

Outcomes of minimally invasive surgery for gallbladder tumorous lesions before and after insurance approval of laparoscopic gallbladder bed resection in Japan

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Abstract

Purpose: The nationwide insurance approval of laparoscopic gallbladder bed resection (GBR) in April 2022 accelerated the adoption of minimally invasive surgery (MIS) for gallbladder cancer in Japan. This study compared surgical outcomes for gallbladder tumorous lesions before and after insurance coverage.

Methods: This retrospective single-center study included 85 patients who underwent surgery for gallbladder tumorous lesions between 2018 and 2024. Patients were divided into a before insurance coverage (BIC, n=45) and after insurance coverage (AIC, n=40) group. Surgical procedures included laparoscopic cholecystectomy, total-layer cholecystectomy, GBR, and extrahepatic bile duct resection.

Results: The proportion of malignant lesions was similar between groups. In suspected T1 cases, secondary GBR was required only in the BIC group, whereas no additional surgery was needed in the AIC group. Laparoscopic GBR was significantly more frequent in the AIC group for suspected T2/T3a disease. R0 resection rates and recurrence patterns were comparable between groups, with no regional

lymph node recurrence observed in this cohort. Among patients postoperatively diagnosed with malignant tumors, Kaplan–Meier analysis demonstrated no significant difference in overall survival between the two groups. Lymph node metastasis was the only significant risk factor for recurrence, whereas the adoption of MIS was not associated with an increased risk of recurrence.

Conclusion: Following insurance approval, a majority of gallbladder tumorous lesions were managed using MIS without an apparent compromise in oncological outcomes and with fewer staged additional resections. However, reliable preoperative differentiation between benign and malignant lesions remains challenging, and the retrospective single-center design of this study represents an important limitation.

Key words: Gallbladder cancer, Laparoscopic gallbladder bed resection, Total-layer cholecystectomy, Minimally invasive surgery

Introduction

Gallbladder tumorous lesions are frequently encountered in routine clinical practice, and the increasing availability of advanced imaging modalities has resulted in rising incidental detection¹. These lesions encompass a broad pathological spectrum ranging from benign entities such as cholesterol and inflammatory polyps to adenomas, intramucosal

carcinoma, and invasive gallbladder cancer^{2,3}. Owing to this pathological heterogeneity and the limited accuracy of preoperative diagnosis, selecting an optimal surgical procedure that avoids both overtreatment and undertreatment remains a major clinical challenge.

Historically in Japan, open surgery was recommended for lesions with malignant potential due to concerns regarding tumor dissemination associated

with gallbladder perforation during minimally invasive surgery (MIS) ⁴. With the accumulating evidence demonstrating favorable oncologic outcomes with laparoscopic procedures, laparoscopic gallbladder bed resection (GBR) was approved for national insurance coverage in April 2022. The latest national guidelines now support laparoscopic surgery for gallbladder cancer up to T2 disease, which has led to its rapid adoption across institutions nationwide (Clinical Practice Guidelines for the Management of Biliary Tract Cancers, 4th edition; Japanese). Despite this paradigm shift, important diagnostic and clinical uncertainties persist, and the real-world impact of expanding MIS indications on surgical decision-making and outcomes remains unclear. In addition, the optimal extent of resection and lymph node dissection for advanced gallbladder cancer remains controversial⁵, with substantial inter-institutional variation, further complicating surgical decision-making.

Following insurance approval, our institution adopted a laparoscopic-first policy, performing Total-layer cholecystectomy (TLC) for suspected T1 disease and laparoscopic GBR for suspected T2/T3a and N0 disease. The purpose of this study was to compare real-world surgical strategies and outcomes for gallbladder tumorous lesions before and after the nationwide insurance approval of laparoscopic GBR in Japan, and to assess the clinical impact of expanded use of MIS in routine practice.

Patients and Methods

Patients

Eighty-five consecutive patients who underwent resection for gallbladder tumorous lesions at Kindai University Hospital between January 2018 and December 2024 were retrospectively reviewed. The last follow-up date was December 2025.

Study groups

Patients were stratified into two cohorts: 45 in the before insurance coverage (BIC) group and 40 in the after insurance coverage (AIC) group. Surgical procedures, short-term outcomes, and long-term oncological outcomes were compared.

Surgical indications

Small gallbladder tumorous lesions were indicated for resection when one or more of the following findings suggested at least suspected T1 disease: lesion diameter ≥ 10 mm, sessile morphology, interval enlargement, or abnormal intralesional vascularity. In

advanced cases, patients with lymph node metastasis beyond the hepatoduodenal ligament, peritoneal dissemination, or distant metastasis were excluded. Neoadjuvant chemotherapy aimed at downstaging or enabling conversion surgery was not performed during this study period.

Selection algorithm for surgical procedures and its implementation

Surgical procedures were determined based on estimated preoperative tumor depth and nodal status; representative imaging findings are shown in Figure 1. For suspected T1a/b lesions (Figure 1a), patients in the BIC period underwent conventional laparoscopic cholecystectomy (LC), followed by secondary open gallbladder bed resection (GBR) when gallbladder cancer was confirmed postoperatively. Extrahepatic bile duct resection (BR) was added when cystic duct invasion or pericyclic duct lymph node (No. 12c) metastasis was identified. In contrast, during the AIC period, laparoscopic TLC was performed, with conversion to open GBR plus BR with regional lymphadenectomy when intraoperative findings demonstrated cystic duct invasion or No.12c metastasis. For suspected T2/T3a (Figure 1b) lesions without radiologic evidence of regional lymph node metastasis, open GBR was indicated during the BIC period—with additional BR if cystic duct invasion or No.12c metastasis was identified intraoperatively—while during the AIC period laparoscopic GBR was performed according to the same intraoperative criteria, with conversion to open BR as required. Hepatic parenchymal transection was performed using well-established techniques routinely employed in laparoscopic hepatectomy. As this surgical strategy was limited to patients without radiologic evidence of lymph node enlargement or suspected invasion of the extrahepatic bile duct, neither lymph node sampling nor lymphadenectomy within the hepatoduodenal ligament was performed in either group. This policy was informed by institutional observations indicating a relatively low frequency of regional nodal recurrence in radiologically N0 cases. For suspected T3b or N1 disease (Figure 1c), both periods consistently employed open GBR plus BR with regional lymphadenectomy. The surgical procedures that are strictly adhered to at our institution are as follows. TLC: To maintain the correct dissection plane, the procedure is performed under temporary hepatic inflow occlusion using the Pringle maneuver. For complete removal of lymphatic and neural tissues surrounding the cystic artery, en-bloc resection including the gallbladder plate is performed.

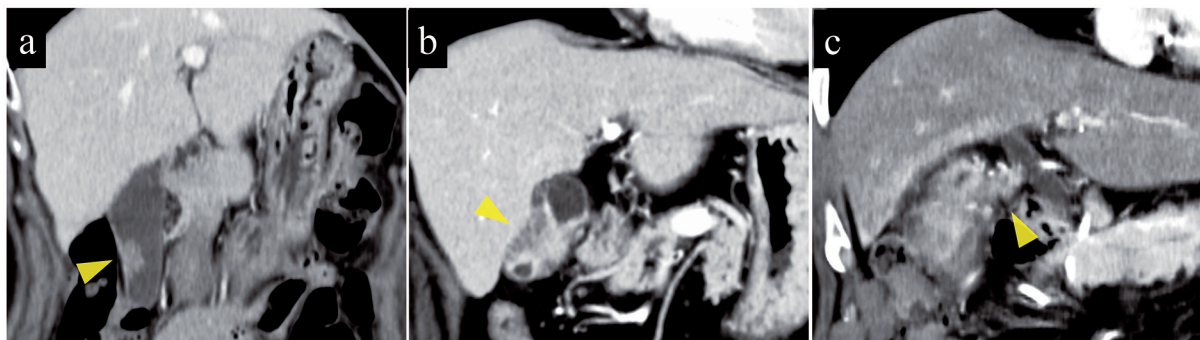


Figure 1

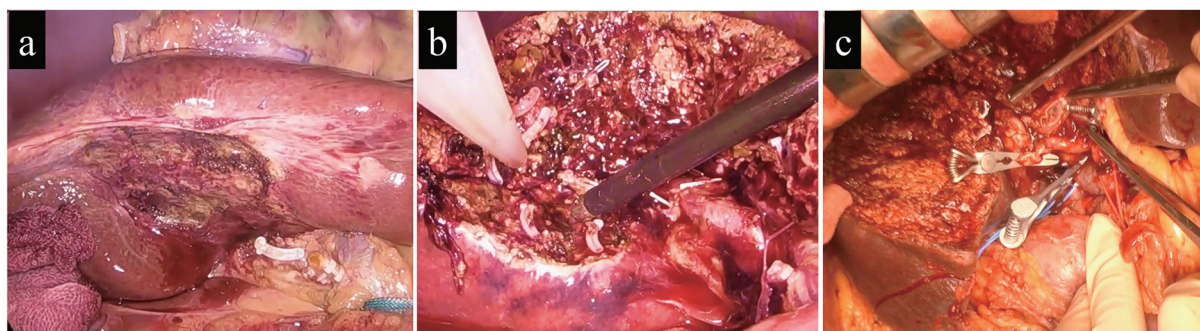


Figure 2

Laparoscopic GBR: Similar to TLC, en-bloc resection including the gallbladder plate is performed. Parenchymal transection is carried out with a surgical margin of at least 1 cm from the gallbladder wall and/or tumorous lesion. Intraoperative images obtained at the completion of transection are shown in Figure 2a, b, c.

Statistical analyses

Statistical analyses were performed using JMP version 17 (JMP Statistical Discovery). Continuous variables were compared using the Student's *t* test or the Mann–Whitney *U* test, as appropriate. Categorical variables were compared using the chi-square test or Fisher's exact test, with statistical significance defined as $p < 0.05$. Overall survival was estimated using the Kaplan–Meier method, and survival curves were generated using the same software. Survival curves were compared using the log-rank test.

Results

Clinical characteristics

Table 1 summarizes demographic and preoperative assessment data. The median age did not differ significantly between the groups (BIC, 67.2 years vs. AIC, 63.2 years), and there were no significant

differences in sex distribution or body mass index (BMI). Contrast-enhanced Computed Tomography (CT), Endoscopic Ultrasonography (EUS), and Magnetic Resonance Cholangiopancreatography (MRCP) were performed in the majority of patients in both groups, with no significant differences in the rates of each modality. EUS-fine needle aspiration test (FNA) was rarely performed (BIC, 1 case; AIC, 2 cases) and was limited to sampling of enlarged lymph nodes rather than intracholecystic lesions. Regarding preoperative staging, approximately half of the cases in both groups were clinically suspected to be T1 disease (BIC, 49%; AIC, 55%), with no significant difference in the distribution of suspected T stages between the groups.

Outcomes of suspected T1 cases

Table 2 shows the outcomes of suspected T1a/b lesions. TLC was significantly more common in the AIC group. The rate of malignancy on final pathology was approximately 20% in both groups. Secondary GBR was required only in the BIC group ($n = 2$). Recurrence occurred only in the BIC group and manifested as distant lymph node metastasis. Although the difference was not statistically significant, intraoperative bile leakage due to gallbladder injury occurred in two patients who

Table 1. Patient characteristics and preoperative assessment.

		BIC (n=45)	AIS (n=40)	<i>p</i> value
Characteristics	Age (years)	67.2 (37-86)	63.2 (36-90)	n.s.
	Sex (Female)	24 (53.3%)	18 (45.0%)	n.s.
	BMI	22.5 (15.1-33.9)	22.0 (14.0-32.6)	n.s.
Examinations	E-CT	42 (93%)	38 (95%)	n.s.
	EUS	38 (84%)	37 (92%)	n.s.
	MRCP	43 (95%)	39 (97%)	n.s.
	ERCP	2 (6%)	2 (5%)	n.s.
	PET	7 (15%)	7 (18%)	n.s.
Pathological Assessment	Biopsy	1 (LN)	2 (LN, liver)	n.s.
	Cytology	0	0	n.s.
Preoperative Evaluation (s/o)	T1a/b	22 (49%)	22 (55%)	n.s.
	T2/T3a	17 (38%)	15 (37%)	n.s.
	T3b-/N1	6 (13%)	3 (8%)	n.s.

BIC, Before Insurance Coverage; AIC, After Insurance Coverage; BMI, Body Mass Index; E-CT, Enhanced Computed Tomography; EUS, Endoscopic Ultrasound; MRCP, Magnetic Resonance Cholangiopancreatography; ERCP, Endoscopic Retrograde Cholangiopancreatography; PET, Positron Emission Tomography;

Table 2. Surgical outcomes of suspected T1a/b lesions.

		BIC (n=22)	AIC (n=22)	<i>p</i> value
Procedure	LC	18 (82%)	0 (0%)	<0.05
	LTC	4 (18%)	22 (100%)	<0.05
	Bile leakage	2 (9%)	0 (0%)	n.s.
Pathological Diagnosis	Benign	17 (77%)	18 (82%)	n.s.
	Malignant	5 (23%)	4 (18%)	n.s.
	T1	2 (9%)	4 (18%)	n.s.
GBR	T2	3 (14%)	0 (0%)	n.s.
	simultaneous	0 (0%)	0 (0%)	n.s.
Prognosis	Sequential	2 (9%)	0 (0%)	n.s.
	Recurrence	1 (5%) distal LN	0 (0%)	n.s.

BIC, Before Insurance Coverage; AIC, After Insurance Coverage; LC, Laparoscopic Cholecystectomy; LTC, Laparoscopic Total-Layer Cholecystectomy; GBR, Gallbladder Bed Resection; LN, Lymph Node;

underwent LC (both benign cases), whereas no bile leakage was observed in the TLC group.

Outcomes of suspected T2/T3a cases

Table 3 summarizes the outcomes of suspected T2/T3a disease. Laparoscopic GBR was significantly more frequent in the AIC group. Malignancy was confirmed in 65% of BIC cases and 47% of AIC cases. Intraoperative frozen-section examination (IOFS) identified metastatic involvement of the 12c lymph node in two cases in each group (not significant). Simultaneous BR was added in approximately 30% of cases in both groups. R0

resection was achieved in all BR cases in the BIC group and in 85% of AIC cases. Recurrence occurred in both groups, but no regional lymph node recurrence was observed.

Outcomes of suspected T3b or N1 cases

Table 4 summarizes the outcomes of suspected T3b or N1 disease. All patients in both groups underwent open GBR + BR, and malignancy was confirmed in all cases. Lymph node metastasis was detected in 33% of the BIC group and 66% of the AIC group. Although most patients exhibited advanced disease as expected, a small proportion of T1/2

Table 3. Surgical outcomes of suspected T2/T3a (N negative) lesions.

		BIC (n=17)	AIC (n=15)	p value
Procedure	GBR (open)	17 (100%)	3 (20%)	<0.05
	GBR (Lap)	0 (0%)	12 (80%)	<0.05
Pathological Diagnosis	Benign	6 (35%)	8 (53%)	n.s.
	Malignant	11 (65%)	7 (47%)	n.s.
	T1/T2	1 (9%) / 9 (82%)	0 (0%) / 3 (43%)	n.s.
	T3a	1 (9%)	4 (57%)	<0.05
Metastasis	I2c (IOFS)	2 (18%)	2 (29%)	n.s.
BR	simultaneous	3 (27%)	2 (28%)	n.s.
Surgical margin	R0	11 (100%)	6 (85%)	n.s.
Prognosis	Recurrence	4 (36%)	1 (14%)	n.s.
	Regional	0 (0%)	0 (0%)	n.s.
	LN recurrence			

BIC, Before Insurance Coverage; AIC, After Insurance Coverage; GBR, Gallbladder Bed Resection; IOFS, Intraoperative Frozen-Section Examination; BR, Extrahepatic Bile Duct Resection; LN, Lymph Node;

Table 4. Surgical outcomes of suspected T3b or N1 disease.

		BIC (n=6)	AIC (n=3)	P value
Procedure	GBR+BR (open)	6 (100%)	3 (100%)	n.s.
Pathological Diagnosis	Malignant	6 (100%)	3 (100%)	n.s.
	T1/T2	1 (16%) / 3 (50%)	0 (0%) / 2 (67%)	n.s.
	T3	2 (33%)	1 (33%)	n.s.
Metastasis	N1	2 (33%)	2 (66%)	n.s.
Surgical Margin	R0	5 (83%)	2 (67%)	n.s.
Prognosis	Recurrence	2 (33%)	1 (33%)	n.s.
	Liver metastasis	1 (50%)	0 (0%)	n.s.
	Peritoneal Dis-semination	1 (50%)	0 (0%)	n.s.
	Bile duct stump	0 (0%)	1 (100%)	n.s.

BIC, Before Insurance Coverage; AIC, After Insurance Coverage; GBR+BR, Gallbladder Bed Resection + Extrahepatic Bile Duct Resection;

lesions were also included due to preoperative overestimation. Both groups showed relatively high rates of R1 resection and subsequent recurrence, reflecting the aggressive tumor biology and disease burden in this cohort.

Impact of minimally invasive surgery on the management of gallbladder cancer

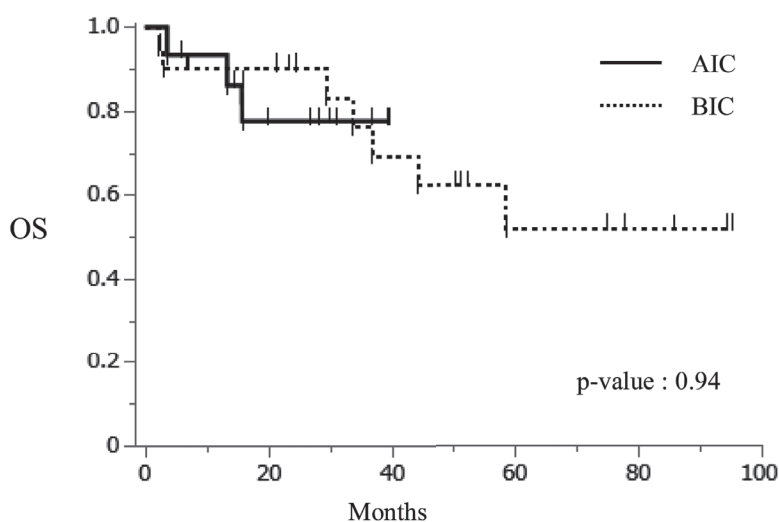
To evaluate the impact of MIS-first strategy on the management of gallbladder cancer, we selected patients who were postoperatively diagnosed with gallbladder cancer, including 22 patients in the BIC group and 14 patients in the AIC group, for further analysis. There were no significant differences between the two groups in patient demographics, tumor size, macroscopic tumor classification,

histological subtype, or lymph node metastasis. The proportion of patients undergoing minimally invasive surgery was significantly higher in the AIC group, whereas the median follow-up period was longer in the BIC group owing to the earlier timing of surgery (Table 5). Kaplan–Meier survival analysis demonstrated no significant difference in overall survival between the two groups (Figure 3). In the analysis of risk factors for recurrence, lymph node metastasis remained the sole significant factor in multivariate analysis after adjustment for potential confounders, while neither the period before or after insurance approval nor the use of laparoscopic surgery was associated with recurrence (Table 6).

Table 5. Characteristics of postoperatively diagnosed malignant cases.

		BIC (n=22)	AIC (n=14)	P value
Characteristics	Age (years)	74.2 (57-86)	73.4 (56-87)	n.s.
	BMI	22.0 (15.1-27.3)	21.7 (16.4-28.8)	n.s.
MIS		4 (18.2%)	10 (71.4%)	<0.05
Sequential op-eration		2(9.0%)	0 (0.0%)	n.s.
Morphological Classification	Papillary type	9 (40.9%)	7 (50.0%)	n.s.
	Nodular type	5 (22.7%)	4 (28.6%)	
	Flat type	8 (36.4%)	3 (21.4%)	
Pathological Classification	Pap.	5 (22.7%)	2 (14.3%)	n.s.
	Tub1	13 (59.1%)	8 (57.2%)	
	Tub2	1 (4.6%)	3 (21.4%)	
	Poor	3 (13.6%)	1 (7.2%)	
Tumor size (mm)		26.7(10-60)	23.5 (10-50)	n.s.
T factor	T1	4 (18.2%)	4 (28.6%)	n.s.
	T2	15 (68.2%)	5 (35.7%)	
	T3	3 (13.6%)	5 (35.7%)	
LN metastasis		4 (18.2%)	4 (28.6%)	n.s.
Recurrence		6 (27.3%)	3 (21.4%)	n.s.
Follow up period (month)		42.0 (2.1-95.2)	22.2 (3.6-39.4)	<0.05

BIC, Before Insurance Coverage; AIC, After Insurance Coverage; BMI; Body Mass Index; MIS, Minimally Invasive Surgery; Pap, papillary adenocarcinoma; tub1, well differentiated adenocarcinoma; tub2, moderately differentiated adenocarcinoma; poor, poorly differentiated adenocarcinoma; LN, Lymph Node;

**Table 6. Risk factors for recurrence.**

	Recurrence (+) N=9	Recurrence (-) N=27	Univariate analysis (p value)	Multivariate Analysis (p value)
Age (years)	79.1 (74-86)	72.5 (56-87)	n.s.	-
BMI	22.4 (16.4-28.8)	21.7 (15.2-27.9)	n.s.	-
MIS	2 (22.2%)	12 (44.4%)	n.s.	n.s.
Sequential operation	0 (0.0%)	2 (7.4%)	n.s.	-
Papillary type	1 (11.2%)	15 (55.6%)	n.s.	-
Nodular type	4 (44.4%)	8 (29.3%)		
Flat type	4 (44.4)	4 (14.1%)		
Tumor size (mm)	28.6 (15-50)	24.1 (10-60)	n.s.	-
T1	1 (11.1%)	5 (18.5%)	n.s.	n.s.
T2	3 (33.3%)	18 (66.7%)		
T3	5 (55.6%)	4 (14.8%)		
LN metastasis	7 (77.8%)	1 (3.7%)	P<0.0001, Odds 91.0, 95% CI 10.1-20289.0	P<0.0001, Odds 50.4, 95% CI 4.4-1679.1
AIC	3 (33.3%)	11 (40.7%)	n.s.	n.s.

BMI; Body Mass Index; MIS, Minimally Invasive Surgery; LN, Lymph Node; AIC, After Insurance Coverage

Discussion

Preoperative diagnostic accuracy for gallbladder tumorous lesions has improved with advances in EUS, with reported sensitivity and specificity of 83.3% and 65%, respectively.^{6,7} The incorporation of contrast harmonic imaging further augments diagnostic capability, raising the sensitivity to 89.6% and specificity to 98%, and has become an important modality for lesion evaluation⁸. However, despite these technological advances, preoperative discrimination between benign and malignant gallbladder lesions remains imperfect. Although bile cytology has shown diagnostic value⁹, technical complexity has prevented its standardization. Similarly, EUS-FNA for intracholecystic lesions has not been widely adopted because most reported cases involve sampling of enlarged lymph nodes or liver invasion^{10,11}. Consequently, current surgical strategies must be designed with the recognition that preoperative diagnosis is not definitive and that a substantial proportion of lesions suspected to be malignant may ultimately prove benign. Thus, current clinical strategies emphasize minimizing the risk of tumor dissemination or residual cancer while maintaining the value of excisional biopsy. Consistent with this principle, many lesions preoperatively suspected as T3a or lower in our cohort were ultimately benign, underscoring the clinical importance of minimally invasive surgical approaches in the management of diagnostically uncertain gallbladder tumorous lesions.

Although the prevalence of early-stage gallbladder cancer among lesions suspected to be T1 was approximately 20% in our cohort, it cannot be reliably excluded preoperatively. TLC is increasingly accepted as a rational approach for suspected T1 gallbladder cancer even in the absence of explicit guideline endorsement¹². Complete full-thickness resection preserves the serosal layer and reduces the risks of peritoneal dissemination and port-site recurrence associated with gallbladder perforation¹³. In addition, even when postoperative pathological examination reveals malignancy, additional GBR is unlikely to be necessary in T1 tumors without serosal invasion, provided that there is no tumor exposure. In our practice, consistent application of the Pringle maneuver facilitates bloodless dissection, enabling preservation of the correct anatomical plane. Complete transection along the gallbladder plate also enables accurate assessment of hepatic hilum invasion and reliable evaluation of the lymph nodes most

closely adjacent to the cystic duct. Because this procedure requires deep manipulation within the hepatic hilum, supervision by hepatobiliary surgeons is essential.

The No. 12c lymph node has been proposed by some groups as a potential sentinel node for gallbladder cancer¹⁴. However, this concept has not been universally accepted, and its clinical applicability remains limited compared with established sentinel node strategies in other malignancies. Several studies have reported using the metastatic status of the No. 12c lymph node to guide decisions regarding extended resection, whereas others have recommended sampling multiple lymph nodes to improve staging accuracy^{15,16,17}. At our institution, the status of the No. 12c lymph node is used as one component of decision-making for additional resection only in patients without radiologic evidence of lymph node enlargement on preoperative imaging. Importantly, regional lymphadenectomy is not omitted in cases with suspected nodal involvement. To minimize the risk of misidentification, the entire tissue block surrounded by the gallbladder plate, common bile duct, and gallbladder neck is excised, and intraoperative frozen-section examination is routinely performed. In our limited cohort, no regional lymph node recurrence was observed in cases with pathologically confirmed absence of No. 12c lymph node metastasis. Although recent reports have suggested the possibility of skip metastasis bypassing the 12c node, highlighting the need for caution^{15,18}. Accordingly, our selective approach should be interpreted as a pragmatic strategy for carefully selected patients rather than a definitive oncologic standard, and further institutional and multicenter validation is required.

For advanced gallbladder cancer, the therapeutic significance of lymphadenectomy remains controversial and there is currently no consensus regarding optimal indications, extent, or technique. Previous studies have reported heterogeneous surgical approaches, and a clear survival benefit of extensive lymphadenectomy has not been consistently demonstrated¹⁹⁻²¹. In our institution, lymphadenectomy within the hepatoduodenal ligament is selectively performed in patients considered at high risk for nodal metastasis and is intended as a complete nodal clearance rather than simple sampling. In such cases, extrahepatic bile duct resection (BR) is added to facilitate en-bloc removal of periductal lymphatic tissue and to minimize the risk of ischemic injury to the bile duct, which can be potentially fatal²². Although these procedures were conducted via open

laparotomy due to their technical complexity, in our series, no severe perioperative complications related to this approach were observed. Nonetheless, patients with lymph node metastasis within the hepatoduodenal ligament generally have a poor prognosis^{23, 24}. In the present study, lymph node metastasis was identified as a risk factor for postoperative recurrence; however, all such cases had undergone complete lymphadenectomy of the hepatoduodenal ligament, highlighting the limitations of radical surgery. In addition, at our institution, cases achieving favorable mid- to long-term outcomes despite multiple lymph node metastases in the hepatoduodenal ligament are currently largely limited to tumors with low malignant potential, such as gallbladder cancers arising from intracystic papillary neoplasms. Given recent advances in neoadjuvant chemotherapy for other malignancies, future indications for surgical intervention in advanced gallbladder cancer may continue to evolve.

Minimally invasive surgery (MIS) for gallbladder cancer in Japan currently includes laparoscopic GBR. Although robotic surgery has not demonstrated clear superiority over laparoscopy²⁵, MIS approaches have been reported to yield outcomes equivalent to open surgery even for technically demanding procedures²⁶. Nonetheless, laparoscopic surgery for gallbladder cancer is still associated with technical limitations, particularly in complex resections involving the hepatic hilum or bile duct. In this regard, robotic-assisted surgery, with its enhanced dexterity and visualization, may facilitate further expansion of MIS indications, including GBR combined with extrahepatic bile duct resection. From this perspective, demonstrating contemporary outcomes of laparoscopic surgery for gallbladder tumorous lesions remains clinically meaningful. These data provide an important benchmark for evaluating the safety and feasibility of MIS in the current era and may serve as a reference framework for future discussions regarding insurance coverage and wider adoption of robotic-assisted surgery for gallbladder cancer.

In this single-center retrospective study, the revised surgical policy—prompted by the expansion of MIS—was associated with surgical outcomes comparable to those of the earlier period and a reduced need for staged additional resections. However, extended resections for benign disease remained frequent, reflecting the limitations of preoperative diagnostics. These findings should be interpreted with caution in light of the retrospective design, single-center setting, limited sample size, and potential selection bias. Importantly, the present study

does not establish definitive conclusions regarding optimal surgical strategies for gallbladder cancer. Because the number of patients undergoing curative surgery for gallbladder cancer is relatively small compared with other malignancies, nationwide data collection and prospective, multicenter validation will be essential to refine patient selection and to establish evidence-based surgical standards.

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Author contributions:

Study conception and design: AT and IM. Curation and acquisition of data: AT, MN, KA, CN, YY, TM, KT, KK. Analysis and interpretation of data: AT and IM. Drafting of article: AT and KK. Critical revision of article: all authors.

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Declarations

Conflict of interest:

The authors have declared no conflicts of interest.

Ethics statements:

Approval of the research protocol: This study was approved by the Institutional Research Ethics Committee (R07-027) and was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments.

Informed Consent:

An opt-out method was used to obtain patient consent.

Registry and the Registration No. of the study/trial:

Not applicable.

Animal Studies:

Not applicable.

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