

Change in quality of life between primary laparoscopic cholecystectomy and laparoscopic cholecystectomy after percutaneous transhepatic gall bladder drainage

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Abstract

One of the most important reasons for avoiding percutaneous transhepatic gall bladder drainage (PTGBD) is the deterioration of quality of life (QOL). However, there is no study comparing the QOL between primary laparoscopic cholecystectomy (LC) and LC following PTGBD.

Among the LC patients, 69 non-PTGBD patients and 21 PTGBD patients were included after excluding the patients with malignant disease or who needed additional common bile duct procedures. Clinicopathologic characteristics and surgical outcomes were compared. QOL was evaluated with questionnaire EORCT-C30 before and after surgery.

The included patients comprised 69 non-PTGBD and 21 PTGBD patients. The PTGBD group include older and higher morbid patients. PTGBD group needed longer operation times than the non-PTGBD group (72.4±34.7 minute vs 52.8±22.0 minute, $P=.022$) Regarding the overall incidence of complication, the PTGBD group had a significantly higher complication rate than the non-PTGBD group (38.1% vs 10.1%, $P=.003$) However, there was no significant difference in severe complication). Regarding the QOL, both the functional and global health scales were improved following surgery compared to the preoperative evaluation. Comparative analysis of the 2 groups showed no significant difference in global health scale either preoperative or postoperatively, while the functional scale and emotional scale were better in the PTGBD group compared to the non-PTGBD group. Regarding the symptom scale, postoperative dyspnea and perioperative diarrhea were better in the PTGBD group.

LC following an interval from earlier PTGBD that targets acute cholecystitis or complicated GB had little to no impact on QOL when compared to standard LC.

Abbreviations: CRP = c-reactive protein, LC = laparoscopic cholecystectomy, PTGBD = percutaneous transhepatic gall bladder drainage, QOL = quality of life, WBC = white blood cell.

Keywords: cholecystectomy, complication, laparoscopy, quality of life

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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1. Introduction

Laparoscopic cholecystectomy (LC) is currently the gold standard treatment for calculous cholecystitis. However, some life-threatening conditions, such as acute cholecystitis or gallbladder empyema, require emergency cholecystectomy or percutaneous transhepatic gall bladder drainage (PTGBD) followed by sequential cholecystectomy.^[1–3] PTGBD is also the preferred treatment for patients with severe comorbidities and poor general condition who are not suitable for emergency surgery.^[4]

However, controversies remain regarding the patient selection for PTGBD, as well as whether cholecystectomy should be performed after the resolution of acute inflammation, and if so, at which point.^[5] Some surgeons prefer emergency cholecystectomy rather than delayed cholecystectomy due to advantages such as lower morbidity, shorter hospital stay, and cost effectiveness.^[2,6] In general, the primary advantage of PTGBD first strategy is considered to be the ability to treat acute inflammation with relatively low risk in comparison to surgery.^[7,8]

Despite this advantage, PTGBD may delay successful treatment, increase medical costs, and increase the difficulty of surgery due to the presence of hard fibrosis.^[9] Moreover, decreased

quality of life (QOL) is another known disadvantage of PTGBD prior to cholecystectomy (e.g., catheter dislodgement or cholecystostomy site abscess).^[10]

However, no previous study has compared the QOL between patients who have undergone PTGBD (PTGBD patients) and those who have not (non-PTGBD), neither at the pre nor postoperative stages.

In this study, the QOL was compared between PTGBD patients and non-PTGBD patients in the patients' cohort underwent prospective study evaluating the complication monitoring and validation.

2. Materials and methods

Ninety-five patients who underwent LC from April 2017 to December 2017 in Eunpyeong St. Mary's hospital, college of medicine, the Catholic university of Korea were included in this study. The included patients were enrolled in the study "Validation of comprehensive complication index for the general surgery patients", in which we surveyed EORCT-C30 QOL questionnaire preoperatively and postoperatively at the first outpatient office visit after discharge.^[11] The inclusion criteria were patients who had undergone LC. The exclusion criteria were patients with malignancy, and patients who required additional procedures, such as common bile duct exploration or T-tube insertion. The included patients were divided into the PTGBD group and non-PTGBD group.

All of the data collection was performed prospectively and included collecting data on patients' baseline characteristics (age, sex, American Society of Anesthesia classification, body mass index, preoperative albumin level) and various types of comorbidities with Charlson Comorbidity index. Gallbladder disease was classified into complicated cholecystitis, acute cholecystitis, chronic cholecystitis, and gallbladder polyp. Pre-PTGBD, preoperative, and predischARGE laboratory exams were evaluated, including white blood cell count (WBC) with segment neutrophil, c-reactive protein (CRP), aspartate aminotransferase, alanine transaminase, platelet count, total bilirubin, direct bilirubin, and alkaline phosphatase.

Perioperative outcomes were evaluated, including the operative time, estimated blood loss, occurrence, and number of postoperative complications, and grading and specific types of complications. This study was approved by institutional review board (IRB approval No.: PC19RESI0115).

2.1. Management protocol

In our institution, among patients who was diagnosed with gallbladder disease, PTGBD was inserted first for patients with severe acute inflammation (grade III) or old aged patients who immediate cardiopulmonary function evaluation was not available, and elective LC was performed after 4 to 6 weeks under confirming absence of acute inflammation. In case of non-PTGBD patients, surgery was performed within 1 week of diagnosis without PTGBD. In both groups, antibiotic treatment was stopped before discharge under the conditions of no fever.

2.2. Preoperative and post-discharge QOL EORCT-C30 evaluation

Using the EORCT-C30 questionnaire, the preoperative QOL estimation was performed the day before elective LC, and the

post-discharge QOL estimation was performed on the first visit after discharge 10 to 14 days after surgery. The EORCT-C30 comprised a functional scale, symptom scale, and global health scale, each of which ranged between 0 and 100. In case the functional scale and global health scale, a higher score indicates a more favorable status. In contrast, in the symptom scale, a higher score indicates a higher severity of symptoms.

Postoperative complications included all minor deviations from the regular postoperative course and was classified using the Clavien–Dindo classification and comprehensive complication index. If a patient had multiple complications, the complication with the most severe grade was expressed with Clavien–Dindo type classification. The comprehensive complication index was calculated according to previously reported complication grade.^[12]

2.3. Statistical analysis

All statistical analyses were performed using PASW statistics version 18.0 (SPSS Inc., Chicago, IL). Continuous variables are described as the mean with standard deviation and were compared using Student *t* test. Nominal variables were compared using chi-square and Fisher exact tests. All statistical analyses were considered significant when the *P* value was < .05.

3. Results

The included patients comprised 69 non-PTGBD patients and 21 PTGBD patients. Regarding the baseline clinicopathologic characteristics, the PTGBD patients were older, had more severe grade American Society of Anesthesia classification, and more comorbidities with higher Charlson comorbidity scores. There was no significant difference in sex, preoperative body mass index, and albumin level between the 2 groups (Table 1). The final diagnosis category was significantly different between the 2 groups; acute cholecystitis was dominant in the PTGBD group, and chronic cholecystitis was more commonly diagnosed in the non-PTGBD group (Table 1). Four patients in the non-PTGBD group had gallbladder polyps.

The surgical results and detailed complications are described in Table 2. The PTGBD group had longer operation times than the non-PTGBD group (72.4 ± 34.7 minute vs 52.8 ± 22.0 minute, respectively; $P = .022$). There was no significant difference in the estimated blood loss between the 2 groups. Regarding the overall incidence of complication, the PTGBD group had a significantly higher complication rate than the non-PTGBD group (8/21 (38.1%) vs 7/67 (10.1%), respectively; $P = .003$). However, there was no significant difference in severe complications (\geq C-D IIIa grade). One patient in the non-PTGBD group required admission to the intensive care unit due to desaturation after surgery. One patient in PTGBD group needed open conversion due to bile duct injury. None of the patients underwent intervention treatment or re-operation. The comprehensive complication index was higher in the PTGBD group, although without statistical significance (6.1 ± 9.0 vs 2.1 ± 7.8 , respectively; $P = .71$). Most of the complications comprised minor complications graded C-D I. One patient in the PTGBD group had a bile leak and was managed with conservative care with antibiotics. There were no mortalities in either group.

3.1. Postoperative clinical course

Peak fever during the hospital stay was significantly higher in PTGBD group. In the PTGBD group, preoperative laboratory

Table 1

Clinicopathologic characteristics between percutaneous transhepatic gall bladder drainage group and non-percutaneous transhepatic gall bladder drainage group.

Variables	Non-PTGBD group (n=69)	PTGBD group (n=21)	P
Age (yrs)	58.9±14.4	69.9±11.4	.002
Median age (yrs)	55 (17-90)	79 (38-84)	
Sex			.227
Male	27 (39.1%)	12 (57.1%)	
Female	42 (60.9%)	9 (42.9%)	
ASA			.012
1	22 (31.9%)	1 (4.8%)	
2	42 (60.9%)	15 (71.4%)	
3	5 (7.2%)	5 (23.8%)	
BMI (kg/m ²)	25.4±3.3	24.9±3.3	.609
Albumin	4.0±0.5	3.7±0.7	.122
Charlson comorbidity score	0.6±1.0	1.3±1.2	.015
Presence of comorbidity	26 (37.7%)	16 (72.2%)	.013
Myocardial infarction	2 (2.9%)	0 (0.0%)	1
Congestive heart failure	1 (1.4%)	1 (4.8%)	.955
Peripheral disease	0 (0.0%)	0 (0.0%)	
Cerebrovascular disease	7 (10.1%)	7 (33.3%)	.026
Dementia	1 (1.4%)	1 (4.8%)	.955
Chronic pulmonary disease	5 (7.2%)	2 (9.5%)	1
Peptic ulcer disease	0 (0.0%)	0 (0.0%)	
Connective tissue disease	1 (1.4%)	0 (0.0%)	1
Mild liver disease	5 (7.2%)	2 (9.5%)	1
Diabetes without end organ damage	11 (15.9%)	10 (47.6%)	.007
Hemiplegia	0 (0.0%)	0 (0.0%)	
Moderate or severe renal disease	1 (1.4%)	0 (0.0%)	1
Diabetes with end organ damage	0 (0.0%)	0 (0.0%)	
Tumor without metastasis	4 (5.8%)	2 (9.5%)	.92
Leukemia, acute or chronic	0 (0.0%)	0 (0.0%)	
Lymphoma	0 (0.0%)	0 (0.0%)	
Moderate or severe liver disease	0 (0.0%)	0 (0.0%)	
Metastatic solid tumor	0 (0.0%)	0 (0.0%)	
AIDS not just HIV positive	0 (0.0%)	0 (0.0%)	
Type of GB disease			<.001
Acute cholecystitis (Grade II/III)	0 (0.0%)	3 (14.3%)	
Acute cholecystitis (Grade I)	11 (15.9%)	17 (81.0%)	
Chronic cholecystitis	54 (78.3%)	1 (4.8%)	
Polyp	4 (5.8%)	0 (0.0%)	

Continuous variables were expressed as mean and standard variation, nominal variables were expressed as number with percentage.

AIDS = acquired immunodeficient disease, ASA = American Society of Anesthesia classification, BMI = body mass index, GB = gall bladder, HIV = human immunodeficiency virus, PTGBD = percutaneous transhepatic gall bladder drainage.

examinations such as elevated WBC, aspartate aminotransferase, and alanine transaminase were nearly normalized at the preoperative evaluation compared to pre-PTGBD period. Significantly higher CRP level and significantly lower platelet count were observed in the PTGBD group compared to the non-PTGBD group. Compared to the laboratory data at pre-PTGBD period, non-PTGBD group showed lower WBC counts, proportion of segment neutrophil, and CRP level. In comparison between pre-PTGBD and pre-operation period in PTGBD group, WBC count and proportion of segment neutrophil were higher in pre-PTGBD period. Liver enzyme and cholestatic markers were elevated marginally in pre-PTGBD period compared to preoperative period in PTGBD group without statistical significance (Table 3).

Table 2

Surgical results and detail of complications after laparoscopic cholecystectomy.

Variables	Non-PTGBD group (n=69)	PTGBD group (n=21)	P
Operation time (min)	52.8±22.0	72.4±34.7	.022
EBL (mL)	7.9±4.8	15.5±21.4	.122
Open conversion	0	1 (4.8%)	.233
Complication	7 (10.1%)	8 (38.1%)	.003
Number of complications			
1	4 (5.8%)	3 (14.3%)	
2	2 (2.9%)	3 (14.3%)	
3	0	2 (9.5%)	
4	1 (1.4%)	0	
Severe complication (Grade ≥ IIIa)	1 (1.4%)	0 (0%)	.579
Comprehensive complication index	2.1±7.8	6.1±9.0	.071
Clavien-Dindo classification			
I	4 (5.8%)	4 (19%)	
Fever (2)		Fever (4)	
Headache (2)			
II	2 (2.9%)	4 (19%)	
Fever (1)		Nausea (2)	
Ileus (1)		Bile leak (1)	
Urticaria (1)			
IVa	1 (1.4%)	0	
Desaturation (1)			

Continuous variables were expressed as mean and standard variation, nominal variables were expressed as number with percentage.

EBL = estimated blood loss, PTGBD = percutaneous transhepatic gall bladder drainage.

3.2. Quality of life

Generally, both the functional and global health scales were improved following surgery compared to the preoperative evaluation, while the symptom scale also showed improvement with varying levels of significance (Table 4). In the preoperative evaluation, there was no difference in global health status and functional status except cognitive function. PTGBD group showed better cognitive function than non-PTGBD group. In the postoperative evaluation, emotional scale was significantly better in PTGBD group (Fig. 1). Regarding the symptom scale, postoperative dyspnea and perioperative diarrhea were better in the PTGBD group. Other QOL components showed no significant differences between the 2 groups (Figures 1–3).

4. Discussion

In the current study, we compared the postoperative complications and QOL between patients who received LC and those who received delayed LC after PTGBD insertion for the treatment of benign gallbladder disease. The key finding of current study is that there was no significant difference in global health score between 2 groups. However, functional and emotional scale were better in the PTGBD group. These findings reflect that PTGBD does not deteriorate the patients' QOL and it can improve QOL by resolving inflammatory conditions.

The choice between early cholecystectomy and delayed cholecystectomy after PTGBD insertion is considered for patients who undergo cholecystectomy, and particularly for those with acute cholecystitis or empyema. While some researchers have found no significant difference between the early cholecystectomy and delayed cholecystectomy regarding the post operative morbidity and mortality,^[2,10] others argue that elective surgery

Table 3
Comparison of perioperative laboratory findings between 2 groups.

Variables	Non-PTGBD group (n = 69)	PTGBD group (Cholecystectomy) (n = 21)	PTGBD group (PTGBD) (n=21)	P (a)	P (b)	P (c)
Peak fever during hospital stay (°C)	37.8±0.6	38.4±0.7	38.7±0.9	<.001	<.001	.045
WBC (10 ⁹ /L)	6.9±2.4	7.1±2.9	12.1±5.0	.730	<.001	<.001
Segment neutrophil (%)	58.8±14.8	65.1±14.0	77.8±14.4	.098	<.001	.002
CRP (mg/dL)	3.6±5.2	10.3±8.8	11.1±10.1	.009	.023	.435
Platelet (10 ⁹ /L)	239.3±65.8	201.5±49.2	209.4±69.8	.017	.81	.387
AST (IU/L)	28.2±14.1	25.4±16.0	124.3±223.9	.448	.076	.065
ALT (IU/L)	37.2±33.1	31.2±26.2	73.8±111.0	.451	.151	.079
Total bilirubin (mg/dL)	0.76±0.38	0.83±0.58	1.14±0.93	.464	.080	.196
Direct bilirubin (mg/dL)	0.31±0.28	0.57±0.76	0.60±0.59	.201	.075	.818
Alkaline phosphatase (IU/L)	266.7±161.9	244.8±142.0	281.1±126.9	.582	.710	.315

AST = aspartate aminotransferase, ALT = alanine transaminase, CRP = c-reactive protein, PTGBD = percutaneous transhepatic gall bladder drainage, WBC = white blood cell.

Continuous variables were expressed as mean and standard variation, nominal variables were expressed as number with percentage.

P for comparison between non-PTGBD group and PTGBD group (pre-cholecystectomy laboratory study).

P for comparison between non-PTGBD group and PTGBD group (pre-PTGBD laboratory study).

P for comparison between pre-cholecystectomy and pre-PTGBD laboratory study withing PTGBD group.

after sufficient medical treatment is safer and reduces the potential need for open conversion.^[7] According to Lin et al, who studied 124 patients ≥65 years old with moderate to severe acute calculus cholecystitis, the 30-day mortality and rate of postoperative complications was higher in the early LC group compared to the delayed LC group.^[13] The decision between

upfront surgery and delayed LC after PTGBD insertion is at the surgeon's discretion, after considering the patient's operative risk status, including age and presence of comorbidities.^[8,14-16] Despite of current controversies, it would be obvious that severely comorbid patients with high perioperative risk need temporary drainage procedure for avoiding the emergency

Table 4
Difference in quality of life status estimated by EORCT-C30 questionnaire.

Variables	Non-PTGBD group (n = 69)	PTGBD group (n = 21)	P
Pre-global health	57.5±26.7	62.7±25.4	.43
Post-global health	65.2±19.9	70.2±18.2	.304
Functional scale			
Pre-physical	80.4±16.7	76.2±24.7	.473
Post-physical	80.4±19.0	82.2±19.8	.702
Pre-role	85.0±20.6	81.0±25.4	.456
Post-role	79.5±26.5	84.9±20.3	.389
Pre-emotional	76.3±22.4	79.0±14.6	.53
Post-emotional	83.9±20.4	91.7±13.2	.047
Precognitive	77.1±22.2	85.7±14.2	.039
Postcognitive	85.5±17.8	88.1±15.0	.548
Pre-social	79.7±27.7	82.5±26.6	.68
Post-social	87.7±20.7	93.7±13.4	.127
Symptom scale			
Pre-fatigue	35.3±26.9	30.2±21.4	.428
Post-fatigue	29.5±21.5	21.7±21.2	.149
Pre-nausea & vomiting	13.5±17.7	7.9±12.5	.181
Post-nausea & vomiting	10.5±20.3	4.8±7.7	.056
Pre-pain	27.5±25.9	26.2±22.1	.83
Post-pain	19.6±20.0	13.5±13.6	.197
Pre-dyspnea	15.9±24.7	7.9±14.5	.071
Post-dyspnea	19.3±27.1	9.5±15.4	.041
Pre-insomnia	23.7±29.2	30.2±27.7	.37
Post-insomnia	21.7±28.5	12.7±16.6	.075
Pre-appetite loss	18.8±25.9	23.8±30.1	.46
Post-appetite loss	20.8±28.6	15.9±25.0	.482
Pre-constipation	22.7±30.0	31.7±32.4	.238
Post-constipation	17.6±26.1	22.2±28.5	.493
Pre-diarrhea	26.6±24.0	14.3±19.9	.036
Post-diarrhea	21.7±24.8	11.1±16.1	.025
Pre-financial difficulties	29.0±33.3	25.4±33.2	.666
Post-financial difficulties	19.3±28.8	11.1±19.2	.138

PTGBD = percutaneous transhepatic gall bladder drainage.

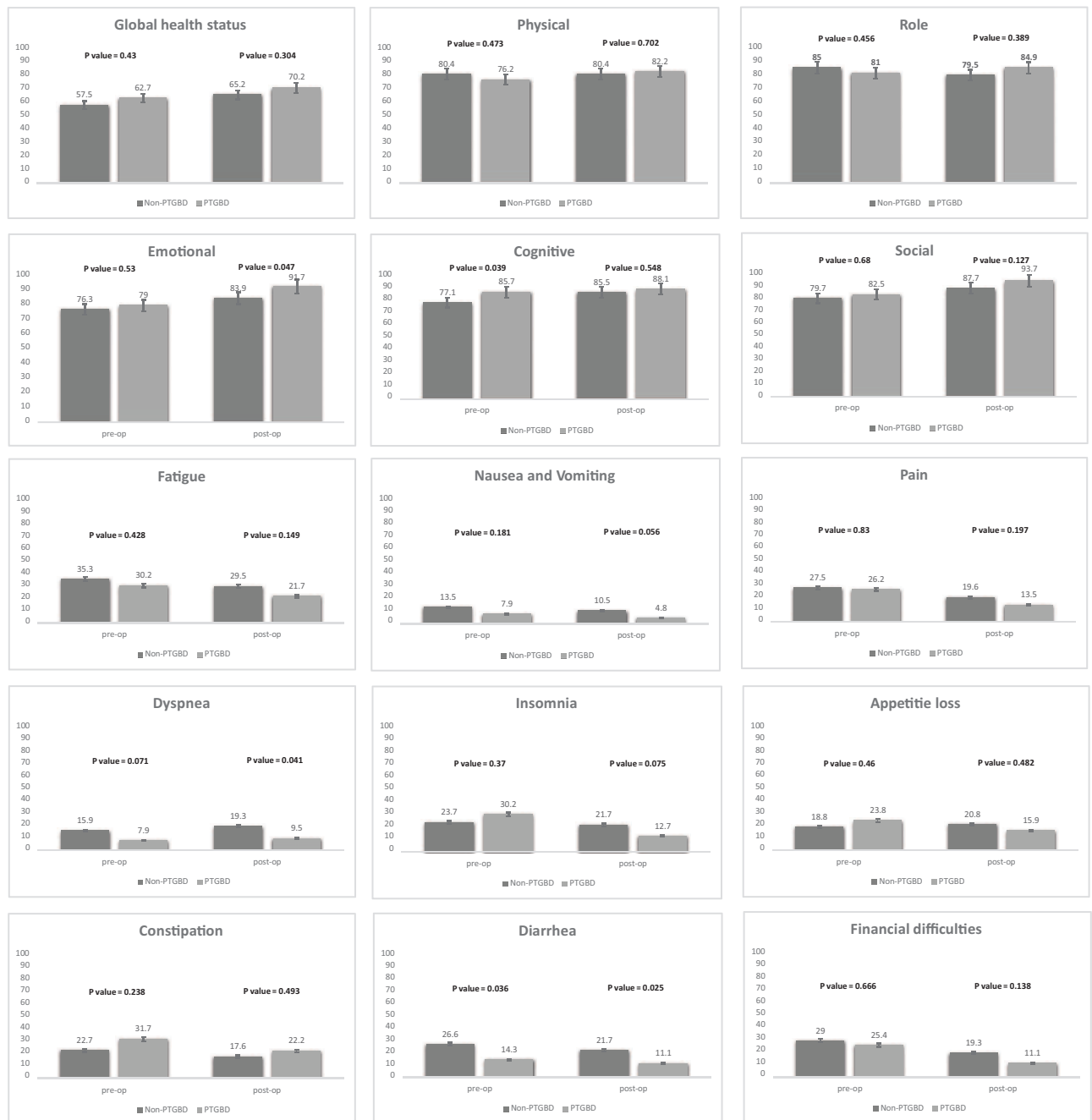


Figure 1. General quality of life result before and after laparoscopic cholecystectomy.

operation. In addition, we needed to consider the complication and QOL after PTGBD for setting the range of indication for the procedure.

The results show that the incidence of postoperative complications after PTGBD was higher in the patients who underwent delayed LC after PTGBD than in patients in the non-PTGBD group who received upfront surgery. This may be related to the statistically significant difference in age and comorbidities between the PTGBD and non-PTGBD groups, both of which were higher in the PTGBD group. Moreover, the fibrotic adhesion to nearby organs that is observed upon recovery from acute cholecystitis after PTGBD insertion is also thought to have

influenced the observations. However, most complications were minor, and the single case of minor bile leak in the PTGBD group after surgery was resolved through conservative care. Therefore, the postoperative complications were not severe when we consider the initial status of PTGBD group.

Several studies have evaluated the postoperative QOL of patients after cholecystectomy regarding the various technical points of view.^[17–19] However, only few studies dealt with the QOL comparison between different timing of LC. Johansson et al^[20] reported statistically superior results in the early LC group in comparison to the delayed LC group using symptom scales measuring diarrhea, indigestion, and abdominal pain,



Figure 2. Comparison of Global and functional scale between PTGBD and non-PTGBD group in preoperative period. PTGBD = percutaneous transhepatic gall bladder drainage.

while no significant differences were observed in the results of the psychologic general well-being index. However, this study did not include PTGBD patients and preoperative QOL was not checked. Currently, no studies have examined the impact of the interval from PTGBD to surgery on postoperative QOL in comparison to the non-PTGBD group in patients who receive surgery after PTGBD following recovery from an acute phase disorder due to high operative risk. Thus, the current research was designed to address this gap in knowledge.

While it is reasonable to group patients with acute cholecystitis based on PTGBD indications in theory, the goal of this study was

to demonstrate that PTGBD itself does not deteriorate the QOL compared to the patients who generally undergo LC for standard indication. Forementioned important findings are better QOL in PTGBD group regarding the preoperative cognitive function and postoperative emotional function. These findings are important evidence for selecting PTGBD procedure when it is needed.

Upon observation of QOL change in each group and other QOL components, both groups showed overall improvement in QOL across scales post-surgery compared to preoperative measurements. Improvement in the early LC group appears to be due to recovery from the target disorder after surgery, whereas

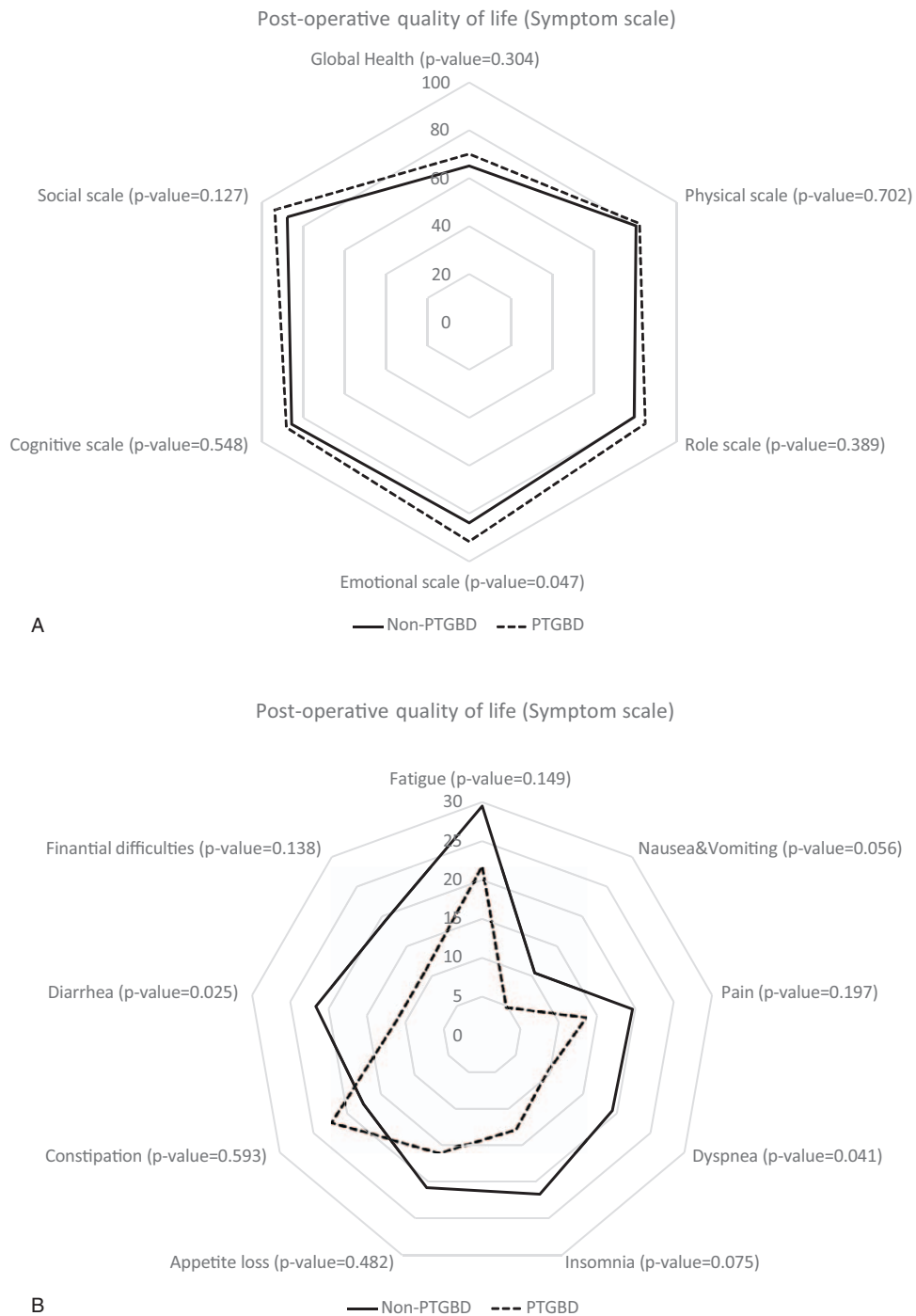


Figure 3. Comparison of Global and functional scale between PTGBD and non-PTGBD group in postoperative period. PTGBD =percutaneous transhepatic gall bladder drainage.

that in the delayed LC group may be influenced by improvements in the patients' condition or confidence as a result of the relief from discomfort of the PTGBD tube upon recovery of their intra-abdominal condition after PTGBD; both emotion and cognitive function are expected to be impacted by such influence.

Patients who received PTGBD showed no significant change in preoperative symptoms when compared to other patients before LC. While the non-PTGBD group had worse gastro-intestinal

symptoms, such as nausea or diarrhea, these may be standard post-cholecystectomy gastro-intestinal symptoms that appear due to the early LC group patients lacking time to adjust to the loss of their gallbladder. In contrast, the delayed LC group patients could adjust during the interval before their surgery.^[21] Although there are also financial issues associated with the readmission of PTGBD patients after initial discharge, there was no significant difference in financial problems compared to

standard LC patients. The current study result needs to be validated from more case volume and external validation to be accepted generally.

This research has several limitations that warrant discussion. First, there is potential for selection bias given the retrospective design of the study, as delayed cholecystectomy after PTGBD is more often performed on elderly patients or those with comorbidities. Second, the 2 comparator groups had variations in diagnoses due to patients with acute cholecystitis receiving delayed cholecystectomy after PTGBD and the early LC group excluding patients with acute cholecystitis or complicated GB. However, both groups were considered to have been equally inspected for QOL before and after elective surgery because the timing of the QOL questionnaire for the PTGBD group was before and after surgery following PTGBD upon the resolution of acute inflammation. Third, the small number of patients undergoing delayed cholecystectomy after PTGBD during the research period is another limitation.

Despite these limitations, the comparison of pre and postoperative QOL between patients who have received surgery after PTGBD and those who have received standard LC can be considered a novelty of this research.

5. Conclusion

LC following an interval from earlier PTGBD that targets acute cholecystitis or complicated GB had little to no impact on QOL when compared to standard LC. Thus, as a procedure favored for older patients with multiple comorbidities, PTGBD increases patient satisfaction by raising the emotional and symptomatic QOL among those with acute cholecystitis to a level similar to that of standard cholecystectomy patients; this is especially true for elderly and high-risk patients.

Author contributions

Conceptualization: DJ Kim.

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Validation: DJ Kim, JH Park.

Visualization: DJ Kim, JH Park.

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