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ORIGINAL ARTICLE

Severity classification and risk factors of seroma after transabdominal preperitoneal hernia repair

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Abstract

Purpose This study aimed to develop a classification to precisely describe seroma following transabdominal preperitoneal hernia repair (TAPP) as well as identify risk factors and create a prediction model for seroma development.

Methods Postoperative seroma was classified into grades 0–IV, with grades ≥ II defined as the seroma group (S group: 265 cases), which was compared with the normal course group (N group: 1,279 cases) to determine risk factors using logistic regression analysis. A prediction model was developed based on these independent predictors. Receiver operating characteristic (ROC) curve analysis was conducted to assess the discriminability and calibrability of the model. Additionally, a model to validate the incidence of seroma was used for risk stratification.

Results This classification revealed grades 0, I, II, III, and IV in 1,194 (70.9%), 85 (5.5%), 236 (15.3%), 12 (0.8%), and 17 (1.1%) patients, respectively. Multivariate analysis revealed risk factors for seroma formation, including age of > 66 years, American Society of Anesthesiologists scores of ≥ 2, surgery for recurrent hernia, size of hernia defect of > 3 cm, and duration of sickness of > 1 year. The prediction model demonstrated the rates of seroma in the low, moderate, and high score groups of 10.5% (103/984), 23.7% (99/417), and 44.1% (63/143), respectively.

Conclusion A postoperative complication of TAPP was proposed as a severity classification of seroma. A model to predict the seroma was developed based on the identified risk factors, thereby confirming the possibility of preoperative prediction of the seroma.

Keywords TAPP · Abandon sac · Inguinal hernia · Risk assessment · Seroma · Seroma classification

Introduction

Seroma, after inguinal hernia repair, is a prevalent and routinely experienced complication. The frequency of seroma widely varies among reports, ranging from 0 to 16.4% in transabdominal preperitoneal hernia repair (TAPP) [1–5]. However, seroma is the most frequent complication of TAPP. This may be because the definition and severity classification of seroma has not been internationally determined, and no criteria have included the diagnosis timing, which has prevented discussion on the etiology and prevention of the complication. Lack of definition prevents discussion of seroma, as stated in the guidelines [6]. The Clavien–Dindo classification, which is predominantly used for postoperative complications, is not useful for seroma, which is a complication that is frequently followed up with observation. It is a prevalent complication, but its etiology remains unclear. Seroma may not be a serious complication, but it should not be ignored, considering that inguinal hernia repair has become minimally invasive after introducing laparoscopic surgery as well as early return to normal activity. The guidelines regarding seroma list heart failure, coagulation disorders, and congestive liver disease as risk factors [6–8]. Recently, Morito et al. revealed that direct inguinal hernia

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and hernia size of ≥3 cm as risk factors for seroma development after TAPP in Japan [9]. However, this report describes no definition and severity of seroma. Methods for preventing seroma have been reported, such as suturing and fixation of transversalis fascia, but cases to which such procedures should be performed remain unclear [10, 11]. Therefore, we developed a severity classification based on the size of the seroma and the residual time since surgery and classified the seroma cases experienced at our institution following this classification. The classification enables an improved discussion on seroma. Additionally, we searched for risk factors among the parameters that could be preoperatively determined to develop seroma diagnosed as moderate or higher in the classification and created a prediction score. Cases that should be treated with preventive procedures for seroma were identified after determining risk factors. This may also contribute to clinical practice.

Materials and methods

Patients

At our institution, 2,141 patients (1,892 unilateral and 249 bilateral) with inguinal hernias older than 16 years were operated on for inguinal hernia repair during 8 years in Kariya Toyota General Hospital. Bilateral cases, emergency surgery, anterior approach, postprostatectomy, and cases undergoing other operations simultaneously were excluded (597 cases). This study included 1,544 patients who underwent TAPP for unilateral lesions. A suitably constituted Ethics Committee of the institution approved the protocol for this study, which conforms to the provisions of the Declaration of Helsinki (Ethics Review Committee of Kariya Toyota General Hospital, Approval No. 205). Patient consent was obtained on an opt-out basis as this is a retrospective study.

Surgical indication and technique

Circular incision TAPP (C-TAPP) is performed in our department. C-TAPP is the primary surgical technique performed in our country. A circular incision is made through the vaginal process and the mesh is inserted into the abdominal side [12]. This is similar to the recently reported method as “abandon sac” [13–15]. This procedure has been performed mainly for indirect inguinal hernias since the 2000s in Japan. The operators ranged from experienced surgeons with >2,000 cases to residents. However, in this study, surgeons with >100 surgeries acted as either supervisors or operators in all surgeries.

Regular follow-up

Patients were discharged from the hospital 1 day postoperatively, and outpatient visits were made before 2 weeks and 3 months postoperatively. The follow-up period was further extended in symptomatic cases. Patients who experience any abnormality after completing the follow-up are advised to visit the outpatient department of our hospital. The presence and size of the serous species are primarily diagnosed by physical examination; however, CT and ultra sound are used when the diagnosis is unclear.

Severity classification for post-TAPP seroma and group classification

The severity classification of seroma has no clear criteria at this time. We classified the seromas into grades 0, I, II, IIIa, IIIb, and IV following the size of the seroma, the duration after surgery, and the presence or absence of aspiration. The long diameter of the seroma was classified as mild (<3 cm), moderate (3–6 cm), or severe (>6 cm), and the follow-up presence or absence of seroma 1 day postoperatively determined postoperative follow-up period, including the first postoperative visit (within 2 weeks), 3 months, and 6 months. Grade 0 indicates that no seroma is observed during the surgical course, grade I if the seroma resolves spontaneously from 1 day postoperatively to the first postoperative outpatient visit, Grade II if the seroma resolves spontaneously from the first postoperative outpatient visit to 3 months postoperatively, grade IIIa if the seroma is mild to moderate at 3 months postoperatively or mild at 6 months postoperatively, grade IIIb if the seroma is severe at 3 months postoperatively or moderate to severe at 6 months or more postoperatively, and grade IV if invasive treatment, such as puncture aspiration was performed (Fig. 1). The highest grade during the course of the study was considered the final diagnosis. Patients with seroma of grade≥II were classified into the seroma group (S group: 265 cases) and the normal course group (N group: 1,279 cases). We compared the S and N groups based on the patient background and investigated the risk factors for developing seroma of grade≥II.

Clinical variables

Clinical variables included age, gender, body mass index, American Society of Anesthesiologists scores (ASA), side of hernia, diabetes, type of hernia, recurrent hernia, abdominal surgical history, duration of sickness, antithrombotic therapy, and size of hernial defect.

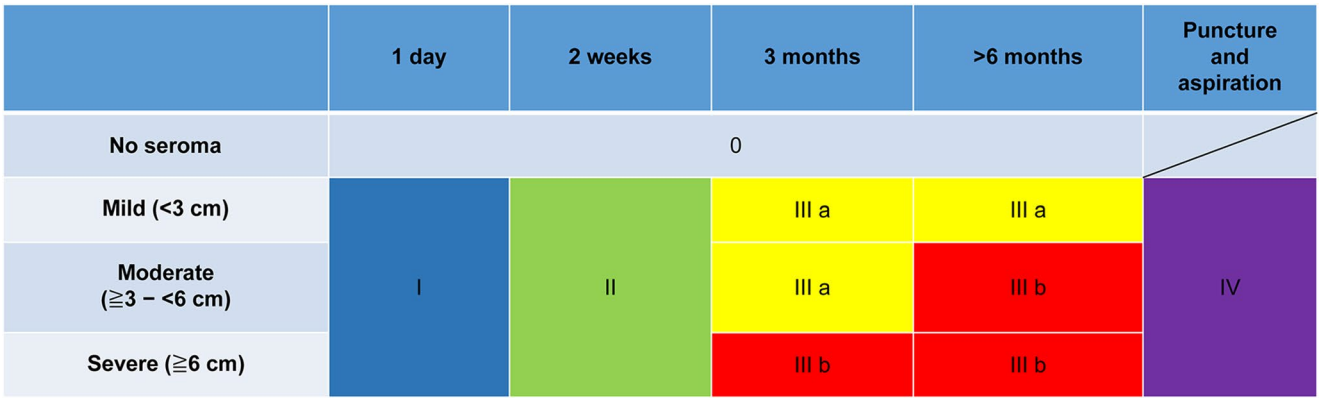

Fig. 1 Seroma classification used in this study

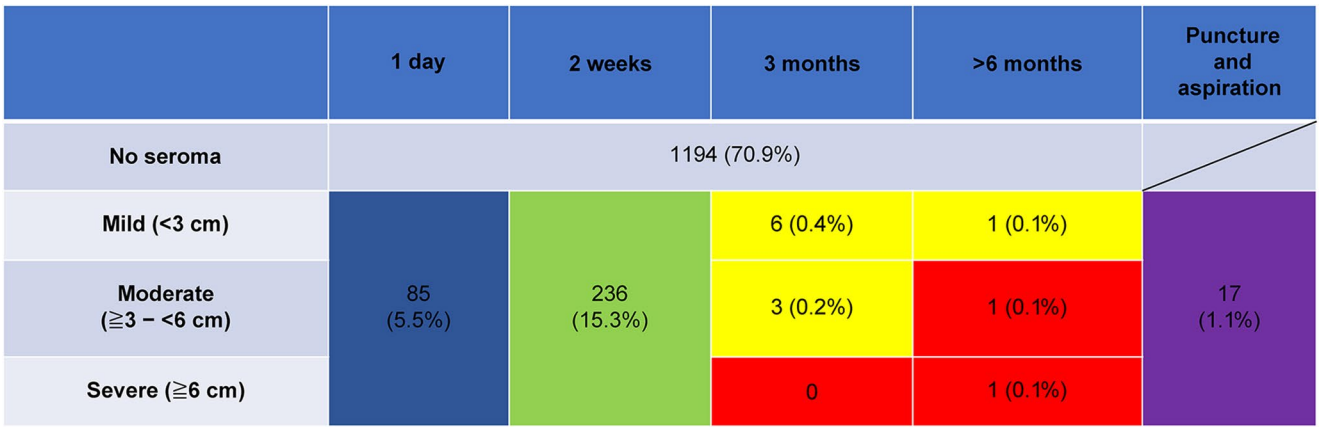

Fig. 2 Frequency of seroma after transabdominal preperitoneal hernia repair at our institution

Statistical analysis

The statistical software EZR was used for statistical analyses [16]. Continuous variables were presented as the median and IQR (25%, 75%), with the Mann–Whitney U test. Categorical variables were presented as numbers and percentages, with the Chi-square test. A significant difference was defined as $p<0.05$. Univariate analysis was conducted to compare clinical variables between the N group and the S group. Significant continuous variables were transformed into categorical variables to determine the cutoff line using receiver operating characteristic (ROC) curves. The suitable cutoff point with the highest sum of sensitivity and specificity was selected for variables. Multivariate analysis using logistic regression included clinical variables with $p<0.05$ on univariate analysis.

Score derivation

Clinical variables with $p<0.05$ by multivariate analysis were considered factors for the prediction score. Odds ratios (ORs) in the multivariate analysis were rounded off to identify the score. An ROC curve was drawn to evaluate the ability of the score to predict forming seroma of ≥II. The statistical information was presented by forest plots. ROC curves were used to evaluate the suitable cutoff points of the factors. The total score calculated was categorized into the low, moderate, and high score groups. The data set of 1,544 cases included herein was used to calculate the frequency of seroma of ≥II in each group.

Results

Result of seroma classification

Figure 2 shows the results of the seroma classification. Grades 0, I, II, IIIa, IIIb, and IV were observed in 1,194 (70.9%), 85 (5.5%), 236 (15.3%), 10 (0.1%), 2 (0.0%), and 17 (1.1%) cases, respectively. Thus, grades ≥ II were observed in 265 (17.2%) patients.

Comparison between the N group and the S group.

Table 1 shows the univariate analysis. The S group included older ($p<0.001$), males ($p=0.037$), higher ASA ($p<0.001$), diabetes ($p<0.016$), recurrence cases ($p=0.023$),

Table 1 Comparison between the S and N group characteristics

	Normal course (1,279)	Seroma (265)	*p*
Median age, y (IQR)*	62 (49, 71)	66 (57, 74)	<0.001
Gender (male)	1,134 (88.7)	247 (93.2)	0.037
BMI (kg/m^2)*	22.7 (20.9, 24.4)	22.6 (21.0, 24.5)	0.883
ASA (1/2/3/4, 5)	585/688/6/0	80/179/6/0	<0.001
Side of hernia(right)	700 (54.7)	157 (59.2)	0.201
Diabetes	61(4.8)	23 (8.7)	0.016
Presence of indirect hernia	1,013 (79.2)	196 (74.0)	0.072
Presence of direct hernia	287 (22.4)	74 (27.9)	0.066
Presence of femoral hernia	42 (3.3)	4 (1.5)	0.178
Surgery for recurrent hernia	45 (3.5)	18 (6.8)	0.023
Abdominal surgical history(n)	448 (35.1)	93 (35.1)	1.000
Period of sickness > 1 year	293 (24.6)	123 (48.6)	<0.001
Antithrombotic therapy (n)	126 (9.9)	30 (11.3)	0.542
Size of hernia defect > 3 cm	408 (31.9)	141 (53.2)	<0.001

Note: Data are shown as number of patients (%)

Abbreviations: ASA: American Society of Anesthesiologists; BMI: body mass indexmedian, IQR: interquartile range (25%, 75%)

Table 2 Seroma predictors; multivariable logistic regression analysis

Variables	Normal course	Seroma	OR	95% CI	*p*
Age≥66	497 (38.9)	139 (52.5)	1.380	1.010–1.900	0.045
Male gender	1,134 (88.7)	247 (93.2)	0.582	0.325–1.040	0.068
ASA≥2	694 (54.3)	185 (69.8)	1.550	1.100–2.170	0.011
Diabetes	61 (4.8)	23 (8.7)	1.520	0.871–2.640	0.141
Surgery for recurrent hernia	45 (3.5)	18 (6.8)	2.060	1.110–3.840	0.022
Size of hernia defect > 3 cm	408 (31.9)	141 (53.2)	1.910	1.420–2.560	<0.001
Period of sickness > 1 year	293 (24.6)	123 (48.6)	2.770	2.070–3.710	<0.001

Note: Data are shown as number of patients (%)

Abbreviations: ASA: American Society of Anesthesiologists; IQR: interquartile range (25–75%)

disease duration of > 1 year (p < 0.001), and hernia defect of > 3 cm (p < 0.001). Table 2 shows the multivariable logistic regression analysis. ASA of ≥2 (OR: 1.55, 95% confidence interval [CI]: 1.10–2.17), recurrent hernia (OR: 2.06, 95% CI: 1.11–3.84), size of hernia defect of > 3 cm (OR: 1.91, 95% CI: 1.42–2.56), and disease duration of > 1 year (OR: 2.77, 95% CI: 2.07–3.71) presented a significantly higher risk of seroma formation.

Prediction model for seroma.

Points were assigned to each of the five variables according to the regression analysis. Age of ≥66 years (1 point), ASA of ≥2 (2 points), recurrent hernia (2 points), size of hernia defect of ≥3 cm (2 points), and disease duration of ≥1 year (3 points) (Table 3). ROC curve was generated to assess the predictive ability. The appropriate cutoff point was 4 (Youden's index was the maximum). The sensitivity and specificity at the cutoff point were 0.69 and 0.61, respectively. The area under the ROC curve (AUC) at the cutoff point was 0.70 (95% CI: 0.66–0.73), which indicated acceptable discrimination (Fig. 3).

Table 3 Seroma prediction model

Variables	Score
Age, year	
<66	0
≥66	1
ASA	
<2	0
≥2	2
Primary or recurrent hernia	
Primary	0
Recurrence	2
Size of hernia defect	
<3 cm	0
≥3 cm	2
Period of sickness	
<1 year	0
≥1 year	3

Abbreviations: ASA: American Society of Anesthesiologists

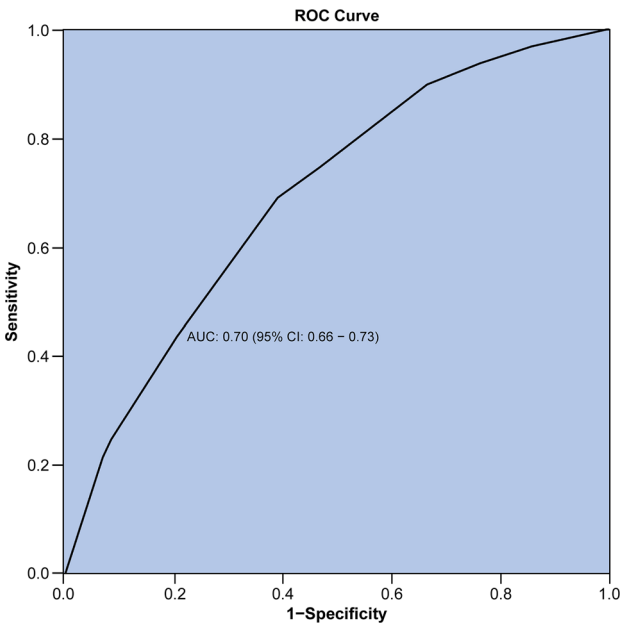

Fig. 3 Receiver operating characteristic (ROC) curve for seroma prediction model

The area under ROC curve (AUC) for this model is 0.70 (95% CI: 0.66–0.73). CI, confidence interval

Validation of prediction model for seroma.

Patients were stratified based on the model into low (scores: 0–3), moderate (scores: 4–6), and high (scores:

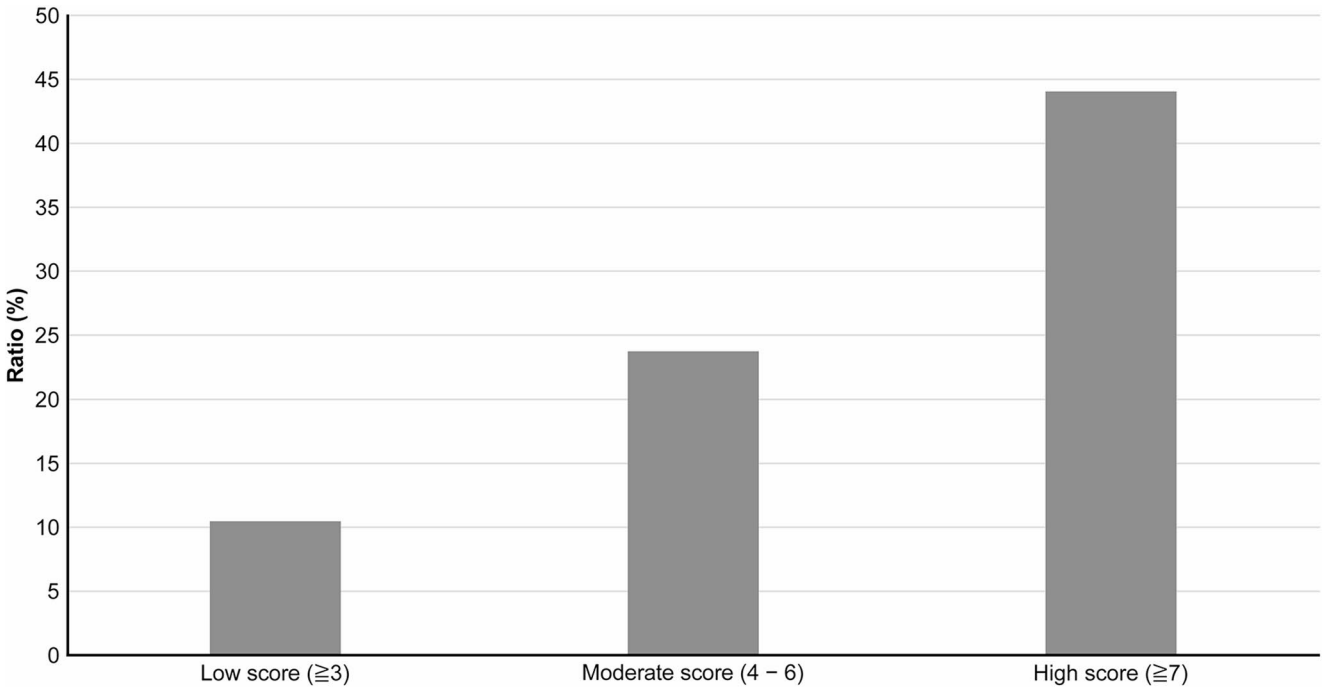

Fig. 4 Risk stratification according to prediction model. Seroma rates in the low, moderate, and high categories are 10.5%, 23.7%, and 44.1%, respectively

7–10) groups, with seroma rates of 10.5% (103/984), 23.7% (99/417), and 44.1% (63/143), respectively (Fig. 4).

Discussion

This study classified the severity of seroma after TAPP. The results revealed that 265 (17.2%) patients had seroma of moderate disease or higher severity (Grade II or higher) including 17 (1.1%) required aspiration. Age of ≥66 years, ASA score of ≥2, size of hernia defect of ≥3 cm, and disease duration of ≥1 year were identified as risk factors for moderate to severe seroma. A seroma prediction model was developed at the point according to each OR, with an AUC of 0.70 (95% CI: 0.66–0.73). This model can be used as an index for predicting seroma. Hence, the formation of postoperative seroma can be predicted to some extent based on preoperative information.

To the best of our knowledge, no report has classified the severity of seroma after TAPP. No study has reported the development of a predictive model for seroma. Morales-Conde et al. reported a classification method for seroma in ventral hernia in 2012. They defined type 0 as no clinical seroma (0a as no seroma after clinical examination and radiological examinations and 0b as those detected radiologically but not detected clinically); type I as clinical seroma lasting for <1 month; type II as seroma with excessive duration, clinical seroma lasting for >1 month (IIa between 1 and 3 months and IIb between 3 and 6 months); type III as symptomatic seromas that may require medical treatment, minor seroma-related complications (seroma lasting for >6 months, with esthetic complaints of the patient due to seroma, discomfort related to the seroma that does not allow normal activity to the patient, pain, and superficial infection with cellulitis); and type IV as seroma that requires treatment, with major seroma-related complications (need to aspirate the seroma, seroma drained spontaneously, applicable to open approach, deep infection, recurrence, and mesh rejection). The classification based on duration is similar to our study [17]. However, the mean size of the seroma is smaller for inguinal hernias than for ventral hernias, and the cutoff values for the disease duration and seroma size are shorter and smaller than those in our study, respectively. Morito et al. 2021 investigated risk factors for seroma and hematoma formation and defined them as cases with direct inguinal hernia and hernia portal size of ≥3 cm [9]. Additionally, they revealed that the risk factor of a hernia size of ≥3 cm was consistent with our study, but our result indicated a direct inguinal hernia as not a risk factor. This point warrants further study in the future. Unfortunately, the report does not clearly define seroma. Globally, our report is the first to develop a risk prediction model for postoperative seroma.

Noteworthily, this study is the first to classify the severity of seroma after TAPP. The degree of severity should be indicated when reporting the frequency of seroma. In recent

years, various techniques have been involved to prevent seroma, such as sac fixation to the pubic bone by inversion, hernial orifice closure, and complete hernia sac isolation [10, 18–20]. However, not only does this technique increase operative time and postoperative pain, but reports indicate that it does not prevent seroma [21]. At least, it is considered an over invasive procedure to perform an antiseroma technique on patients with a low risk of developing seroma. Performing procedures to only prevent seroma in high-risk cases is possible if the risk prediction model derived in this study can be used to determine the risk of developing seroma preoperatively.

Limitations of this study include its retrospective design and the timing of aspirating the seroma, which is left to the attending surgeon's discretion. Additionally, we determine the size of the seroma primarily by physical examination; however, we add CT or ultra sound when the size is not clear upon the physical examination alone. If we do not suspect seroma at all on physical examination, imaging examinations are not performed. Because only surgeons with a certain level of experience perform the physical examinations, the frequency is low; however there may be a few cases in which the seroma is missed on physical examination and imaging examinations, such as CT or ultra sound, are not performed. Moreover, the AUC of 0.70 is slightly weak as a predictive model. This may be because the risk factor parameters were limited to only information that were preoperatively identified. This is to quantify the risk based on preoperative information and to modify the content of the surgical procedure. Preoperative information alone may be insufficient to predict risk factors because a complex of factors, including intraoperative manipulation, may cause seroma formation. This is the first report of this study after inguinal hernia surgery, and new factors are expected to be investigated based on the results of this study to develop more powerful models in the future.

We propose a novel classification system for the severity of post operative seromas following TAPP inguinal hernia repairs. Additionally, a risk prediction model for seromas has been developed based on regression analysis, which requires validation in large scale datasets.

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Author contributions SH, TH made substantial contributions to the conceptualization and design of the work. KW, KS, HS, HM, MY, MT substantial contributions to acquisition of the data. SH wrote the first manuscript, and it was revised by KK, RO, ST. All authors checked the final draft and approved it.

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Declarations

Ethical approval A suitably constituted Ethics Committee of the institution (Ethics Review Committee of Kariya Toyota General Hospital, Approval No. 2050) approved the protocol for this research project, which conforms to the provisions of the Declaration of Helsinki.

Informed consent Patient consent was obtained on an opt-out basis because of this study's retrospective design.

Animal studies Not applicable.

Competing interests Drs. Shunsuke Hayakawa, Tetsushi Hayakawa, Kaori Watanabe, Kenta Saito, Hirotaka Miyai, Hiroyuki Sagawa, Ryo Ogawa, Minoru Yamamoto, Kenji Kobayashi, Moritsugu Tanaka, and Shuji Takiguchi declare that they have no conflict of interest.

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