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LONG-TERM RESULTS BETWEEN INTERVAL SURGERY AND FOLLOW-UP AFTER PERCUTANEOUS CHOLECYSTOSTOMY: A RETROSPECTIVE COHORT STUDY.

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KEY WORDS
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ABSTRACT

Introduction. *Although cholecystectomy is the treatment of choice for acute cholecystitis (AC), in patients with high surgical risk percutaneous cholecystostomy (PC) is chosen in some cases. The aim of this report is to follow up these patients and evaluate biliary recurrences after PC.*

Methods. *A descriptive retrospective study was carried out in a third level hospital from August 2005 to December 2014. All patients diagnosed with acute lithiasis cholecystitis who were indicated as initial treatment with antibiotic therapy and PC echo-guided were included. Patients requiring emergent cholecystectomy during hospital and those who died during the AC episode were excluded. After hospital discharge, the patients were divided into two groups: group 1 (interval cholecystectomy) and group 2 (no surgery).*

Results. *From the 86 healed patients, there were 8 losses in the follow-up, so 78 patients were analyzed: group 1 (n=12) and group 2 (n=66).*

INTRODUCTION

Acute cholecystitis (AC) is a common entity in the western world, involving annually 1-4% of patients with cholelithiasis[1], and as a special situation, between 0.2-0.4% of critically ill patients without lithiasis[2].

Emergent cholecystectomy (EC) is the treatment of choice[3], preferably by laparoscopy if feasible. However, the treatment of patients with multiple comorbidities makes AC a therapeutic challenge, and percutaneous cholecystostomy (PC) is reserved for these cases[4]; although the identification of such high-risk patients is difficult and, thus, the role of PC is not yet fully established[5].

Classically, PC has been considered a temporary solution in case of patient poor condition. Sometimes interval surgery at discharge[6] is considered in case of improvement of the patient functional situation. However, the advanced age of the population has led to an increase in PC performance, reaching an annual increase in American series of up to 567% while that the increase of cholecystectomy was only 3%[7].

PC is a relatively easy and accessible treatment and its results are highly satisfactory[8,9], but it is necessary to bear in mind the possibility of treatment failures and complications during the procedure, resulting in the need to replace the drainage or urgent intervention.

In some studies, PC has been considered as a definitive treatment, showing low recurrence figures of cholecystitis [10,11,12], so the number of interval cholecystectomies has been decreasing. Even so, there are not guidelines or established consensus due to the differences in the management of PC, the lack of randomized studies and the limited long-term follow-up. In addition, the increase in life expectancy and survival after PC favour recurrences and biliary events[13].

Therefore, the aim of this study is to analyse the short and long-term outcomes of patients with AC who have been treated with PC, comparing later recurrences and biliary events in patients who underwent interval cholecystectomy with those who were not intervened.

MATERIAL AND METHODS

Patients. Retrospective study of patients with the diagnosis of AC between 2005 and 2014 in the University Hospital Marqués de Valdecilla (Santander, Spain). Data were extracted from the clinical records and those having been treated by percutaneous cholecystostomy were included in the study (n=109). Some of these patients were included in a previous study of short-term results [14].

The diagnosis was done according to the Tokyo Guidelines (TG 13-18) 3 and confirmed by ultrasonography in every patient.

PC indication was made according to the criterion of the attendant surgeon, based on comorbidities and advanced age. PC were performed by radiologists and ultrasound-guided in all the cases, through a transhepatic approach, with an 8.5F pig-tail catheter (Dawson-Mueller / Cook Medical Incorporated, Bloomington, IN), under local anesthesia. The gallbladder content was aspirated and bile samples were sent for culture. The catheter was then maintained without suction until clinical, analytical and ultrasound resolution.

Patients requiring emergent cholecystectomy during hospital admission due to treatment failure and those who died during the AC episode were excluded of the follow-up.

After hospital discharge, the patients were divided into two groups: group 1 (interval cholecystectomy) and group 2 (no surgery).

We defined IC as an elective cholecystectomy planned at the time of hospital discharge. Upon discharge and according to the personal decision of the attendant surgeon and patient wishes, scheduled cholecystectomy (interval cholecystectomy) was performed. Postoperative complications were classified according to the Dindo-Clavien classification [15].

We defined biliary event during follow-up as any documented clinical event related to gallbladder or gallstones (biliary colic, AC, pancreatitis or choledocholithiasis).

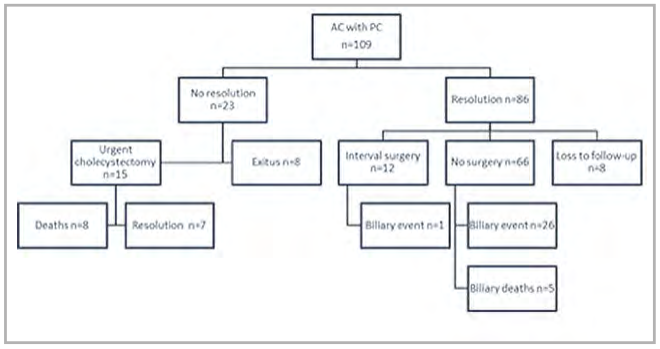

Figure 1.- *AC, acute cholecystitis. PC, percutaneous cholecystostomy.*

Statistical analysis

A bivariate analysis was performed to compare the patients with interval surgery and those who were not operated, using the chi square and the t test for categorical and continuous variables, respectively. In situations where the expected frequencies were less

Table I.-

ASA, THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA) PHYSICAL STATUS CLASSIFICATION SYSTEM.

Characteristics	Total n=109	Interval surgery n=12	Without surgery n=6	P
Age, years (σ*)	80.0 (9.7)	72.1 (7.1)	80.6 (10.1)	0.007
Gender (%):				0.341
Male¯	71 (65.1)	9 (75)	42 (63.3)	
Female	38 (34.9)	3 (25)	24 (36.4)	
Charlson CI (σ)	7.4 (2.4)	5.8 (2.1)	7.5 (2.1)	0.012
ASA (%):				0.272
I 3 (2.7)	0 (0)	2 (3%)		
II 13 (11.9)	4 (33.3)	9 (13.6%)		
III 66 (60.6)	7 (58.3)	39 (59.1%)		
IV 27 (24.8)	1 (8.3)	16 (24.2%)		
Arterial hypertension (%)	79 (72.5)	7 (58.3)	45 (68.2)	0.361
Diabetes mellitus (%)	29 (26.6)	6 (50)	18 (27.3)	0.111
Severity by Tokyo (%):				0.300
Grade I	20 (18.4)	4 (33.3)	14 (21.2)	
Grade II	64 (58.7)	5 (41.7)	43 (65.2)	
Grade III	25 (22.9)	3 (25)	9 (13.6)	
Pancreatitis (%)	7 (6.4)	0 (0)	3 (4.5)	0.503
Hospital stay (σ)	17.0 (18,7)	15.6 (9.9)	17.0 (20.8)	0.823
Resolution (%)	86 (78.9)	78 (100)		
Complications PC (%):	8 (7.3%)	0 (0)	2 (3)	0.503
Biloma	4 (3.7)			
Involuntary withdrawals	3 (2.8)			
Hepatic bleeding	1 (0.9)			
Hospitalary death (%)	16 (14,7)			
Cholecystectomy (%):	PC hospitalization 15 (13.8)	Interval surgery 12 (100)		
Laparoscopy	5 (33.3)	5 (41.7)		
Open surgery	10 (66.7)	4 (33.3)		
Laparoscopy converted	0 (0)	3 (25)		

σ*, *standard deviation.* *CCI, Charlson comorbidity index.* *PC, percutaneous cholecystostomy.*

than 5, Fisher's exact test was used. Kaplan-Meier and Cox regression were performed for survival analysis and calculation of the Hazard ratio. Statistical significance was established at $p \leq 0.05$.

RESULTS

From 109 patients, AC was healed in 86 (78.9%) patients. Fifteen (13.8%) required EC because failure to improve, laparoscopic in 5 patients and open in 10. Sixteen (14.7%) patients died because of sepsis progression, 8 treated only by PC and 8 after EC.

Mean hospital stay was 17 days. There was not mortality directly related with the PC technique. Eight (7.3%) patients had complications: 4 (3.7%) bile collections, 3 (2.8%) incidental catheter loss and 1 (0.9%) case of abdominal bleeding requiring surgery.

From the 86 healed patients, there were 8 losses in the follow-up, as a result, the long-term results of 78 patients were analyzed: group 1 (n=12) and group 2 (n=66) (**Figure 1**).

Patient clinical features are shown in the **Table I**. Patients both groups were comparable in terms of gender, ASA score, frequency of diabetes mellitus or hypertension and AC severity score. However, the Charlson comorbidity score mean value and the mean age of the group 2 patients were higher, reflecting the selection criteria for IC.

Surgery was performed after a mean period of 146.6 days (ds: 126.9) and was laparoscopic in 8 (67%) patients – conversion needed in 3– and open in 4 (33%). The mean hospital stay was 4.1 days. There were 4 complications: 4 grade I, 1 grade II and 1 grade IIIb of the Dindo-Clavien classification.

The mean follow-up was 32.9 months (**Table II**). More biliary events happened in the group 2 (39,4%) than in the group 1 (8,3%), the odds ratio being 7.14 and the hazard ratio 4.76 (p=0,126). The mean time to the event are 1 month in the group 1 and 8 months in the group 2, taking place during the first year the 100% and the 87.4% of them respectively (**Figure 2**).

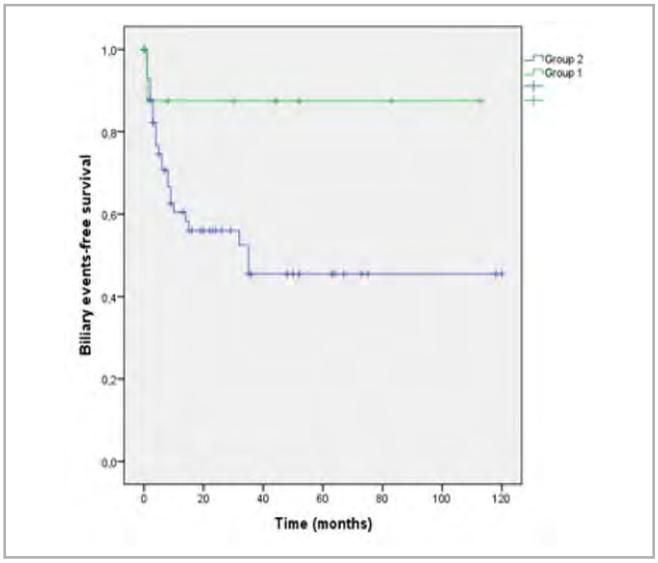

Figure 2.- *. Group 1: Interval surgery. Group 2: Without surgery*

This was principally due to a higher frequency of new bouts of AC in the group 2 -17 cases-, as well as 6 choledocholithiasis and 3 acute biliary pancreatitis. They were treated by antibiotic therapy alone in 11, ERCP in 7, a second PC in 4 and EC in 2 patients.

In group 1, only one choledocholithiasis occurred; being posterior to cholecystectomy and was managed by ERCP.

Although there are differences in overall mortality: 8.3% in group 1 vs 50% in group 2 (p=0.006); there is no statistical significance (p=0.423) in terms of biliary mortality: 0% vs 7.6%.

Table II.-

Follow up	Total n=78	Interval surgery n=12	Without surgery n=66	P
Months	32.9	34.5	32.7	0.847
Biliary event (%):	27 (34.6)	1 (8.3)	26 (39.4)	0.033
Cholecystitis	17 (21.8)	0 (0)	17 (25.8)	
Choledocolithiasis	7 (9)	1 (8.3)	6 (9.1)	
Pancreatitis	3 (3.8)	0 (0)	3 (4.5)	
Treatment (%)		1 (8.3)	24 (36.4)	0.056
Antibiotic therapy		0 (0)	11 (16.7)	
Another PC		0 (0)	4 (6.1)	
Cholecystectomy		0 (0)	2 (3)	
ERCP		1 (8.3)	7 (10.6)	
Time to event (months)	8.3	1	8.6	0.469
1st year biliary event		1 (8,3)	21 (31,8)	0.096
1st year cholecystitis recurrence		0 (0)	14 (21,2)	
Biliary event-free survival (months)	66.9	99.0	60.6	0.086
Estimated survival (months)	66.1	92.7	60.8	0.065
Deaths (%)	34 (43.6)	1 (8.3)	33 (50)	0.006
Biliary deaths (%)	5 (6.4)	0 (0)	5 (7.6)	0.423

PC, percutaneous cholecystostomy. ERCP, Endoscopic Retrograde Cholangio Pancreatography.

DISCUSSION

Early cholecystectomy is being used with increasing frequency for AC. Today is widely accepted as the treatment of choice, even in severe cases in patients with more than 5 days of abdominal pain or 72 hours of clinical AC [3,17-19]. In some cases, a high risk situation can be predicted either by local inflammatory conditions heralding postoperative morbidity, or poor physiological condition and advanced age. In these cases, PC is a safe treatment and its indication is recognized [20]. In our previous experience, PC is not superior to EC, so it should be limited to the patient who does not fit for surgery 14. The TG 18 guidelines recommend consideration of PC in case the patient cannot withstand surgery [21]. However, the definition of such patients is not clear. The TG 18 guidelines propose scores of CCI≥4 and ASA≥3, as well as neurological or respiratory dysfunction, and coexistence of jaundice (TBil ≥ 2mg/dL) [21].

When comparing our current results with other published experiences, we found a lower success rate of PC: 78.9% versus 91-100% [4,8,13]. Our 7.3% complication rate is, however, much lower than the 21.4-46% reported by the same works. The differences could be explained because we always remove the catheter upon clinical resolution, before discharge. Nevertheless, there are not to date evidence concerning any influence of time of catheter presence on the results [22]. The differences could also be explained by the preferential surgical management of AC in our center, leaving PC treatment for very high risk patients [23]. Actually, the mean age of our patients is 10 years higher and the CCI is 2 points greater than those of the patients of other series, which to some extent, could limit the extrapolation of results to other series and conditions.

But, what about log-term results? What is the probability of having new bouts of AC or biliary pancreatitis or choledocholithiasis? The answer is difficult because this topic has seldom been studied.

If the patient is treated by cholecystectomy, few biliary problems are expected. In a very low number of cases a retained common bile stone can be found. However, if the patient is treated by PC, the problem comes after the clinical resolution and discharge. What patient is to be operated? Some patients have an "acute" poor physiological condition –acute renal insufficiency, hyperbilirrubinemia, liver failure, arrhythmias– which could improve after resolution of the AC. These patients have probably a considerable life expectancy, and, therefore, a high probability of biliary events. These patients are probably good candidates for interval cholecystectomy. On the other hand, patients with high CCI or ASA scores, reflecting "chronic" poor physiological condition, are not good candidates to surgery, because their high surgical risk. To study this aspect, comparison with patients of similar CCI/ASA values with and without interval cholecystectomy is needed, but the numbers of the present study were too small.

In our experience, a new bout of AC happens in 25.8%, comparable to 25.5% in another study of 11184 patients having received a PC [24]. The AC recurrence rate within one year of PC varies from 6 to 20% across various studies [25], while we obtain an AC recurrence of 21.2 in the first year. Our results suggest, despite the advanced age of the population studied, a considerable survival after interval cholecystectomy, with a reduction over 470% of biliary events; being our percentage of biliary events (group 1: 8.3 vs. group 2: 39.4, p=0.033) comparable to other experiences (6.8 vs 21.1, p = 0.002)[13].

In addition to the relatively small number of patients, other limitations were the retrospective nature of the study and the fact that the decision to perform interval cholecystectomy was not based on a protocol but in the decision of the attendant surgeon.

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