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Acute cholecystitis in high-risk patients: percutaneous cholecystostomy vs conservative treatment

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Abstract Our objective was to compare the effectiveness of percutaneous cholecystostomy (PC) vs conservative treatment (CO) in high-risk patients with acute cholecystitis. The study was randomized and comprised 123 high-risk patients with acute cholecystitis. All patients fulfilled the ultrasonographic criteria of acute inflammation and had an APACHE II score ≥ 12 . Percutaneous cholecystostomy guided by US or CT was successful in 60 of 63 patients (95.2%) who comprised the PC group. Sixty patients were conservatively treated (CO group). One patient died after unsuccessful PC (1.6%). Resolution of symptoms occurred in 54 of 63 patients (86%). Eleven patients (17.5%) died either of ongoing sepsis ($n=6$) or severe underlying disease ($n=5$) within 30 days. Seven patients (11%) were operated on because of persisting symptoms ($n=3$), catheter dislodgment ($n=3$), or unsuccessful PC

($n=1$). Cholecystolithotripsy was performed in 5 patients (8%). Elective surgery was performed in 9 cases (14%). No further treatment was needed in 32 patients (51%). In the CO group, 52 patients (87%) fully recovered and 8 patients (13%) died of ongoing sepsis within 30 days. All successfully treated patients showed clinical improvement during the first 3 days of treatment. Percutaneous cholecystostomy in high-risk patients with acute cholecystitis did not decrease mortality in relation to conservative treatment. Percutaneous cholecystostomy might be suggested to patients not presenting clinical improvement following 3 days of conservative treatment, to critically ill intensive care unit patients, or to candidates for percutaneous cholecystolithotripsy.

Keywords Acute cholecystitis · Percutaneous treatment · Cholecystostomy · APACHE II score

Introduction

Open or laparoscopic cholecystectomy is the treatment of choice for cholecystitis [1, 2, 3]; however, surgically high-risk patients with severe underlying disease or with a debilitated general condition are initially treated conservatively. Percutaneous cholecystostomy (PC), a minimally invasive method, appears to be a reasonable alternative for these patients, promising prompt clinical response with only few procedure-related complications [4, 5, 6, 7]. Percutaneous cholecystostomy has not been

compared with conservative treatment as the initial treatment of choice in surgically high-risk patients. This study was designed to evaluate the effectiveness, possible advantages, and complications of PC in relation to conservative treatment in this group of patients.

Patients and methods

The study comprised 123 surgically high-risk patients with symptoms of acute cholecystitis and an APACHE II score of 12 or more admitted to our hospital during a 4-year period, from 1995–1999.

The age range was 43–95 years (mean age 79.1 years). Sixty-one patients were men (age range 43–92 years, mean age 78.2 years), and 59 were women (age range 51–95 years, mean age 79.3 years).

All patients had clinical signs and symptoms of acute cholecystitis and laboratory tests compatible with the disease. In addition, all patients fulfilled the ultrasonographic criteria of inflammatory gallbladder (GB) involvement, with a minimum of two criteria present in each case [6, 8]. Criteria included: GB distension; GB wall >3 mm; positive US Murphy sign; pericholecystic fluid; and presence of stones.

Eight patients were referred from the intensive care unit (ICU) in septic condition with laboratory tests suggesting acute cholecystitis.

After patients' referral, randomization took place. Patients were randomly assigned into two groups by drawing a playing card. Black cards sent the patients to the CO group ($n=60$), where conservative treatment was administered, whereas red cards sent patients to the group ($n=63$) for PC. Six ICU patients were randomized in the PC group and 2 in the CO group. Two specialized and dedicated interventional radiologists performed all procedures.

Conservative treatment, which included intravenous (IV) administration of fluids, broad spectrum antibiotics, and non-steroid anti-inflammatory drugs combined with proton pump inhibitors for stomach protection, was immediately given to all patients after their referral. If patients were randomized in the PC group, PC was attempted within the first 24 h following their referral.

Forty-two CO-group patients suffered from calculous and 18 from acalculous cholecystitis (2 ICU patients). Of 60 patients (age range 69–93 years, mean age 80.3 years), 32 were men (age range 69–91 years, mean age 78.5), and 28 were women (age range 70–93 years, mean age 80.6 years).

Percutaneous cholecystostomy was successfully performed in 60 patients (age range 43–95 years, mean age 77.2 years): 29 men (age range 43–92 years, mean age 78.3 years); and 31 women (age range 51–95 years, mean age 77.1 years). Forty-one suffered from calculous and 19 from acalculous disease (6 ICU patients).

Computer tomographic guidance for PC was used early in our series in 17 patients, because the performing radiologists were more experienced with this method. Ultrasound guidance was used during the last 43 cases, after the interventional team gained experience with this technique. The Seldinger technique was employed for all CT-guided cases and a Trocar catheter-needle system for all US-guided punctures. Catheters used were of 7–10 F and inserted through a transhepatic (TH, $n=34$) or a transperitoneal (TP, $n=26$) access route. In the first 17 cases, which were CT guided, simple 7- to 8-F nephrostomy catheters were employed, whereas 7-F van Sonnenberg or 8- to 10-F Flexima locking pigtail catheters were used in the remaining 43, which were US-guided cases (all 60 catheters were from Boston Scientific, Bloomington, Mass.). The locking pigtail catheters were until then not available in our department.

The PC catheter was left open, connected with a collection bag and flushing with saline solution was ordered only if bile was not draining satisfactorily. Transcatheter cholangiography was performed 3–4 days after PC. Appropriate catheter position, patency of cystic and common bile ducts, as well as the presence and location of stones were evaluated during the procedure. The catheter was withdrawn following confirmation of ductal system patency and demonstration of a mature cystocutaneous fistula by fistulography. The latter was performed 2 weeks after a transhepatic PC and 3 weeks after a transperitoneal PC. In cases where the fistula failed to close, a new catheter was inserted for one more week and a fistulography was repeated at the end of this week. A follow-up period of 12 months was set for all survivors.

The PC was considered successful when clinical improvement was observed with the decrease or disappearance of pain, fever, and leukocytosis along with the absence of complications related

to PC or catheter removal. If improvement of patient's condition was not apparent 3 days following PC, an emergency operation was conducted provided the patient's APACHE II score was ≤ 15 . If the score was higher than 15, no further invasive treatment was attempted. Elective cholecystectomy was proposed after successful treatment of all calculous cases presenting an APACHE II score lower than 12 from both groups. Percutaneous lithotripsy was proposed in calculous cases where the APACHE II score remained higher than 12 after a successful PC.

Statistical analysis was performed using the chi-square test with Yate's correction and Student's *t*-test. A *p* value less than 0.05 was considered statistically significant.

The review board of our hospital approved the study protocol.

Results

All patients had positive clinical, laboratory, and US findings for acute cholecystitis. Gallbladder was distended with a volume of more than 70 ml in all patients. Right upper abdominal pain and fever were the apparent symptoms in 115 patients, where vomiting was present in 36 of these cases. Increased alkaline phosphatase, γ -GT, SGOT, and SGPT levels were found in 76, elevated serum bilirubin in 38, and leukocytosis in 102 of these patients. Gallbladder wall thicker than 3 mm was identified in 85 patients, a positive US Murphy sign existed in 79, and pericholecystic fluid in 15 cases. Gallstones were recognized in 83 patients, in 12 of whom they were associated with common bile duct (CBD) stones. One patient was diagnosed with having a CBD-obstructing pancreatic head carcinoma and another one a CBD-obstructing pseudocyst.

Sixty-three patients were initially included in the PC group. The PC was successfully performed in 60 patients (95.2%). Early in our experience, the procedure using the Seldinger technique was not completed in three uncooperative patients. All three cases of technical failure were included in the PC group. The CT guidance was utilized in these cases using either TH ($n=2$) or TP access route ($n=1$). The two transhepatically punctured patients presented no complications, and were therefore conservatively treated. The trans-peritoneal punctured patient (APACHE II score=14) showed symptoms of bile peritonitis and died during emergency surgery (procedure related mortality 1.6%; Table 1).

After gaining experience, we moved from CT- to US-guided PCs that were completed in a much shorter operation time and with less discomfort for the patients. The TH drainage was performed in all calculous cases, to ensure better and safer surgical conditions for percutaneous lithotripsy, if needed. Delayed dislodgment of non-locking nephrostomy catheters used early in our series was observed in 9 patients, all with APACHE score ≤ 15 ; 3 of them (5%) underwent uneventful emergency operation because of bile peritonitis (Table 1), whereas the remaining 6 who showed no clinical worsening were conservatively treated with positive outcome.

Table 1 Percutaneous cholecystostomy (PC) group: results. *TP* transperitoneal access route

Acute cholecystitis	Emergency surgery due to persistent symptoms (uneventful)	Emergency surgery due to unsuccessful PC (patient died)	Emergency surgery due to catheter dislodgment (uneventful)	Percutaneous lithotripsy	Elective surgery	No further treatment
APACHE II score ≥ 12	APACHE II score ≤ 15	APACHE II score ≤ 15	APACHE II score ≤ 15	APACHE score ≥ 12	APACHE II score < 12	
Calculous ($n=44$)	2 of 44	1 of 44	3 of 41 (TP)	5 of 44	9 of 44	19 of 44
Acalculous ($n=19$)	1 of 19	0 of 19	0 of 19	0 of 19	0 of 19	13 of 19
Total ($n=63$)	3 of 63 (5%)	1 of 63 (1.6%)	3 of 60 (5%)	5 of 63 (8%)	9 of 63 (14%)	32 of 63 (51%)

Table 2 Percutaneous cholecystostomy group: results. *ICU* intensive care unit patients; *TP* transperitoneal access route

Acute cholecystitis	Successfully performed PCs	Symptom resolution after successful PC	Symptom resolution after unsuccessful PC	Symptom resolution after PC	30-day mortality despite symptom resolution, due to the underlying disease	No symptom resolution after PC	30-day mortality, no symptom resolution due to ongoing sepsis	30-day mortality
APACHE II score ≥ 12					APACHE II score ≥ 12		APACHE II score ≥ 12	
Calculous ($n=44$)	41 of 44	37 of 41	2 of 3	39 of 44	3 of 39	5 of 44	3 of 44 (1 PC failure)	6 of 44 (1 PC failure)
Acalculous ($n=19$)	19 of 19 (6 ICU)	15 of 19 (3 ICU)	0	15 of 19 (3 ICU)	2 of 15	4 of 19 (3 ICU)	3 of 19 (3 ICU)	5 of 19
Total ($n=63$)	60 of 63 (95.2%)	52 of 60 (87%)	2 of 3 (67%)	54 of 63 (86%)	5 of 54 (9%)	9 of 63 (14%)	6 of 63 (9.5%)	11 of 63 (17.5%)

Resolution of symptoms during the first three post-procedural days was noted in 54 of 63 PC-group patients (86%; Table 2); these included 2 patients with unsuccessful PC, who were treated conservatively and recovered uneventfully. Six cases of acalculous cholecystitis represent ICU patients, three of which recovered after successful PC (Table 2). Of the 54 patients with symptom resolution after PC, 5 died during the first 30 days (9%), despite initial clinical improvement, because of severe underlying diseases (APACHE II score ≥ 12). In total, 9 of 63 patients showed no symptom resolution after PC (14%). Six of them died due to ongoing sepsis during the first 30 days after successful PC (9.5%), one of whom died during emergency surgery after PC failure, due to bile peritonitis and sepsis (1.6%). All 6 patients had an APACHE II score ≥ 12 . In total, 11 patients, all with an APACHE II score ≥ 12 , died during the first 30 postprocedural days, 10 of them because of non-procedural related causes (total 30-day mortality rate=17.5%; Table 1). Another 3 patients with no clinical improvement after successful PC and an APACHE II score ≤ 15 were uneventfully surgically treated on an emergency basis (5%). In total, 7 patients with an APACHE II score of ≤ 15 were operated on, due to catheter dislodgment

($n=3$), persisting symptoms ($n=3$), or after unsuccessful PC ($n=1$); 6 of 7 recovered uneventfully (86%).

Nine of the 44 patients with post-PC resolution of symptoms – all with calculous cholecystitis – underwent elective cholecystectomy without complications 3–6 months later. In all cases the APACHE II score was under 12 at the time of operation (Table 1). In five more patients with GB stones, percutaneous cholecystolithotomy was performed, 3–6 weeks after effective PC. In these patients the APACHE II score remained over 12 due to the severe underlying diseases. The procedure was successful in 3 patients, whereas in 2 it was not completed due to the patient's limited cooperation, but without any clinical consequences. In the remaining 32 of 44 patients, including the 2 patients with unsuccessfully attempted PC, no additional treatment was administered (Table 1). In 1 case recurrence of calculous cholecystitis occurred 70 days following PC. This patient refused new PC and was successfully operated on (APACHE II score=13). In another patient, an abdominal wall abscess was developed 180 days after catheter removal. Superficial draining was performed, but the abscess recurred 50 days later. Subsequent deeper surgical draining and exploration revealed a stone fixed in the ab-

Table 3 Conservative treatment group: results. ICU intensive care unit patients

Acute cholecystitis APACHE II score \geq 12	Clinical improvement	30-day mortality due to ongoing sepsis APACHE II score $>$ 12	Elective surgery APACHE II score $<$ 12	No further treatment
Calculous ($n=42$)	35	7	7	28
Acalculous ($n=18$)	17 (1 ICU)	1 (ICU)	0	17
Total ($n=60$, 2 ICU)	52 (87%)	8 (13%)	7 (12%)	45 (75%)

dominal wall, at the initial site of the PC tract. No correlation existed between clinical response and US evidence of pericholecystic fluid ($p>0.10$). There was also no statistically significant relevance either between technical success and guiding method, access route, puncturing technique, or presence of GB stones ($p>0.10$).

Resolution of symptoms occurred in 52 patients (1 ICU patient) of the CO group (clinical response 87%), whereas the remaining 8 patients (APACHE score $>$ 12) died of ongoing sepsis (13%), 7 of which with calculous and 1 with acalculous disease (1 ICU patient; Table 3).

There was not a statistically significant difference noted in mortality rates between the PC and the CO group ($p>0.05$). The APACHE II score of the CO-group patients at admission showed no significant differences ($p>0.10$) between the patients who survived and those who did not (mean score of 13.9 for survivors and 14.2 for non-survivors). Seven patients (12%) with calculous cholecystitis and an APACHE II score $<$ 12 were successfully operated on after cessation of acute inflammation. No further treatment was considered necessary in 28 calculous and 17 acalculous cases (Table 3). Three patients with GB stones had recurrent cholecystitis 2–6 months following treatment and were again conservatively treated with uneventful recovery.

Discussion

The treatment of choice for acute cholecystitis in the elderly is either surgery on an emergency basis or conservative treatment followed by elective cholecystectomy later [1]. The procedure has significant mortality rates of 4.4–7.5% related to the advanced age and coexisting diseases implying high surgical risk to the patient [1, 9]. Overall mortality decreased to 1.0–1.8% with laparoscopic cholecystectomy [1, 2]. Of major concern is the medical morbidity of 13% in 65- to 75-year-old and of 18% in over 75-year-old patients, because of various coexisting diseases [2]. Medical morbidity or mortality is defined as either an exacerbation of a preoperative medical problem – not related to cholecystitis – requiring treatment or a complication that arises after surgery which is not directly related to an error in surgical technique [2]. Since elective surgery is safer than emergency surgery, conservative treatment has been suggested during the

acute phase, to stabilize patients until elective surgery [3]. Surgical cholecystostomy (SC) has also been proposed instead of conservative treatment or cholecystectomy in order to avoid emergency open surgery [10]; however, mortality rates of 4.2% reported with SC in older patients [2, 10] did not encourage the use of the method. Recently, PC was introduced to decrease morbidity and mortality in surgically high-risk patients with acute cholecystitis and to lead to safer elective surgery [6, 8, 11]. More specific indications include decompression of the GB in acute cholecystitis, obstructive jaundice, hemorrhagic or emphysematous cholecystitis, and GB perforation [12, 13, 14, 15].

Although PC has been proposed as an alternative to conservative treatment in the initial stages of acute cholecystitis, to the best of our knowledge, the two treatment options have not been previously compared with each other. The aim of this prospective, randomized study was to evaluate the effectiveness and complications of PC, and to examine whether or not it offers any advantage over conservative treatment in the management of surgically high-risk patients with acute cholecystitis. The APACHE II scoring system [16] was used to evaluate the patients' clinical status; those with a score equal to or higher than 12 were considered as surgically high-risk candidates [17].

Technical success of PC can be very high in experienced hands with reported rates of 95–100% [4, 8, 11, 18, 19]. Learning curve of the performing team can decrease these rates. The 95.2% technical success in our series is comparable with these rates. Mortality related to PC has a prevalence of 0–3% [4, 6, 7, 8, 11, 18, 19, 20], whereas minor post-PC complications have been mentioned in 4–18% of the cases [4, 7, 18, 20, 21]. Bile leakage is the most common complication which may lead to life-threatening peritonitis [19]. We encountered one procedure-related death in 63 PC attempts (1.6% mortality rate). It was an uncooperative patient who developed bile peritonitis after CT-guided puncture early in our series.

Not uncommon complications in our series were accidental dislodgment of non-locking nephrostomy catheters in 9 patients, all with an APACHE score \leq 15, followed by bile peritonitis in 3 cases where the patients underwent transperitoneal PC puncture. These patients were operated on, with a positive outcome. After the in-

roduction of the locking pigtailed catheters, which were initially not available, no further catheter dislodgment was noted. Nevertheless, patients with catheter dislodgment were treated either conservatively or by surgical means. This kind of treatment did not change patient outcome or increase the mortality rate, so there was no significant influence on our results. Reported complications in previous studies, such as vagal reaction, hemorrhage, acute respiratory distress, or intestinal perforation, were not observed in our series [4, 5, 22]. Only one late complication in the form of a recurrent abdominal wall abscess was noted, due to a GB stone which probably escaped into the cysto-cutaneous fistula after catheter removal [23]. In this case lithotripsy was not attempted.

Ultrasound-guided procedures are considered more preferable than CT-guided procedures in experienced hands [4, 7, 8]. We started with CT guidance because this method offers some advantages to less experienced centers. Our results may have been influenced by the lack of experience in US-guided percutaneous cholecystostomy at the beginning of our study, but despite that fact, our total technical success rate is comparable with that of other series in the literature, as mentioned previously. The optimum puncture route in PC, i.e., transperitoneal or transhepatic, remains controversial. The transperitoneal access is considered safe, easy to perform, and less traumatic than the transhepatic access in cases where either the GB is large and protrudes under the right costal margin or there is severe liver disease or coagulopathy present [24]. The TH route is considered more appropriate for patients without liver pathology, and in cases of calculous disease where percutaneous lithotripsy is scheduled [7]. Nevertheless, van Overhagen et al. [7] found no difference in the complication rates between the two techniques. The TH approach is associated with faster tract maturation [25], especially in the presence of ascites.

Resuming our experience, a US-guided locking-pig-tail-Trocar system, through a TH route, targeting the so-called bare area of the GB provides shorter procedural time, a low number of punctures, and decreased patient discomfort. This is in accordance with the practice of previous authors [19, 25]. The 8-F Flexima pigtail locking catheters presented excellent performance in our series since they are well seen on US, are easily inserted, do not bend or nick, and almost never dislodge accidentally. We tried to set a TH drainage in all calculous cases, to ensure better and safer operation conditions for percutaneous lithotripsy, in case it might be necessary.

Sepsis of unknown origin in critically ill patients, and especially in intensive care unit (ICU) patients, may be due to acalculous cholecystitis. In unconscious or intubated patients, subjective criteria of acute cholecystitis, such as positive US Murphy sign or abdominal pain and tenderness, are difficult to evaluate [6, 8]. In such cases, US findings are valuable and placement of a PC catheter with positive clinical response may verify GB pathology

as the source of inflammation. A relatively low clinical response (<60%) is reported in ICU patients [6, 8]. In our series 6 ICU patients with acalculous cholecystitis were included in the PC group and 2 in the CO group; only 4 of them showed rapid clinical response (50%). Boland et al. [6] stressed that an aggressive approach toward PC in critically ill patients with unexplained sepsis is justified, because PC has a reasonable rate of success. Using this technique, Boggi et al. [18] presented a very high success rate of 91% in ICU patients.

England et al. [8] suggested that PC can be beneficial when US reveals gallstones, wall thickening, GB distension, or pericholecystic fluid. The three former criteria were also found in the majority of our cases with a positive outcome, but no correlation existed between pericholecystic fluid and patient recovery after PC.

Severe underlying diseases in patients with an APACHE II score higher than 15, followed by the absence of clinical response to PC, increased our 30-day mortality rate. Our overall mortality rate of 17.5% is comparable to rates of 3–36% reported in previous studies [4, 8, 21]. The negative outcome may also be the result of sepsis not originating from GB pathology or could also be related to the severe and non-reversible clinical condition with or without the presence of gangrenous or necrotic cholecystitis [7, 8]. In cases where the APACHE II score was ≤ 15 , we noted good results by performing an emergency cholecystectomy if the patients showed no clinical improvement 3 days after catheter placement.

In our CO group the resolution of symptoms was observed in 87% of the patients after the third day of treatment. The 30-day mortality rate of 13%, due to ongoing sepsis, was not considered high when taking into account the severe clinical condition of the patients. The APACHE II score did not differ between the patients who survived and those who did not, so that no speculation can be made about relating the mortality rate with the APACHE II score or about regarding the rightness of threshold of 12 used in the present study. It is worth noting that all patients with a negative outcome did not show any clinical improvement during the first 3 days of conservative treatment. On the contrary, all patients who survived presented significant clinical improvement during the same period of treatment. The presence or absence of clinical response during the first 3 days was considered a useful prognostic factor that may be of value in the further management of conservatively treated patients. For example, PC might be beneficial in patients presenting no improvement after 3 days of conservative treatment.

In the PC group, the 30-day survival rate was 82.5%, which was lower but comparable with that of the CO group. The positive response rate would have probably risen in the PC group if the 6 ICU patients had not been taken into account. Percutaneous cholecystostomy pro-

vided the potential for subsequent percutaneous lithotripsy in 5 patients, with a final success in 3 of them. Nine PC-group patients and 7 CO-group patients with calculous cholecystitis were electively operated on after the APACHE II score fell under 12, whereas in the remaining 17 and 28 patients, respectively, no further treatment was undertaken. Only 1 patient with GB stones who showed recurrence was surgically treated. In this patient the underlying disease was in the meanwhile treated and he had a score of 10 during surgery. All acalculous cases remained without symptoms during the follow-up period.

We conclude that our results indicate a new approach for high-risk patients with acute cholecystitis. Initially, these patients can be conservatively treated for 3 days. When clinical improvement occurs, therapy is continued until the patient's full recovery. No further treatment is needed in acalculous cases, whereas in calculous disease, surgery may be proposed on an elective basis. If there is no response to the initial 3-day conservative treatment, PC is suggested. Percutaneous cholecystostomy should be performed by experienced interventional radiologists, using locking pigtail catheters under US guidance. No response after PC will probably be followed by a fatal

outcome, so that an emergency operation should be attempted. We practiced this with an APACHE II score threshold of 15. When a patient recovers as a result of PC, no further treatment is required for acalculous cases. In calculous cases, patients may either be electively operated on if the APACHE II score falls under 12, or they may undergo percutaneous cholecystolithotripsy if the score remains over 12, whereas no further treatment is also an alternative [7, 11, 20, 26]. If PC has to be performed and no liver disorders or coagulopathy exist, a TH route should be selected for calculous cases when lithotripsy is a therapeutic option. A transhepatic route is also preferable when GB is small and not protruding from liver anterior edge, if ascites is present, and in uncooperative patients in order to prevent bile leakage after eventual puncture failure. According to the results of our study, PC could not be suggested as the initial treatment of choice in surgically high-risk patients with acute cholecystitis, since it did not present lower mortality rates than conservative treatment. Percutaneous cholecystostomy may be performed in selected cases which include patients not presenting clinical improvement after 3 days of conservative treatment, critically ill ICU patients, and candidates for percutaneous lithotripsy.

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