OR was shown to be the same as that in the main analysis. A possible explanation is that factors such as the postoperative management in each hospital or infection control may have contributed to the reduction in the risk of SSIs in OIHR, although this relationship was not clear. We would require further analysis of a dataset with detailed hospital information in the future. Finally, PS matching cannot adjust for unmeasured confounders. Hence, it cannot be denied that there is bias in the target population despite the adjustment. Unlike RCTs, the generalizability of the analysis results obtained from these data is not high; therefore, the results of this study should be interpreted with caution.

In conclusion, we found that the number of LIHRs increased every year, and the risk of SSI and postoperative pain following LIHRs was lower than that following OIHRs. These results suggest that LIHR might be superior to OIHR in terms of surgical complications; therefore, LIHR could become a

more common choice than OIHR in the future. Further studies are necessary to understand the clinical effects of the increased adoption of LIHR.

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## References

- 1) Jenkins JT, O'Dwyer PJ. Inguinal hernias. *BMJ* 2008; 336(7638): 269–372
- 2) Schumpelick V, Treutner KH, Arlt G. Inguinal hernia repair in adult. *Lancet* 1994; 344(8919):375-379
- 3) Ger R, Monroe K, Duvivier R, Mishrick A, Management of indirect inguinal hernias by a laparoscopic closure of the neck of the sac. *Am J Surg* 1990; 159:370-373
- 4) Popp LW, Endoscopic patch repair of inguinal hernia in a female patient. *Surg Endos* 1990; 4:10-12
- 5) Schultz L, Graber J, Pietrafitta J, Hickok D. : Laser laparoscopic herniorrhaphy : a clinical trial preliminary results. *J Laparoendoscop Surg* 1991; 1:41-45
- 6) PavloskyKK, Vossler JD, Murayama SM, et.al. Predictors of laparoscopic versus open inguinal hernia repair. *Surg Endosc* 2019; 33:2612–2619
- 7) Chung RS, Rowland DY. Meta-analyses of randomized controlled trials of laparoscopic vs conventional inguinal hernia repairs. *Surg Endosc* 1999; 13:689–694
- 8) EU Hernia Trialists Collaboration. Laparoscopic compared with open methods of groin hernia repair: systematic review of randomized controlled trials. *Br J Surg* 2000; 87:860-867
- 9) Grant AM, EU Hernia Trialists Collaboration. Laparoscopic versus open groin hernia repair: meta-analysis of randomised trials based on individual patient data. *Hernia* 2002; 6:2–10
- 10) Voyles CR, Hamilton BJ, JohnsonWD, et.al. Meta-analysis of laparoscopic inguinal hernia trials favors open hernia repair with preperitoneal mesh prosthesis. *Am J Surg* 2002; 184:6–10

- 11) Memon MA, Cooper NJ, Memon B, et al. Meta-analysis of randomized clinical trials comparing open and laparoscopic inguinal hernia repair. *Br J Surg* 2003; 90: 1479–1492
- 12) Bittner R, Sauerland S, Schmedt CG. Comparison of endoscopic techniques vs Shouldice and other open nonmesh techniques for inguinal hernia repair. *Surg Endosc* 2005; 19: 605–615
- 13) Kuhry E, van Veen RN, Langeveld HR, et al. Open or endoscopic total extraperitoneal inguinal hernia repair? A systematic review. *Surg Endosc* 2007; 21:161–166
- 14) EU Hernia Trialists Collaboration. Repair of groin hernia with synthetic mesh meta-analysis of randomized controlled trials. *Ann Surg* 2002; 235:322–332
- 15) Schmedt CG, Sauerland S, Bittner R. Comparison of endoscopic procedures vs Lichtenstein and other open mesh techniques for inguinal hernia repair: A meta-analysis of randomized controlled trials. *Surg Endosc* 2005; 19:188–199
- 16) O'Reilly EA, Burke JP, O'Connell PR. A meta-analysis of surgical morbidity and recurrence after laparoscopic and open repair of primary unilateral inguinal hernia. *Ann. Surg* 2012; 255:846-853
- 17) Langeveld HR, van't Riet M, Weidema WF, et.al. Total extraperitoneal inguinal hernia repair compared with Lichtenstein (the LEVEL-Trial): a randomized controlled trial. *Ann Surg* 2010; 251: 819–824
- 18) Ekiund A, Carlsson P, Rosenblad A, et.al. Long-term cost-minimization analysis comparing laparoscopic with open (Lichtenstein) inguinal hernia repair. *Br J Surg* 2010; 97:765–771
- 19) The HerniaSurge Group. International guidelines for groin hernia management. *Hernia*. 2018; 22:1–

- 20) Japan hernia society guideline committee. The practical guideline of inguinal hernia. 2015. Available from: [https://jhs.mas-sys.com/pdf/sokeibuhernia\\_guideline2015.pdf](https://jhs.mas-sys.com/pdf/sokeibuhernia_guideline2015.pdf) (in Japanese)
- 21) Neumayer LA, Gawande AA, Wang J, et.al. Proficiency of surgeons in inguinal hernia repair effect of experience and age. *Ann. Surg* 2005; 242:344–352
- 22) Vandembroucke JP, von Elm E, Altman DG, et al. Strengthening the reporting of observational studies in epidemiology (STROBE): explanation and elaboration. *Epidemiology* 2007; 18:805–35
- 23) JMDC Inc. Tokyo. JMDC claims database; 2021. Available from: <https://www.jmdc.co.jp/en/jmdc-claims-database>. accessed May 8, 2021
- 24) Japanese Society for Pharmacoepidemiology. Survey of Japanese databases in Japan available for clinical/pharmaco-epidemiology; 2020. Available from: [http://www.jspe.jp/mt-static/FileUpload/files/JSPE\\_DB\\_TF\\_E.pdf](http://www.jspe.jp/mt-static/FileUpload/files/JSPE_DB_TF_E.pdf). Accessed May 6, 2021
- 25) Medical Information System Development Center.  
<https://www2.medis.or.jp/stdcd/byomei/index.html>. Accessed May 2021 (in Japanese)
- 26) Miyajima A. Inseparable interaction of the prostate and inguinal hernia. *Int J Urol* 2018; 25:644-648
- 27) Charlson ME, Pompei P, Ales KL and Mackenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987; 40:373-83
- 28) Quan H, Sundararajan V, Halfon p, et al. Coding algorithms for defining comorbidities in ICD-9-CM

- and ICD-10 administrative data. *Med Care* 2005; 43:1130-9
- 29) Nakashima M, Ide K, Kawakami K. Laparoscopic versus open repair for inguinal hernia in children: a retrospective cohort study. *Surg Today* 2019; 49:1044-1050
- 30) Austin PC. An introduction to propensity score methods for reducing the effects of confounding in observational studies. *Multivariate Behav Res* 2011;46(3):399-424
- 31) 14th nationwide survey of endoscopic surgery in Japan. *JSES* 2018; 23:754-759
- 32) Karthikesalingam A, Markar SR, Holt PJ, et al. Meta-analysis of randomized controlled trials comparing laparoscopic with open mesh repair of recurrent inguinal hernia. *Br J Surg* 2010; 97:4-11
- 33) Aufenacker TJ, Koelemay M J W, Gouma D J, Simons M P. Systematic review and meta-analysis of the effectiveness of antibiotic prophylaxis in prevention of wound infection after mesh repair of abdominal wall hernia. *Br J Surg* 2006; 93:5-10
- 34) Fukuda H. Patient-related risk factors for surgical site infection following eight type of gastrointestinal surgery. *J Hosp Infect* 2016; 93:347-354
- 35) De Oliveira AC, Ciosak SI, Ferraz EM, et al. Surgical site infection in patients submitted to digestive surgery: risk prediction and NNI risk index. *Am J Infect Control* 2006 May; 34:201-207
- 36) Neumayer L, Grobbee-Hurder A, Jonasson Olga, et al. Open mesh versus laparoscopic mesh repair of inguinal hernia. *NEJM* 2004; 350:1819-1827
- 37) Lau H, Patil NG, Yuen WK, et al. Learning curve for unilateral endoscopic totally extraperitoneal

- (TEP) inguinal hernioplasty. *Surg Endosc* 2002; 16:1724-1728
- 38) Glance LG, Lustik SJ, Hannan EL, et al. The surgical mortality probability model: derivation and validation of a simple risk prediction rule for noncardiac surgery. *Ann Surg* 2012; 255:696-702
- 39) Zieren J, Zieren HU, Jacobi CA, et al. Prospective randomized study comparing laparoscopic and open tension-free inguinal hernia repair with Shouldice's operation. *Am J Surg* 1998; 175:330-333
- 40) Hamilton EC, Scott DJ, Kapoor A, et al. Improving operative performance using a laparoscopic hernia simulator. *Am J Surg* 2001; 182:725-728
- 41) Zendejas B, Cook DA, Bingener J, et al. Simulation-based mastery learning a randomized controlled trial. *Ann Surg* 2011; 254:502-509

## **Tables**

**Table 1** Characteristics of the patients before and after propensity score matching

**Table 2** Outcomes after propensity score matching

**Table 3** Sensitivity analysis between different postoperative periods



## **Figure Legends**

**Figure 1:** Flowchart of patient recruitment

**Figure 2:** Annual number of laparoscopic and open inguinal hernia repair procedures

## **Supplementary Resources**

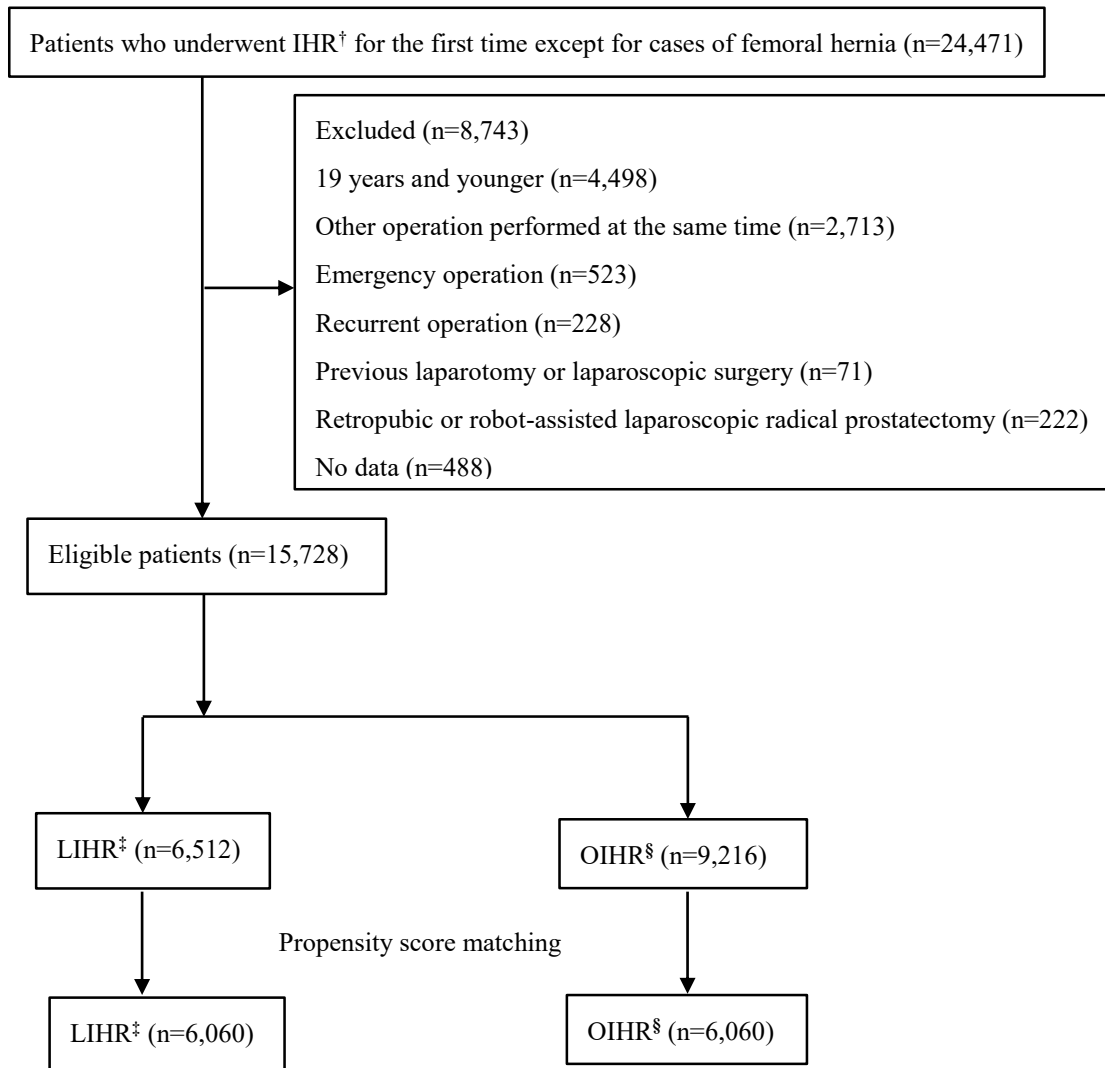
**Online resource 1** MEDIS-DC code for comorbidities

**Online resource 2** Outcomes before propensity score matching

**Online resource 3** Outcomes of propensity score matching in 2009-2015 and 2016-2020

**Online resource 4** Sensitivity analysis with multilevel model

**Figure 1 Flowchart of the patient recruitment**

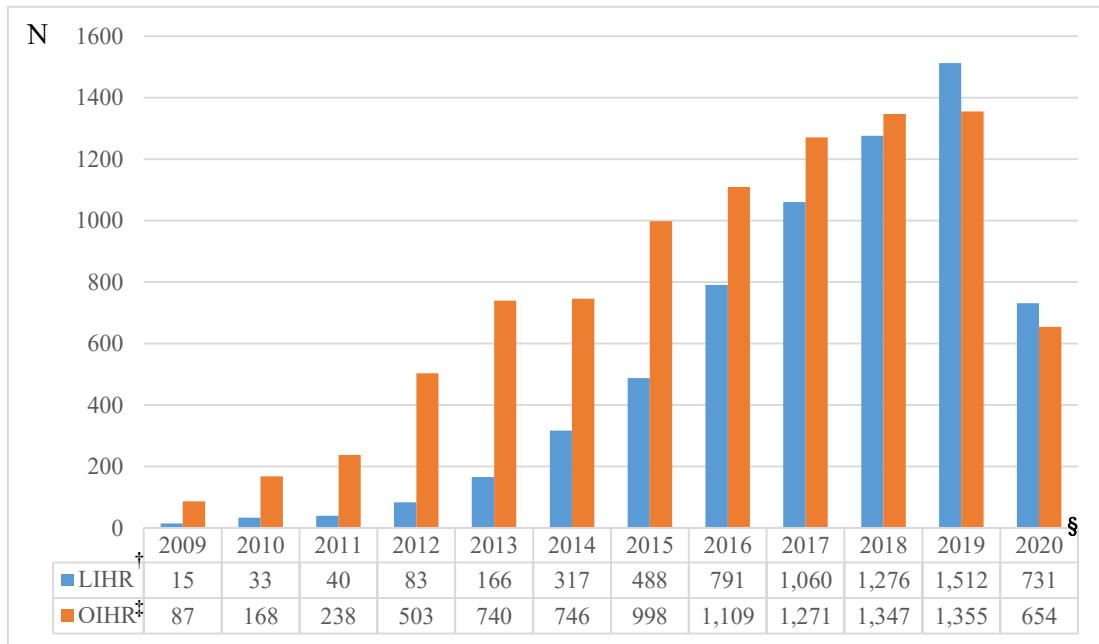


†IHR=inguinal hernia repair,

‡LIHR=laparoscopic inguinal hernia repair

§OIHR=open inguinal hernia repair

Figure 2 Annual number of laparoscopic and open inguinal hernia repair



† LIHR=laparoscopic inguinal hernia repair,

‡ OIHR=open inguinal hernia repair

§ six months period

Table 1 Characteristics of the patients before and after propensity score matching

	Before propensity score matching (n=15,728)			After propensity score matching (n=12,120)		
	Laparoscopic (n=6,512)	Open (n=9,422)	Standardied difference	Laparoscopic (n=6,060)	Open (n=6,060)	Standardied difference
Sex male, n(%)	6,002 (92.2)	8,421 (91.4)	2.9	5,579 (92.1)	5,560 (91.8)	1.1
Age (years), mean (SD)†	52.6 (11.9)	53.0 (12.3)	3.6	52.4 (11.9)	52.6 (12.5)	1.1
hernia, n(%)						
Bilateral	909 (14.0)	449 (4.9)	31.5	515 (8.5)	413 (6.8)	5.8
Comorbidities, n(%)						
Myocardial infarction	30 (0.5)	80 (0.9)	5	29 (0.5)	32 (0.5)	0
Congestive heart failure	15 (0.2)	36 (0.4)	3	15 (0.2)	18 (0.3)	0.9
Cerebrovascular disease	358 (5.5)	568 (6.2)	2.8	337 (5.6)	351 (5.8)	1
Chronic obstructive pulmonary disease	1,169 (18.0)	1,480 (16.1)	5	1,072 (17.7)	1,015 (16.7)	2.5
Mild liver disease	1,025 (15.7)	1,408 (15.3)	1.3	958 (15.8)	919 (15.2)	1.8
Diabetes without complications	191 (2.9)	272 (3.0)	0.1	179 (3.0)	179 (3.0)	0
Diabetes with complications	146 (2.2)	232 (2.5)	1.8	138 (2.3)	135 (2.2)	0.3
Renal disease	85 (1.3)	182 (2.0)	5.3	82 (1.4)	95 (1.6)	1.7
Cancer	184 (2.8)	482 (5.2)	12.3	184 (3.0)	191 (3.2)	0.6
Charlson comorbidities index score, median (IQR)‡	0 (0-1)	0 (0-1)	6.6	0 (0-1)	0 (0-1)	0.7
Medication, n(%)						
Corticosteroid	497 (7.6)	377 (4.1)	15	393 (6.5)	318 (5.2)	5.3
Anticoagulant	311 (4.8)	586 (6.4)	7	303 (5.0)	328 (5.4)	1.8
Facility information, n(%)						
University hospital	392 (6.0)	481 (5.2)	3.5	358 (5.9)	334 (5.5)	1.7
Number of bed						
0-19	559 (8.6)	1,248 (13.5)	15.9	557 (9.2)	650 (10.7)	4.9
20-99	211 (3.2)	611 (6.6)	15.7	211 (3.5)	209 (3.4)	0.2
100-199	826 (12.7)	1,359 (14.7)	6	785 (13.0)	898 (14.8)	5.4
200-299	731 (11.2)	809 (8.8)	8.2	689 (11.4)	617 (10.2)	4
300-499	2,274 (34.9)	2,661 (29.0)	13	2,072(34.2)	1,966 (32.4)	3.8
≥500	1,911 (29.3)	2,528 (27.4)	4.2	1,746 (28.8)	1,720 (28.3)	1
Year, n(%)						
2009	15 (0.2)	87 (0.9)	9.4	15 (0.2)	22 (0.4)	1.5
2010	33 (0.5)	168 (1.8)	12.3	33 (0.5)	35 (0.6)	0.3
2011	40 (0.6)	238 (2.6)	15.7	40 (0.7)	47 (0.8)	0.9
2012	83 (1.3)	503 (5.5)	23.3	83 (1.4)	82 (1.4)	0
2013	166 (2.5)	740 (8.0)	24.8	166 (2.7)	168 (2.8)	0.1
2014	317 (4.9)	746 (8.1)	13.1	317 (5.2)	300 (5.0)	1.1
2015	488 (7.5)	998 (10.8)	11.6	486 (8.0)	532 (8.8)	2.6
2016	791 (12.1)	1,109 (12.0)	0.3	745 (12.3)	868 (14.3)	6.2
2017	1,060 (16.3)	1,271 (13.8)	7	985 (16.3)	1,025 (16.9)	1.9
2018	1,276 (19.6)	1,347 (14.6)	13.3	1,174 (19.4)	1,157 (19.1)	0.7
2019	1,512 (23.2)	1,355 (14.7)	21.9	1,362 (22.5)	1,232 (20.3)	5.5
2020	731 (11.2)	654 (7.1)	14.4	654 (10.8)	592 (9.8)	3.6

† SD=standard deviation, ‡ IQR=interquartile range

Table 2 Outcomes after propensity score matching

	Laparoscopic	Open	Unadjusted analysis			Adjusted analysis				
			OR <sup>†</sup>	CI <sup>‡</sup> (95%)	p	OR <sup>†</sup>	CI <sup>‡</sup> (95%)	p		
Complication, n (%)										
Surgical site infection	172 (2.6)	350 (3.8)	0.69	0.57-0.83	<0.0001	0.70	0.56-0.86	0.0007		
Acute postoperative pain	390 (6.0)	670 (7.3)	0.81	0.71-0.93	0.0016	0.69	0.60-0.79	<0.0001		
Bleeding	47 (0.7)	93 (1.0)	0.71	0.50-1.01	0.0601	0.84	0.56-1.25	0.3863		
Seroma / Edema	6 (0.1)	16 (0.2)	0.53	0.21-1.37	0.1854	0.39	0.12-1.24	0.1096		
Fever	32 (0.5)	42 (0.5)	1.08	0.68-1.71	0.7475	1.00	0.59-1.69	0.9956		
Pneumonia	9 (0.1)	11 (0.1)	1.16	0.48-2.80	0.7441	1.13	0.38-3.41	0.8261		
Urinary tract infection	42 (0.6)	44 (0.5)	1.35	0.87-2.07	0.1620	1.21	0.75-1.95	0.4309		
Bowel obstruction	5 (0.08)	4 (0.04)	1.77	0.48-6.60	0.3950	2.08	0.78-9.12	0.3303		
Chronic postoperative pain	284 (4.4)	581 (6.3)	0.68	0.59-0.78	<0.0001	0.83	0.70-0.98	0.0291		
Recurrence, n (%)	46 (0.7)	117 (1.3)	0.53	0.39-0.78	0.0007	0.68	0.45-1.01	0.0558		
			Unadjusted		Adjusted					
			Laparoscopic	Open	Laparoscopic	Open				
			Means ±SD <sup>§</sup>	Means ±SD <sup>§</sup>	Difference±SE <sup>¶</sup>	p	Means ±SD <sup>§</sup>	Means ±SD <sup>§</sup>	Difference±SE <sup>¶</sup>	p
Length of hospital stay (day)			2.92±1.91	2.98±2.69	0.06±0.03	0.1013	2.91±1.94	2.97±2.61	0.06±0.04	0.1307

†OR odds ratio, ‡CI confidential interval, §SD standard deviation, ¶ SE standard error

Table 3 Sensitivity analysis with changing postoperative period

	Unadjusted analysis			Adjusted analysis		
	OR <sup>†</sup>	CI (95%) <sup>‡</sup>	p	OR <sup>†</sup>	CI (95%) <sup>‡</sup>	p
Complication within 30 days						
Surgical site infection	0.69	0.57-0.83	<0.000	0.70	0.56-0.86	0.0007
Acute postoperative pain	0.81	0.71-0.93	0.0016	0.69	0.60-0.79	<0.0001
Bowel obstruction	1.77	0.48-6.60	0.3950	2.08	0.78-9.12	0.3303
Complication within 60 days						
Surgical site infection	0.77	0.65-0.92	0.0041	0.79	0.64-0.96	0.0159
Acute postoperative pain	0.86	0.80-0.94	0.0005	0.82	0.75-0.90	<0.0001
Bowel obstruction	1.18	0.36-3.87	0.7852	1.10	0.32-3.90	0.8728
Complication within 90 days						
Surgical site infection	0.77	0.65-0.91	0.0020	0.78	0.64-0.95	0.0114
Acute postoperative pain	0.86	0.80-0.94	0.0004	0.82	0.74-0.90	<0.0001
Bowel obstruction	1.18	0.36-3.87	0.7852	1.11	0.32-3.90	0.8728
Chronic postoperative pain						
above 90 days	0.68	0.59-0.78	<0.0001	0.83	0.70-0.98	0.0291
above 120 days	0.67	0.58-0.79	<0.0001	0.83	0.70-0.98	0.0324
above 180 days	0.67	0.58-0.78	<0.0001	0.83	0.70-0.98	0.0324

<sup>†</sup>OR odds ratio, <sup>‡</sup>CI confidential interval

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**Online resource 1 MEDIS-DC codes for complications**

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Surgical site infection	6829010, 6829014, 6829029, 6869050, 7290026, 8799006, 8833977, 8835326, 8835353, 8836665, 8836796, 8839756, 8845681, 9983005, 9985006, 9985039
Acute postoperative pain	8835913 8836793 8838060 8845802 9989020 8832414
Bleeding	4590002, 8830697, 8833916, 8835847, 9249027
Edema	8848922, 8830618 6072008 8830705 6248005 8835852
Fever	7806011, 8835356
Urinary tract infection	5950005, 5959003, 5959015, 5978015, 5990009, 8838561
Vas deferens injury	8835836
Intestinal injury	8834767, 8837685
pneumonia	9973011, 4860030
Bowel obstruction	8835320, 9974018
Chronic postoperative pain	8835913 8836793 8838060 8845802 9989020 8847821

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## Online resource 2 Outcomes before propensity score matching

	Laparoscopic	Open	Unadjusted analysis		
	(n=6,512)	(n=9,216)	OR <sup>†</sup>	CI <sup>‡</sup> (95%)	p
<b>Complication, n (%)</b>					
Surgical site infection	172 (2.6)	350 (3.8)	0.69	0.57-0.83	<0.0001
Acute postoperative pain	390 (6.0)	670 (7.3)	0.81	0.71-0.93	0.0016
Bleeding	47 (0.7)	93 (1.0)	0.71	0.50-1.01	0.0601
Seroma / Edema	6 (0.1)	16 (0.2)	0.53	0.21-1.37	0.1854
Fever	32 (0.5)	42 (0.5)	1.08	0.68-1.71	0.7475
Pneumonia	9 (0.1)	11 (0.1)	1.16	0.48-2.80	0.7441
Urinary tract infection	42 (0.6)	44 (0.5)	1.35	0.87-2.07	0.1620
Bowel obstruction	5 (0.08)	4 (0.04)	1.77	0.48-6.60	0.3950
Chronic postoperative pain	284 (4.4)	581 (6.3)	0.68	0.59-0.78	<0.0001
Recurrence, n (%)	46 (0.7)	117 (1.3)	0.53	0.39-0.78	0.0007
			Difference±SE <sup>¶</sup>	p	
<b>Anesthesia</b>					
Time (min), mean (SD <sup>§</sup> )	141 (±49.4)	51.4 (±54.8)	88.3 ±1.17	<0.0001	
Missing data, n (%)	2,981 (45.8)	4,676 (50.7)			
Length of hospital stay (day), mean ±SD <sup>§</sup>	2.92±1.91	2.98±2.69	0.06±0.03	0.1013	

†OR odds ratio, ‡CI confidential interval, §SD standard deviation, ¶ SE standard error



Online resource 3 Outcomes of propensity score matching in 2009-2015 and 2016-2020

	Adjusted analysis in 2009-2015			Adjusted analysis in 2016-2020		
	OR <sup>†</sup>	CI <sup>‡</sup> (95%)	p	OR <sup>†</sup>	CI <sup>‡</sup> (95%)	p
<b>Complication</b>						
Surgical site infection	0.58	0.36-0.96	0.0323	0.73	0.58-0.91	0.0061
Acute postoperative pain	0.69	0.49-0.95	0.0229	0.69	0.59-0.80	<0.0001
Bleeding	0.93	0.37-2.36	0.8819	0.79	0.50-1.24	0.3043
Seroma	NA <sup>§</sup>			0.64	0.21-2.00	0.4464
Fever	0.84	0.27-2.59	0.7627	0.94	0.53-1.67	0.8313
Pneumonia	NA <sup>§</sup>			1.07	0.31-3.71	0.9183
Urinary tract infection	2.47	0.87-7.00	0.0882	1.06	0.63-1.81	0.8191
Bowel obstruction	NA <sup>§</sup>			2.26	0.40-13.00	0.3601
Chronic postoperative pain	0.71	0.54-0.84	0.0170	0.90	0.74-1.11	0.3412
Recurrence	0.50	0.26-0.98	0.0422	0.91	0.57-1.45	0.6681
	Laparoscopic	Open		Laparoscopic	Open	
	Means ±SD <sup>§</sup>	Means ±SD <sup>§</sup>	Difference±SE <sup>¶</sup> p	Means ±SD <sup>§</sup>	Means ±SD <sup>§</sup>	Difference±SE <sup>¶</sup> p
Length of hospital stay (day)	2.96±1.87	3.17±2.83	0.21±0.09 0.0240	2.89±1.95	2.96±2.55	0.07±0.05 0.1333

†OR odds ratio, ‡CI confidential interval, §NA not available

Online resource 4 Sensitivity analysis with multilevel model

	Unadjusted analysis			Adjusted analysis		
	OR <sup>†</sup>	CI <sup>‡</sup> (95%)	p	OR <sup>†</sup>	CI <sup>‡</sup> (95%)	p
Complication						
Surgical site infection	0.69	0.57-0.83	<0.0001	0.91	0.69-1.20	0.4795
Acute postoperative pain	0.81	0.71-0.93	0.0016	0.66	0.55-0.80	<0.0001
Bleeding	0.71	0.50-1.01	0.0601	0.78	0.46-1.32	0.358
Seroma / Edema	0.53	0.21-1.37	0.1854	Non-estimated value		
Fever	1.08	0.68-1.71	0.7475	Non-estimated value		
Pneumonia	1.16	0.48-2.80	0.7441	Non-estimated value		
Urinary tract infection	1.35	0.87-2.07	0.1620	1.44	0.86-2.43	0.1672
Bowel obstruction	1.77	0.48-6.60	0.3950	3.10	0.71-13.07	0.133
Chronic postoperative pain	0.68	0.59-0.78	<0.0001	0.85	0.71-1.01	0.0577
Recurrence	0.53	0.39-0.78	0.0007	0.70	0.48-1.04	0.0782

<sup>†</sup>OR odds ratio, <sup>‡</sup>CI confidential interval