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ORIGINAL SCIENTIFIC REPORT

The Efficacy of PTGBD for Acute Cholecystitis Based on the Tokyo Guidelines 2018

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Abstract

Backgrounds We usually performed percutaneous transhepatic gallbladder drainage (PTGBD) for moderate and severe acute cholecystitis (AC) prior to cholecystectomy. But, the validity of preoperative drainage for AC is still controversial. The aim of this study is to evaluate the efficacy and safety of PTGBD for moderate and severe AC, based on the Tokyo Guidelines 2018.

Materials Total of 146 AC patients from 2012 to 2017 were enrolled. Patients were classified in the grade of severity according to TG18, compared with PTGBD and non-PTGBD group. We retrospectively reviewed clinical backgrounds and laboratory data at admission. We evaluated surgical performances as the primary outcomes and recovery periods based on guidelines.

Results A total of 61 cases were moderate, and 18 cases were severe AC, and PTGBD were performed in 34 cases. For moderate AC, age, DM rate and ASA in PTGBD group were significantly higher than those in non-PTGBD group. Also, serum albumin and hemoglobin at admission were significantly lower in the PTGBD group. However, surgical outcomes were almost the same. For severe AC patients, laparoscopic cholecystectomy was performed safely in all of pre-operating drainage cases, while almost all of non-PTGBD cases underwent open laparotomy and needed transfusion for massive bleeding.

Conclusions Preoperative PTGBD is a useful and safe procedure for AC patients with comorbidities, especially in severe AC cases. Treatment flowchart in TG18 can be feasible to make accurate prediction for surgically high-risk patients in AC.

Introduction

The number of patients for acute cholecystitis (AC) has been increasing year by year, and there are many discussions about treatment. The first choice of treatment for mild AC is to use antibiotics systemically in order to improve inflammation and keep general condition stable.

If inflammation or vital signs cannot be improved, we should consider the other treatment options as moderate AC, whether we should select drainage and decompression in the gallbladder or early cholecystectomy. Treatment result was improved this day; however, perioperative complications and the mortality rate for severe cholecystitis are still high [1].

Percutaneous transhepatic gallbladder drainage (PTGBD) plays an important role for both moderate and severe AC in aspect of stability of general condition before operation. PTGBD can become less invasive drainage

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method, and we can evaluate anatomy of cystic duct or common bile duct and also evaluate whether a gallstone drops in common bile duct (CBD) or not, via drainage tube by contrast, unless the existence of obstructive jaundice.

No clinical diagnostic criteria and treatment flowchart for AC and each hospital had performed original treatments in various ways over the world until Tokyo Guidelines 2007. At first, Tokyo Guidelines 2007 (TG07) focused mainly on unifying the diagnostic criteria [2]. Then, Tokyo Guidelines (TG13) made decision not only for the diagnostic criteria but also for the degree of severity, treatment flowcharts, bundles, and the choice of antibiotics, which drastically became the gold standard for AC and cholangitis all over the world [3, 4]. Treatment strategy for AC and acute cholangitis was newly revised in Tokyo Guidelines 2018 (TG18) in place of TG13. In TG18, there are some change points about treatment for AC; the most revised point is that the treatment flowchart of moderate and severe AC became more systematic and complicated using American Society of Anesthesiologists (ASA) classification, Charlson comorbidity index (CCI) [5, 6]. Especially, for severe AC, negative predictive factors and favorable organ system failure (FOSF) were also set up in order to decide whether PTGBD or operation should be performed or not. However, it is actually difficult for many hospitals to perform early or urgent cholecystectomy in accordance with TG18 because of the lack or limitation of medical environment. Therefore, many hospitals perform PTGBD at first for controlling inflammation from AC and then perform delayed cholecystectomy.

In this study, we focused patients for moderate and severe acute cholecystitis, who were diagnosed and treated in our hospital. We analyzed and researched retrospectively using our medical records about clinical backgrounds, surgical and hospitalized outcomes. We evaluated the impact of PTGBD for acute cholecystitis according to grade of severity.

Materials and methods

Totally 146 cases who were diagnosed and treated as AC were enrolled from January in 2012 to December in 2017 in our hospital. These patients were also classified in the grade of severity according to TG18. We analyzed and evaluated only the patients for moderate (Grade II) and severe (Grade III) AC, with comparison between those who were taken PTGBD (PTGBD group), and those who were not (non-PTGBD group). It is because none of mild AC underwent PTGBD. All patients in PTGBD group were taken drainage tube into gallbladder, no one was taken aspiration, and they were kept PTGBD tube (8Fr pigtail) open until operation. In our hospital, if inflammation or vital signs cannot be improved after treatment for 24 h in moderate AC. In severe AC, we always consider PTGBD, otherwise the use of antiplatelet or anticoagulant agents and poor PS.

We perform cholecystectomy at least 4 weeks after PTGBD, regardless of whether continuing hospital stay or not. In our hospital, we do not have a choice of early cholecystectomy, so we usually select antibiotics or PTGBD. During initial treatments, we examine cardiac and pulmonary function to evaluate the operability. Finally, good PS, tolerance for cholecystectomy, and normal cognitive function are important factors for performing operation. We consider open cholecystectomy only when patients are needed emergency treatment because of inflammation or sepsis.

We retrospectively reviewed the hospital's medical database for information including age, gender, body mass index (BMI), smoking history, the rate of diabetes mellitus (DM), and American Society of Anesthesiologists (ASA) classification. Laboratory data, serum levels of white blood cell (WBC), C-reactive protein (CRP), hemoglobin (Hb), albumin (Alb), platelet count (Plt), total bilirubin (T-Bil), creatinine (Cr), prothrombin time (PT) were obtained immediately at admission and compared between the two groups.

The main outcome is the surgical outcomes, that is operation time, blood loss, and intraoperative or postoperative complications, and mortality. After operation, hospital stays, days of restart oral diet, days until normalizing WBC, and days until CRP < 3 were also reviewed. Furthermore, we calculated the intubated rate of bacteria from bile culture gained by PTGBD.

Comparisons between groups for categorical variables, such as smoking history, the rate of DM, ASA classification, were assessed using the χ^2 test and Fisher's exact. The student t test and Mann–Whitney U test were used to compare two groups for abnormally distributed quantitative variables. Statistical analyses were performed using IBM SPSS statistics for Mac (version 25.0; IBM Corp., Armonk, NY, USA), and all statistical tests were two-sided. $p < 0.05$ was considered to be statistically significant.

Results

1. Flowchart of patients for AC (Fig. 1)

Of 146 cases, 67 cases (45.9%) of them were grade I (mild), 61 cases (41.9%) were grade II (moderate), and 18 cases (12.3%) were grade III (severe) acute cholecystitis, respectively.

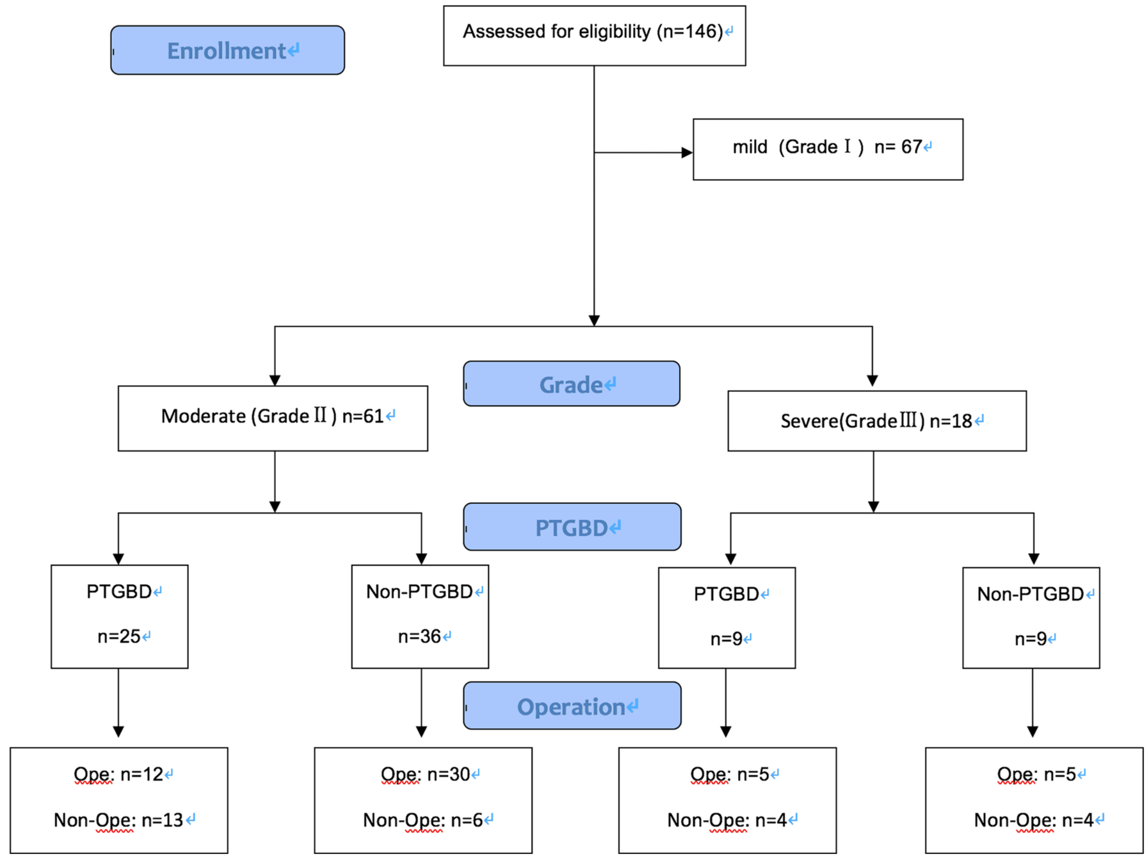

Fig. 1 Flowchart of patients for AC

There were 89 males and 57 females, and the rate of smoking (former or current) was 37.7%, and that of DM was 21.9%. Thirty-two cases (22%) were ASA 3 or 4, and 95 cases (65%) were performed operation.

PTGBD was performed in 34 cases (23.3%); 25 cases (17.1%) were in moderate AC, and 12 (8.2%) of them were performed operation. In severe AC, 9 (6.2%) cases were taken PTGBD, and 5 (3.4%) of them were performed operation. None of mild AC was taken PTGBD.

2. Clinical backgrounds and laboratory data at admission for AC (Tables 1, 2)

Of moderate AC patients, PTGBD group was 25 patients (41.0%); non-PTGBD group was 36 patients (59.0%). The clinical backgrounds and laboratory data at admission between two groups are shown in Table 1.

At first, there were no significant differences between with and without PTGBD groups in gender, BMI, smoking history.

However, patients in PTGBD group were significantly older than those in non-PTGBD group (83 years vs. 75.5 years, $p = 0.006$), and DM rate was significantly higher in the PTGBD group ($p = 0.039$). More than half of the patients in PTGBD group had high ASA (3 or 4), which was significantly different compared with those in non-PTGBD group ($p < 0.0001$). Furthermore, with regard to laboratory data at admission, serum albumin and hemoglobin were significantly lower in the PTGBD group ($p = 0.0001$ and 0.0031, respectively).

Of severe AC patients, PTGBD group was 9 patients; non-PTGBD group was 9 patients. The clinical backgrounds and laboratory data at admission between two groups are shown in Table 1. Patients in PTGBD group were older than those in non-PTGBD group (89 years vs. 83 years, $p = 0.053$), and DM rate had a tendency to get high in the PTGBD group ($p = 0.07$), but not significantly. With regard to laboratory data at admission, serum platelet counts were significantly lower in the PTGBD group ($p = 0.005$).

Table 2 shows clinical backgrounds and laboratory data at admission in operation-group for moderate and severe AC, which finds serum CRP was higher in PTGBD group. Other measures were the same as Table 1.

So, we tend to select PTGBD especially for surgically high-risk patients or those who are in unstable conditions. There were no major complications related to PTGBD.

Table 1 Clinical backgrounds and laboratory data for moderate and severe acute cholecystitis

Variable	Moderate			Severe		
	PTGBD $N = 25$	Non-PTGBD $N = 36$	p	PTGBD $N = 9$	Non-PTGBD $N = 9$	p
Age (years)	83.0	75.5	0.006	89	83	0.053
Sex						
Male	16	24	0.59	4	7	0.335
Female	9	12		5	2	
BMI (kg/m^2)	21.4	22.6	0.15	21	22	0.807
Smoking history						
Never	17	25	1	5	7	0.62
Former/current	8	11		4	2	
DM						
Yes	10	7	0.039	5	2	0.07
No	15	29		4	7	
ASA-PS						
1	1	15	<0.0001	0	3	0.292
2	10	12		3	1	
3	13	5		5	4	
4	1	0		1	1	
WBC (/μL)	13,460	11,755	0.69	21,980	14,780	0.297
CRP (mg/dL)	15.9	13.9	0.16	24	12.9	0.475
T-Bil (mg/dL)	1.2	1.25	0.81	1.2	1.4	0.306
Plt (/μL)	198,000	194,000	0.89	91,000	167,000	0.005
Cr (mg/dL)	0.8	0.92	0.3	1.96	1.32	0.588
PT (%)	87	89	0.44	64	83	0.191
Alb (mg/dL)	2.9	3.8	0.0001	2.9	3.6	0.09
Hb (g/dL)	12.3	13.6	0.0031	11.8	12.8	0.5

3. Surgical outcomes for AC (Table 3)

At first, of patients in PTGBD group for moderate AC, 12 patients were taken operation and 13 were not. Thirteen patients could not be done operation because of severe adverse events during hospitalization (e.g., acute myocardial infarction, cerebral infarction, and so on), poor performance status (PS), super-aging, and not hoping operation. Laparoscopic cholecystectomy could be performed safely in all 12 PTGBD cases, and there were no significantly differences between two groups in mean operation time (PTGBD: 144 min vs. non-PTGBD: 144 min, $p = 0.98$) and mean blood loss (PTGBD: 37 mL vs. non-PTGBD: 92 mL, $p = 0.087$), which suggests PTGBD may bring a safe operation even for surgically high-risk patients (Table 3).

For severe AC patients, laparoscopic cholecystectomy could be performed safely in all of PTGBD cases; however, only one patient of non-PTGBD cases was underwent laparoscopic cholecystectomy. Moreover, three patients in non-PTGBD groups for severe AC were needed blood transfusion due to massive blood loss during surgery. Mean operation time was almost the same (PTGBD: 184 min vs. non-PTGBD: 160 min, $p = 0.59$), but there was a significant difference between two groups about mean blood loss (PTGBD: 97 mL vs. non-PTGBD: 812 mL, $p = 0.018$) for severe AC.

4. Recovery periods for AC (Tables 4, 5)

In Table 4, there were no significant differences in lengths of postoperative stay, time to start eating, and time to normalize inflammation markers (WBC, CRP) between PTGBD and non-PTGBD group with operation in both moderate and severe AC. Length of stay means the periods from performing PTGBD to discharge in PTGBD group, and in non-PTGBD group, the periods from the onset of cholecystitis to discharge.

However, considering without operation, PTGBD makes longer than non-PTGBD in length of stay and time to start eating (Table 5). One of reasons is that keeping PTGBD

Table 2 Clinical backgrounds and laboratory data at admission in the operation group for moderate and severe AC

	PTGBD $N = 17$	Non-PTGBD $N = 35$	p
Age (years)	77	76	0.058
Sex			
Male	9	25	0.22
Female	8	10	
BMI (kg/m^2)	22	23	0.1
Smoking history			
Never	11	24	0.58
Former/current	6	11	
DM			
Yes	8	6	0.023
No	9	29	
ASA			
1	1	15	0.014
2	10	16	
3	6	3	
4	0	1	
WBC (/μL)	13,460	12,560	0.29
CRP (mg/dL)	21	14	0.02
Plt (/μL)	1,79,000	1,96,000	0.11
T-Bil (mg/dL)	1	1.4	0.85
PT (%)	87	92	0.5
Cr (mg/dL)	0.89	0.93	0.81
Alb (mg/dL)	2.9	4	<0.01
Hb (g/L)	13	13.8	0.008

Table 3 The surgical outcomes for moderate and severe AC

Variables Moderate	PTGBD $N = 12$	Non-PTGBD $N = 30$	p
Operation time (min)	144	144	0.98
Blood loss (mL)	37	92	0.087
Laparoscopic surgery	12	28	
Intraoperative complication	0	1	
Postoperative complication	0	0	
Mortality	0	0	
Severe	$N = 5$	$N = 5$	
Operation time (min)	184	160	0.59
Blood loss (mL)	97	812	0.018
Laparoscopic surgery	5	1	
Intraoperative complication	0	3	
Postoperative complication	0	1	
Mortality	0	0	

tube makes difficult to discharge or transfer to other hospitals.

5. Results of bacteria from bile cultures gained by PTGBD (Fig. 2)

Bile cultures were collected from all patients in PTGBD group, and 43 kinds of bacteria were detected. Of 43 kinds of bacteria, *Escherichia coli* was the highest frequency (26%), and *Klebsiella pnumoniae*, *Klebsiella oxytoca*, Enterococcus species were second (9%). On the other hand, no bacteria were detected from bile cultures gained by those who received antibiotic therapy for AC.

Discussion

We researched the safety and efficacy of PTGBD for moderate and severe AC. There are four discussions about our research.

First, regarding the moderate AC, patients with PTGBD are older, hyperglycemia, and surgically high risk. Then, PTGBD groups have tendency of higher inflammation, anemia, and malnutrition. Nevertheless, we found that PTGBD groups can take as safe Lap-C as non-PTGBD groups. There are some studies that PTGBD has a possibility not only for improving surgical outcomes in elderly patients with comorbidities, but also for producing better outcomes with a lower conversion rate and fewer procedure-related complications [7–10]. Therefore, PTGBD is a kind of bridging therapies in order to perform safe Lap-C. However, at the same time, some people in PTGBD group could not take operation because of poor PS and some adverse events, and they had to spend longer time in hospital than patients with operation. So, we consider careful selection of patients whether to operable or not, and we should have a various ways of treatment options, for patients who do not have tolerance for operation because of poor PS or adverse events. This day, there are many drainage options, which have both merits and demerits. Percutaneous transhepatic gallbladder aspiration (PTGBA) is one of the most affordable methods for drainage, but it makes only decompression of gall bladder, so recurrence of cholecystitis may become problem [11]. Once cholecystitis may occur again, it is more difficult to accomplish Lap-C, so we need a continuous drainage for AC. Recently, endoscopic transpapillary gallbladder drainage and endoscopic ultrasound-guided gallbladder drainage have been introduced [12, 13]. In TG18, this procedure appears to be especially suitable for patients with severe coagulopathy, thrombocytopenia, or an anatomically inaccessible location [14]. However, in order to perform the safe endoscopic drainage, well-trained endoscopists are required. For many hospitals like our institution, PTGBD can be feasible and

Table 4 Recovery periods for moderate and severe AC with operation

Variable Moderate	PTGBD $N = 12$	Non-PTGBD $N = 30$	p
Length of stay (days)	18.5	14	0.162
Time to start eating (days)	5	6	0.536
Time to normalize WBC (days)	4.5	5.5	0.731
Time to become CRP < 3 (days)	8	8	0.301
Severe	$N = 5$	$N = 5$	
Length of stay (days)	19.6	35	0.093
Time to start eating (days)	7.8	22.6	0.058
Time to normalize WBC (days)	6.4	10	0.108
Time to become CRP < 3 (days)	15	12.2	0.108

Table 5 Recovery periods for moderate and severe AC without operation

Variable Moderate	PTGBD $N = 13$	non-PTGBD $N = 6$	p
Length of stay (days)	45	19	0.018
Time to start eating (days)	10	6	0.031
Time to normalize WBC (days)	13	6	0.504
Time to become CRP < 3 (days)	13	6	0.278
Severe	$N = 4$	$N = 4$	
Length of stay (days)	43	39	0.858
Time to start eating (days)	12	6	0.346
Time to normalize WBC (days)	14	8.5	0.44
Time to become CRP < 3(days)	20	14	0.287

convenient. In addition, we have no ICU and not enough medical staff, which makes us difficult to do early Lap-C and perform endoscopic drainage, so PTGBD is the first line for AC resistant for antibiotics.

Second, in severe AC, both operable and inoperable patients should take PTGBD for patient's survival. Operable patients, in particular, could take Lap-C safely by intervention of PTGBD, with no complication. However, three operated patients without PTGBD had one of negative predictive factors, and all of them had no choice but to do by open laparotomy and receive blood transfusion due to massive blood loss during surgery. According to TG18, negative predictive factors, that is, neurological dysfunction, respiratory dysfunction, and coexistence of jaundice (T-Bil $\geq$ 2 mg/dL) are shown as independent factors to be associated with a significant increase mortality rates within 30 days after surgery [5]. Therefore, severe AC patients with negative predictive factors should take PTGBD at first in order to keep stable condition. We believe that PTGBD is essential for treating grade III AC, and negative predictive factors may be one of sensitive markers for suitability of PTGBD.

Third, the optimal timing for cholecystectomy following PTGBD keeps still controversial today. A consensus has not been reached in TG18, since there are no reports providing quality scientific evidence on the best timing for surgery after PTGBD [5]. Some reports insists that early scheduled Lap-C following PTGBD is a safe and effective therapeutic option for patients with acute cholecystitis especially in elderly and complicated patients [14]. Other research reported, however, postoperative complications occurred more frequently when the interval was less than 216 h compared to when it was more than 216 h, and cholecystectomy for severe acute cholecystitis was technically difficult when performed within 216 h after PTGBD [15]. In our hospital, we perform cholecystectomy at least 4 weeks after PTGBD, and the mean period is 40 days. There was no complication about PTGBD and operation such as massive bleeding, bile leakage, or common bile duct damage. We think this is because remaining PTGBD tube for a certain period can make fistula between gallbladder, liver, and peritoneal wall, which makes risk for bleeding or bile leakage reduced. However, waiting for 40 days is too long compared with other reports, and patient's quality of life may get lower, so we should perform PTGBD more effectively.

Finally, we can obtain bacteria from bile culture only gained by PTGBD and found that *E. coli* was the highest frequency. Interestingly, *Pseudomonas aeruginosa* or extended-spectrum beta-lactamases (ESBL)-producing *E. coli* was also detected. In TG18, like also TG13, carbapenems, piperacillin/tazobactam, and ceftazidime or cefepime, each combined with metronidazole have been recommended because of resistant *Pseudomonas aeruginosa*, ESBL-producing *E. coli*, and so on [16]. In our hospital, we use routinely cefoperazone/sulbactam as the first line antibiotics for acute cholecystitis, because this drug has a good bile migration and has an effect to *Pseudomonas aeruginosa*. However, considering our results and TG18, we should use antibiotics with broader spectrum at first such as piperacillin/tazobactam or carbapenems, which can target ESBL-producing bacteria.

This study has some limitations: (1) the retrospective design of the study; and (2) direct comparisons with patients for PTGBD and early Lap-C were not performed in this study because of the insufficiency for environment; and (3) the optimal timing of cholecystectomy from PTGBD was unclear, and (4) there were few patients for severe acute cholecystitis. To overcome these problems, randomized clinical trials are required in the future to assess the most reasonable first-line approach for AC.

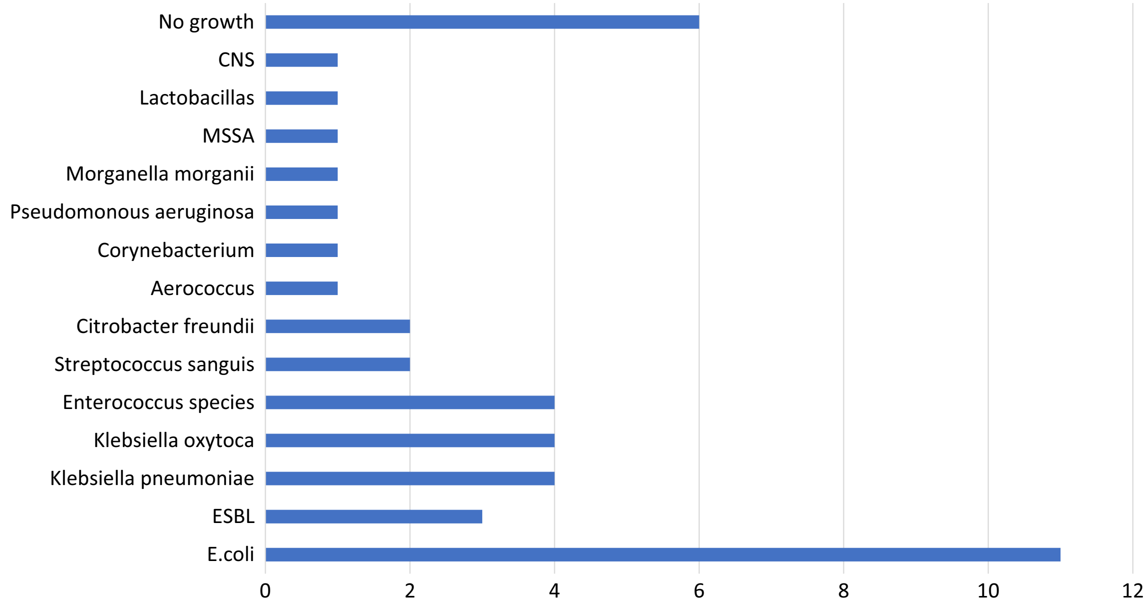

Fig. 2 Results of bacteria from bile cultures gained by PTGBD

Conclusion

In conclusion, preoperative PTGBD could yield a certain clinical benefit, which is the capability of safe Lap-C, for the patients with high-risk factors, especially in severe AC cases. Treatment flowchart in TG18 can be useful and feasible to make accurate prediction for surgically high-risk patients in AC.

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Compliance with ethical standards

Conflict of interest The authors have no conflict of interest to this report.

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