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REVIEW ARTICLE

Systematic review of cholecystostomy as a treatment option in acute cholecystitis

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Abstract

Objectives: Percutaneous cholecystostomy (PC) is an established low-mortality treatment option for elderly and critically ill patients with acute cholecystitis. The primary aim of this review is to find out if there is any evidence in the literature to recommend PC rather than cholecystectomy for acute cholecystitis in the elderly population.

Methods: In April 2007, a systematic electronic database search was performed on the subject of PC and cholecystectomy in the elderly population. After exclusions, 53 studies remained, comprising 1918 patients. Three papers described randomized controlled trials (RCTs), but none compared the outcomes of PC and cholecystectomy. A total of 19 papers on mortality after cholecystectomy in patients aged >65 years were identified.

Results: Successful intervention was seen in 85.6% of patients with acute cholecystitis. A total of 40% of patients treated with PC were later cholecystectomized, with a mortality rate of 1.96%. Procedure mortality was 0.36%, but 30-day mortality rates were 15.4 % in patients treated with PC and 4.5% in those treated with acute cholecystectomy ($P < 0.001$).

Conclusions: There are no controlled studies evaluating the outcome of PC vs. cholecystectomy and the papers reviewed are of evidence grade C. It is not possible to make definitive recommendations regarding treatment by PC or cholecystectomy in elderly or critically ill patients with acute cholecystitis. Low mortality rates after cholecystectomy in elderly patients with acute cholecystitis have been reported in recent years and therefore we believe it is time to launch an RCT to address this issue.

Keywords

cholecystostomy, acute, cholecystitis, elderly, review

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Introduction

The first cholecystotomy was performed by Bobbs in 1867 and the first cholecystectomy by Langenbuch in 1874. Four years later, surgical cholecystostomy was described when, in 1878, the surgeons Sims, Kocher and Keen each performed this procedure independently of one another. Only Kocher's patient survived.[1] Cholecystectomy remains the reference standard for treating acute cholecystitis, but perioperative mortality rates in the elderly or critically ill population are reportedly high (up to 19%).[2–4] Therefore, cholecystostomy is considered a treatment option for this patient group. Cholecystostomy is regarded as a safe alternative which occasions a good therapeutic response, especially in surgically high-risk populations. However, data from open cholecystostomies series show mortality rates as high as 20–30%.[5–7]

The first ultrasound-guided percutaneous cholecystostomy (PC) was performed in a jaundiced patient in 1979 by Elyaderani and Gabriele.[8] In 1982 Radder,[9] followed a year later by Elyaderani *et al.*,[10] attempted the procedure in patients with acute cholecystitis. The method was further developed by Shaver *et al.*[11] and became established as a minimally invasive alternative in patients not considered fit for cholecystectomy. Percutaneous

cholecystostomy can be used as a treatment for acute cholecystitis in elderly or critically ill patients, allowing subsequent elective cholecystectomy with minimal mortality.[12] In some cases PC may be the definitive treatment for gallstone disease.[13–15]

There is some belief that PC is better tolerated than cholecystectomy in elderly septic or otherwise seriously ill patients, but no randomized controlled trials (RCTs) have been carried out to substantiate this. Several reviews on the topic of cholecystostomies are available, three of which cover indications for PC and outcomes in patients with acute cholecystitis treated with PC.[16–18] None of the reviews claim to be systematic and none compare differences in outcome between treatment with cholecystectomy and PC. The primary aim of this review is to find evidence in the literature to support the recommendation of PC rather than cholecystectomy for acute cholecystitis in the elderly population.

Our secondary (descriptive) aims were to establish:

1 the success rate of PC;
2 morbidity and mortality rates after PC;
3 the proportion of patients treated with PC who undergo subsequent cholecystectomy, and
4 the differences in mortality rates after PC with or without cholecystectomy vs. acute cholecystectomy in the elderly population.

Materials and methods

In April 2007, a search of PubMed (851 hits), CINAHL (eight hits), EMBASE (422 hits) and the Cochrane Library (12 hits) was performed using 'cholecystostomy' as the keyword. Cross-references were then examined through the database aid 'related articles' and through reference lists in the selected articles.

Inclusion criteria

All papers in English or Swedish that report a series of at least six patients with acute cholecystitis who were treated with percutaneous ultrasound- or computed tomography (CT)-guided cholecystostomy were considered for inclusion.

These reports were sifted to include only those that feature information on at least two of the following parameters: procedure attempted; complications; mortality; therapeutic effects; frequency of surgical intervention, and/or perioperative mortality.

Exclusion criteria

Case reports, reviews, methodological papers and papers describing laparoscopic or open cholecystostomy procedures were excluded. Various studies using PC, but describing gallstone extraction, crushing or dissolution techniques were also excluded. The excluded papers were used as cross-references to ensure that no papers were missed in the review. If more than one clinical paper on the topic had been published by the same hospital, the earlier papers were excluded if the study times overlapped in case the same patients had been reported more than once.[19–21] One study was excluded as PC had been attempted in patients with jaundice.[22]

After exclusions, 12 prospective[12,23–33] and 41 retrospective[13–15,34–71] studies remained, which together address a total of 1918 patients. All but one of the papers on PC describe series of less than 100 patients (median 30 patients, range 6–145) Almost all the studies are descriptive, but three papers describe RCTs.[12,23,24] However, none of these trials compared the outcomes of PC vs. those of cholecystectomy. One RCT compared PC with gall bladder aspiration (and favoured PC),[23] the second compared PC with antibiotic treatment (and found no difference)[24] and the last RCT compared early and delayed cholecystectomy following PC.

In a second phase, PubMed was searched again using the terms 'elderly', 'acute', 'cholecystitis' and 'cholecystectomy' (1745 hits). The abstracts of these papers were examined and the reference lists of eligible articles were cross-examined. PubMed was then searched again using the search function 'related articles'. This resulted in a final sample of 21 articles[2–4,72–89] addressing mortality after acute cholecystectomy in patients aged ≥60 years ($n = 3466$). No further systematic search was performed. Data from the Swedish cholecystectomy registry were retrieved,[90] including records for patients aged ≥70 years who had been operated for acute cholecystitis between 2005 and 2008 ($n = 622$).

Statistical analysis

All figures are mean values unless stated otherwise. Fisher's exact test was used to make comparisons between groups. A P-value <0.05 was considered significant.

Results

No controlled studies evaluating the outcomes of PC vs. those of cholecystectomy have been published and we therefore classify all the papers reviewed as being of evidence grade C. The PC study population includes 1918 patients reported in 53 papers. The mean ages of the patients included in the individual papers are presented in Table 1. Six papers report median age (Table 1); these six papers are included in the overall mean age calculated for patients described in this review, which is 68.1 years. One study[34] reports a minimum age of 75 years and is thus not included in the report of overall mean age.

These papers describe 1925 successful PCs. Some patients received more than one PC and some attempts to place a PC failed. Fifty papers report the rate of technically successful PC placement: 1693 of 1712 attempts were successful, giving an overall success rate of 98.9%.

The presence of gall bladder stones is reported in 42 papers; in 1120 of 1619 patients (69.2%) diagnosis was verified by ultrasonography.

Rate of successful outcome after PC intervention

All the papers that report successful intervention define 'success' as clinical improvement within 48–72 h after insertion of the PC. In

Table 1 Descriptive data and outcome of percutaneous cholecystostomies (PCs)

Study	Year	Mean age, years	Origin of study	PCs	Patients	Attempts	Gall bladder stones	Gall bladder stones	PC success	PC success	Procedure mortality	Procedure mortality	Biliary mortality	Biliary mortality	Total mortality	Total mortality	Complications	Complications	Dislodged	Dislodged	Acute surgery	Acute surgery	Elective surgery	Elective surgery	Mortality surgery	Mortality surgery
				n	*n*	*n*	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%			*n*	%	*n*	%	*n*	%	*n*	%
Akyurek *et al.*[12]	2005	62	Turkey	38	37	38	37	100%	31	82%	0	0%	0	0%	0	0%	2	6%	1	3%	0	0%	35	95%	0	0%
Ito *et al.*[23]	2004	NR	Japan	30	30	30	28	93%	30	100%	0	0%	0	0%	0	0	NR	NA	1	3%	0	0%	27	90%	NR	NA
Hatzidakis *et al.*[24]	2002	79	Greece	60	63	63	41	65%	54	86%	1	2%	6	10%	11	17%	1	2%	9	15%	7	11%	9	14%	1	6%
Kim *et al.*[25]	2000	67	South Korea	33	33	33	26	79%	33	100%	0	0%	0	0%	0	0	1	3%	0	0%	0	0%	0	0%	NR	NA
Borzellino *et al.*[26]	1999	81	Italy	83	84	84	NR	NA	82	98%	0	0%	0	0%	0	0	5	6%	NR	NA	2	2%	70	83%	0	0%
Sugiyama *et al.*[27]	1998	85	Japan	38	38	38	25	66%	36	95%	0	0%	1	3%	4	11%	5	13%	NR	NA	1	3%	12	32%	0	0%
Lee *et al.*[28]	1998	77	Taiwan	42	42	42	36	86%	42	100%	0	0%	0	0%	0	0	NR	NA	NR	NA	0	0%	32	76%	0	0%
Hatzidakis *et al.*[29]	1998	73	Greece	36	40	40	22	55%	35	88%	0	0%	0	0%	3	8%	0	0%	3	8%	0	0%	10	25%	NR	NA
de Manzoni *et al.*[30]	1992	NR	Italy	27	29	29	25	86%	27	100%	0	0%	0	0%	0	0	0	0%	1	4%	1	3%	23	79%	NR	NA
Lee *et al.*[31]	1991	NR	USA	24	24	24	6	25%	14	58%	0	0%	0	0%	6	25%	2	8%	0	0%	1	4%	NR	NA	NR	NA
Van Steenbergen *et al.*[32]	1990	77	Belgium	10	10	10	10	100%	NR	NA	0	0%	0	0%	0	0	1	10%	1	10%	1	10%	3	30%	0	0%
van Sonnenberg *et al.*[33]	1990	NR	USA	11	11	11	NR	NA	NR	NA	0	0%	NR	NA	NR	NA	NR	NA	2	18%	NR	NA	NR	NA	NR	NA
Macri *et al.*[35]	2006	76	Italy	27	27	27	27	100%	25	93%	0	0%	1	4%	1	4%	0	0%	0	0%	0	0%	25	93%	1	4%
Makela *et al.*[34]	2005	75+	Finland	41	43	43	39*	95%	NR	NA	NR	NA	NR	NA	5	12%	NR	NA	NR	NA	NR	NA	NR	NA	NR	NA
Welschbillig-Meunier *et al.*[36]	2005	78	France	63	65	65	49	75%	55	87%	0	0%	1	2%	9	14%	3	5%	3	5%	2	3%	10	15%	1	2%
Basaran *et al.*[37]	2005	68	Turkey	18	18	NR	12	67%	12	67%	0	0%	1	6%	3	17%	1	6%	0	0%	6	33%	0	0%	0	0%
Li *et al.*[38]	2004	81	Hong Kong	25	25	25	23	92%	23	92%	0	0%	1	4%	5	20%	0	0%	4	18%	3	12%	6	24%	NR	NA
Byrne *et al.*[39]	2003	63	USA	45	45	45	41	91%	36	80%	0	0%	1	2%	9	20%	6	13%	1	2%	0	0%	19	42%	NR	NA
Hadas-Halpern *et al.*[40]	2003	80	Israel	91	80	91	65	81%	52	57%	0	0%	2	3%	12	15%	2	3%	NR	NA	NR	NA	32	40%	0	0%
Berman *et al.*[41]	2002	78	Israel	10	10	10	10	100%	9	90%	1	10%	1	10%	1	10%	1	10%	0	0%	0	0%	2	20%	0	0%
Spira *et al.*[42]	2002	74	Israel	57	55	57	NR	NA	51	93%	0	0%	3	5%	3	5%	1	2%	9	16%	2	4%	30	55%	0	0%
Granlund *et al.*[43]	2001	71	Sweden	51	51	51	28	55%	46	90%	0	0%	0	0%	8	16%	2	4%	13	25%	4	8%	4	8%	0	0%
Andren-Sandberg *et al.*[44]	2001	71	Norway	86	86	86	NR	NA	NR	NA	0	0%	1	1%	5	6%	8	9%	4	5%	2	2%	8	9%	NR	NA
Chopra *et al.*[45]	2001	66	USA	21	22	22	13	62%	20	95%	0	0%	1	5%	3	14%	3	14%	0	NR	NR	NA	4	18%	NR	NA
Patel *et al.*[46]	2000	63	USA	53	53	53	39	74%	44	83%	0	0%	6	11%	20	38%	2	4%	4	8%	0	0%	25	47%	0	0%
Tseng *et al.*[47]	2000	71	Taiwan	145	145	NR	135	93%	135	93%	0	0%	9	6%	10	7%	2	1%	NR	NA	0	0%	117	81%	0	0%
Chang *et al.*[48]	2000	65	USA	24	24	24	17	71%	18	75%	0	0%	2	8%	6	25%	2	8%	2	8%	NR	NA	10	42%	0	0%
Berber *et al.*[49]	2000	75	USA	15	15	15	NR	NA	13	87%	0	0%	2	13%	3	20%	1	7%	3	20%	1	7%	12	80%	1	8%
Davis *et al.*[50]	1999	77	USA	22	22	22	16	73%	18	8%	0	0%	0	0%	8	36%	3	14%	1	5%	1	5%	2	10%	1	33%

Table 1 Continued

Study	Year	Mean age, years	Origin of study	PCs	Patients	Attempts	Gall bladder stones	Gall bladder stones	PC success	PC success	Procedure mortality	Procedure mortality	Biliary mortality	Biliary mortality	Total mortality	Total mortality	Complications	Complications	Dislodged	Dislodged	Acute surgery	Acute surgery	Elective surgery	Elective surgery	Mortality surgery	Mortality surgery
				n	*n*	*n*	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%			*n*	%	*n*	%	*n*	%	*n*	%
Boggi *et al.*[51]	1999	66	Italy	11	11	11	8	73%	10	91%	0	0%	0	0%	0	0%	2	18%	0	Nr	1	9%	4	36%	0	0%
Kiviniemi *et al.*[52]	1998	78	Finland	69	69	NR	49	71%	60	87%	0	0%	3	4%	13	19%	17	25%	12	17%	2	3%	3	4%	NR	NA
Hamy *et al.*[53]	1997	78	France	41	41	41	37	90%	31	76%	0	0%	4	10%	5	12%	NR	NA	NR	NA	4	10%	0	0%	0	0%
England *et al.*[54]	1997	63	USA	61	59	63	31	52%	43	73%	1	2%	6	10%	13	22%	6	10%	NR	NA	2	13%	18	42%	NR	NA
Hultman *et al.*[55]	1996	52	USA	33	33	33	12	50%	22	92%	0	0%	NR	NA	16	48%	0	0%	NR	NA	1	4%	2	8%	NR	NA
Van Overhagen *et al.*[56]	1996	65	Netherlands	33	33	33	22	67%	30	91%	0	0%	1	3%	4	12%	0	0%	1	3%	2	6%	9	28%	1	9%
Famulari *et al.*[57]	1996	66	Italy	22	23	23	15	65%	22	100%	0	0%	NR	NA	NR	NA	NR	NA	NR	NA	1	4%	13	57%	NR	NA
Patterson *et al.*[58]	1996	60	Canada	50	50	50	29	58%	45	90%	0	0%	0	0%	9	18%	2	4%	NR	NA	7	14%	18	36%	0	0%
Melin *et al.*[59]	1995	68	USA	27	22	27	11	50%	17	77%	1	5%	4	18%	9	41%	0	0%	6	22%	1	5%	3	14%	1	25%
Avrahami *et al.*[60]	1995	76	Israel	10	10	10	8	80%	10	100%	0	0%	0	0%	0	0%	1	10%	0	0%	2	20%	1	10%	0	0%
Lo *et al.*[61]	1995	67	USA	58	58	58	28	58%	42	88%	1	2%	2	5%	7	15%	7	15%	2	4%	1	2%	18	38%	2	11%
Boland *et al.*[62]	1994	70	USA	26	26	26	NR	NA	NR	NA	0	0%	NR	NA	7	27%	NR	NA	1	4%	1	4%	7	37%	2	25%
Shirai *et al.*[15]	1993	56	Japan	15	15	15	0	0%	14	93%	0	0%	0	0%	1	7%	2	13%	NR	NA	1	7%	1	7%	0	0%
Browning *et al.*[63]	1993	57	USA	49	49	50	11	22%	31	63%	0	0%	0	0%	25	51%	3	6%	3	6%	1	2%	3	6%	NR	NA
Vauthey *et al.*[64]	1993	63	Switzerland	18	18	18	8	44%	16	88%	1	6%	1	6%	1	6%	1	6%	1	6%	3	17%	2	11%	1	20%
Van Steenbergen *et al.*[65]	1993	78	Belgium	32	32	32	32	100%	32	100%	0	0%	0	0%	1	3%	0	0%	3	9%	2	6%	16	50%	0	0%
Teplick *et al.*[66]	1991	64	USA	16	16	16	2	12%	15	94%	0	0%	2	12%	9	56%	1	6%	NR	NA	3	19%	NR	NA	NR	NA
McGahan *et al.*[67]	1989	67	USA	39	37	40	8	22%	39	98%	0	0%	0	0%	22	60%	0	0%	2	5%	4	11%	NR	NA	NR	NA
Berger *et al.*[14]	1989	62	Germany	8	8	8	0	0%	8	100%	0	0%	0	0%	1	12%	NR	NA	NR	NA	0	0%	0	0%	0	0%
Werbel *et al.*[68]	1989	67	USA	23	22	23	16	73%	16	94%	0	0%	0	0%	2	9%	5	22%	5	23%	1	6%	8	47%	0	0%
Klimberg *et al.*[69]	1987	57	USA	17	17	17	10	59%	14	82%	0	0%	1	6%	4	24%	NR	NA	NR	NA	0	0%	6	35%	0	0%
Dunham *et al.*[70]	1985	71	Belgium	14	14	14	13	93%	14	100%	NR	NA	NR	NA	NR	NA	1	7%	NR	NA	NR	NA	7	50%	NR	NA
Eggermont *et al.*[13]	1985	64	Netherlands	6	6	6	0	0%	6	100%	0	0%	0	0%	0	0%	0	0%	NR	NA	1	14%	0	0%	0	0%
Pearse *et al.*[71]	1984	0	USA	21	22	22	NR	NA	20	91%	1	5%	1	5%	1	5%	2	9%	NR	NA	2	9%	15	68%		NA
		68.1		1925	1918	1712	1120	69%	1498	86%	7	0.36%	64	3.6%	288	15.4%	104	6.2%	98	8.6%	77	4.5%	681	38%	12	2.1%

NA, not applicable; NR, not reported

almost every study, this was indicated by loss of fever, lessened symptoms and reduction of leucocytosis. Successful intervention was reported in 85.6% of patients (1498/1751; 48 papers) (Table 2).

In the studies that report strictly calculous acute cholecystitis,[12,32,35,65] the success rate of PC was 90.7% (97/107 PCs) vs. 85.2% (1401/1644) among patients with mixed acalculous and calculous cholecystitis (not significant [NS], $P = 0.15$).

Morbidity and mortality rates after PC

Slippage of the PC catheter was reported in 8.57% of patients (98/1144 patients; 35 papers) (Table 1). It is possible that this rate represents an underestimation as follow-up generally included only in-hospital time and records of the duration of in-dwelling catheters are vague. It is also unclear how many of the slipped PCs needed to be re-inserted or how often surgery was necessary to handle this complication. The drainage catheters were of various types, but the majority of the later studies used locking pigtail catheters. Whether or not this decreased the risk of slippage cannot be deduced from this material.

A total of 44 papers report other complications: 6.24% of patients (104/1687) experienced some kind of adverse event. The most frequently reported complication was pneumonia. The individual papers report complication rates with great variability in quality and thus no analysis of complication rates or types can be made. We chose not to compare complication rates after PC with those after cholecystectomy because of the uncertain quality of reported data.

Mortality figures have been analysed in three groupings. Total mortality includes all deaths, defined as 30-day mortality or in-hospital death, according to whichever is described in each individual paper. Mortality caused by biliary infection refers to those deaths that are believed to be related to or to have resulted from the cholecystitis (e.g. overwhelming biliary sepsis, myocardial infarction with ongoing cholecystitis, procedure mortality and death during emergency cholecystectomy). Procedure-related mortality includes deaths that were directly linked to a complication of the procedure to drain the gall bladder (bowel perforation, leakage or bleeding). Cases included in the 'procedure mortality' group are therefore included in all three mortality groups, just as all 'biliary deaths' are included in the 'total mortality' group.

Rates for mortality caused by biliary infection and associated with the procedure itself were 3.6% (64/1768 patients; 47 papers) and 0.36% (7/1861 patients; 51 papers), respectively. The overall mortality was 15.4% (288/1870 patients; 50 papers) (Table 1).

Some studies included large numbers (19–55%) of patients with 'unclear' diagnoses (i.e. sepsis of unknown origin), a large proportion (33–100%) of whom were admitted to the intensive care unit (ICU).[31,46,48,51,54,55,59,63,66,68] A comparison of these studies with those that describe a more reliable diagnosis of acute cholecystitis shows a lower success rate (71.7% vs. 89.2%; $P < 0.001$) and a higher total mortality rate (33.9% vs. 11.7%; $P < 0.001$) in the 'unclear' diagnosis group. It can therefore be argued that correct diagnosis of acute cholecystitis yields a higher patient benefit. This was also noted in an ICU series presented by Hultman *et al.*[55]

Number of patients treated with PC who underwent subsequent cholecystectomy

More than 40% of the patients eventually came to surgery (Table 1). Therapeutic failure, recurring cholecystitis or procedural complications led to emergency surgery in 4.5% of patients (77/1724; 47 papers). Elective cholecystectomy after PC (mainly laparoscopic, either sub-acute or delayed) was performed in 38.1% of patients (681/1787; 48 papers).

Difference in mortality rates after PC +/– cholecystectomy vs. acute cholecystectomy in the elderly population

Mortality rates after cholecystectomy are reported in 33 papers, covering 76.1% (577/758) of patients who were cholecystectomized. Overall operative mortality was 2.08% (12/577 patients) (Table 1). The mortality rates were 0.96% (5/523 patients) in elective and 13.0% (7/54 patients) in emergency surgery.

This review indicates that mortality resulting from the PC procedure is low (0.36%), but that 30-day or in-hospital (whichever is reported) mortality rates after PC are high (15.4%). To fully elucidate the overall mortality rate, it may be reasonable to add the mortality rate after elective cholecystectomy (for the group of PC patients who underwent cholecystectomy), which hikes the total mortality rate to 16.4% (15.4 + 0.96%) in the reviewed patient group. Although death caused by biliary disease is fairly low, it seems that overall short-term (i.e. 30-day) survival is the most appropriate parameter to use when comparing outcomes after interventional procedures in this elderly population with poor longterm prognosis.

A comparison of the total mortality rate in the earlier papers (22.1% in 20 papers published before 1996) with that in the more recent series (13.3% in 32 papers published after 1995) shows a significant difference ($P < 0.001$).

Table 2 shows data from recent studies which report in-hospital or 30-day mortality data after cholecystectomy in patients aged ≥60 years.

The comparison of the mortality rate after PC (15.4%) (Table 1) with that after acute cholecystectomy (4.5%) (Table 2) shows a significant difference ($P < 0.001$) in favour of acute cholecystectomy.

Discussion

The evidence for the therapeutic effect of PC is based on case series with highly varied inclusion criteria. The figures presented within this review are of evidence grade C. More importantly, there is absolutely no evidence to support the recommendation of PC rather than cholecystectomy in elderly or critically ill patients with acute cholecystitis. Indeed, the figures provided by this

Table 2 Outcome of cholecystectomies in elderly subjects

Study	Publication year	Patient age, years	Patients	Acute surgery	Elective surgery	Mortality total	Mortality total	Mortality acute	Mortality acute	Mortality elective	Mortality elective
			n	*n*	*n*	*n*	%	*n*	%	*n*	%
Huber *et al.*[3]	1983	70+	93	43	50	7	7.5	**6**	**14**	1	2.0
Houghton *et al.*[2]	1985	64+	151	21	130	5	3.3	**4**	**19**	1	0.8
van der Ham *et al.*[72]	1986	75+	109	109	NR	14	13	**14**	**13**	NR	NR
Margiotta *et al.*[4]	1988	70+	137	59	78	10	7.3	**7**	**12**	3	3.8
Hidalgo *et al.*[73]	1989	60+	59	59	0	4	6.7	**4**	**6.7**	NR	NR
Roslyn *et al.*[74]	1993	65+	12415	NR	NR	62	0.5	NR	NR	NR	NR
Callaghan[75]	1995	75+	200	NR	NR	7	3.5	NR	NR	NR	NR
Firilas *et al.*[76]	1996	65+	217	15	202	2	0.9	NR	NR	NR	NR
Maxwell *et al.*[77]	1998	80+	18500	NR	NR	666	3.6	NR	NR	NR	NR
Decker *et al.*[78]	2001	75+	32	32	0	1	3.1	**1**	**3.1**	NR	NR
Uecker *et al.*[79]	2001	80+	70	53	17	7	10	**7**	**13**	0	0
Brunt *et al.*[80]	2001	65+	421	22	399	2	0.5	**1**	**4.5**	1	0.3
Chau *et al.*[81]	2002	75+	73	73	NA	3	4.1	**3**	**4.1**	NR	NR
Hazzan *et al.*[82]	2003	80+	67	33	34	0	0	**0**	**0**	0	0
Bingener *et al.*[83]	2003	65+	395	67	328	6	1.5	**6**	**8.9**	0	0
Nilsson *et al.*[84]	2005	80+	4996	2190	2806	165	3.3	**95**	**4.3**	70	2.5
Coenye *et al.*[85]	2005	75+	20	20	0	2	10	**2**	**10**	NR	NA
Tambyraja *et al.*[86]	2005	80+	70	19	51	0	0	**0**	**0**	0	0
Kauvar *et al.*[87]	2005	65+	59	NR	NR	1	1.7	NR	NR	NR	NR
Yi *et al.*[88]	2006	60+	137	137	NA	1	0.7	**1**	**0.7**	NR	NR
Kwon *et al.*[89]	2006	65+	516	14	502	0	0	**0**	**0**	0	0
Gallriks[90]	2008	70+	2128	620	1508	15	0.7	**9**	**1.5**	6	0.4
			40865	3586	6105	980	2.4	**160**	**4.5**	82	1.4

NA, not applicable; NR, not reported

review show better mortality rates for patients treated with acute cholecystectomy than for patients treated with PC.

Can recommendations for the treatment of elderly and critically ill patients with acute septic cholecystitis be drawn from this review?

Many of the studies reviewed here summarize their findings in terms such as: 'PC is safe in the elderly and critically ill with acute cholecystitis, seems to improve prognosis and also make later elective (laparoscopic) cholecystectomy feasible with low mortality.' This is said in the light of the general opinion that: 'Acute cholecystectomy in the septic elderly or critically ill patient has always been considered a high-risk procedure.' Acute cholecystectomy is, however, a one-shot definitive treatment for gallstone disease and recent advances in perioperative care may have changed views on how to manage this population of patients.

As we have shown, PC is a low-mortality procedure (0.36%) with a high success rate (85.6%). There is no doubt that PC, together with antibiotics, can convert a septic cholecystitis into a non-septic condition. It is then possible to perform a subsequent laparoscopic cholecystectomy with low (0.96%) mortality. In some studies, critically ill ICU patients received PC in an effort to treat sepsis of unknown origin and, consequently, their success rates may be falsely low and mortality rates falsely high. In this review, cases with 'uncertain cholecystitis' had a total mortality rate of 33.1% vs. 11.7% in those with a more reliable diagnosis of acute cholecystitis ($P < 0.001$). This may mean that the success rate of PC performed strictly in patients with a clear diagnosis of calculous acute cholecystitis may be even higher (90.7% according to this review).

A few papers report a better outcome of PC if certain criteria are met. Pericholecystic fluid collection[54] or positive bile culture[55] seem to improve outcomes, but these studies also included patients with unclear diagnosis. This probably indicates that patients with these findings had a correct diagnosis of acute cholecystitis. The largest study in this review[47] included only patients with gall bladder empyema; this population showed a 100% response rate to PC, further underlining the fact that correct diagnosis is essential for a positive response to PC.

There are some reports about the risk of recurring cholecystitis after a bout of acute cholecystitis (irrespective of PC or antibiotic treatment). Longterm follow-up studies from the pre-ultrasound era indicate recurrences of cholecystitis in 10–20% of patients and, in the majority of cases, recurrences within 1 year.[91] Issues of health economics and patient suffering are raised by Thornton *et al.*,[92] Cheruvu and Eyre-Brook[93] and Somasekar *et al.*,[94] all of whom report readmission rates for gallstone-related complications. Median waiting times for elective cholecystectomy were 2, 6 and 12 months and readmission rates were 5.6%, 11.5% and 23%, respectively. Cheruvu and Eyre-Brook[93] also note that, of those who initially presented with emergent gallstone disease, 28% were readmitted before the planned cholecystectomy. Although this is not reported in this review, it is possible that 10–20% of patients who underwent PC may have had recurring cholecystitis within 1 year.

Despite the short length of follow-up, almost half of the patients (40%) treated with PC eventually came to surgery, which indicates that PC alone is not a final treatment. The high mortality rate after PC (15.4%) indicates that these were very sick patients, but this mortality rate is so much higher than that for patients treated with surgery (4.5%) that it raises questions about the validity of the PC procedure. It should also be remembered that there is a significant risk for catheter slippage (8.57%), which often leads to re-intervention, as well as risks for general complications (6.24%) and emergency surgery. Complication rates may be higher after cholecystectomy, but the lack of reliable data prevents such a comparison. The material gathered in the review suggests that cholecystectomy is superior to PC, even in elderly and critically ill patients.

However, a critical examination of the figures reveals several confounding factors.

There is evidence of selection bias, which varies among studies. For instance, some studies included patients by age,[26–28,30,35] acalculous cholecystitis only[13–15] or high anaesthetic risk.[38–41,44,48,55,58,60–66,68,69,71] One study specifically excluded the most critically ill patients.[26] Several sets of inclusion criteria were used, which varied from those defined by the American Society of Anesthesiologists (ASA),[26,36,43,68] APACHE (*a*cute *p*hysiological *a*ssessment and *c*hronic *h*ealth *e*valuation)[29,59] and hospital-specific risk-scoring systems[57] to a range of subjective medical risk factors.[13,15,25,37–42,44–56,58,60–66,69–71] Most retrospective studies included all patients who underwent PC[13,15,25,36–41,43–48,50–54,56–66,68–71] over a certain time period, regardless of diagnosis (e.g. ICU patients with unclear sepsis, acalculous cholecystitis or jaundiced patients). One of these studies[47] included attempts to treat most patients with acute cholecystitis (145/198) with PC prior to cholecystectomy (success rate 93%, total mortality 6.9%).

Only rarely do either the prospective or retrospective studies note how many patients were actually admitted to the relevant department with a diagnosis of acute cholecystitis during the study period.[23,24,26,34,50] None of the papers that report the total number of patients admitted with cholecystitis make any comment on outcomes in the rest of the cholecystitis population or compare its results with those in the PC group.

Another detail indicating selection bias concerns the unexpectedly low frequency of gall bladder stones (68%), which possibly reflects incorrect diagnosis, over-representation of acalculous cholecystitis in ICU patients or suboptimal ultrasound technique.

Likewise, there is no uniform description of selection criteria in the studies that report cholecystectomy in elderly patients.[78–81,84,86,87] Of course, similar selection biases may exist in the studies describing cholecystectomies in elderly subjects. For example, two retrospective studies[76,87] included only laparoscopic procedures and do not report their selection criteria or the number of patients admitted with acute cholecystitis in the respective departments.

The high total mortality rate in patients treated with PC probably reflects the poor prognosis of these patients in general. The

11.8% mortality rate unrelated to cholecystitis (15.4% minus 3.6%) indicates that patients selected to treatment with PC are poor candidates for cholecystectomy. It could be argued that outcomes in these patients may have been worse if they had undergone surgery. Given the data at hand, this question will remain unanswered until a properly designed study is carried out.

There are also discrepancies between studies in terms of follow-up times: most studies report in-hospital mortality rates, but some report 30-day mortality. In this old and sometimes critically ill population, total mortality may reflect a generally poor longterm prognosis rather than biliary-related mortality, thereby making study population selection critical.

A few randomized studies are covered in this review, but none addressed the difference in mortality rate between PC and acute cholecystectomy. None of the studies present a control group vs. a PC group. One Finnish retrospective study[34] compared mortality rates in patients with acute cholecystitis between 1988–1992 (mainly cholecystectomies) with equivalent rates in 1998–2002 (mainly PCs) and found similar overall mortality rates for acute cholecystitis (8% vs. 6%). Postoperative mortality rates were 9% (in emergency surgery patients) and 10% (in elective patients), but there were more re-admittances in the later period.

In the individual papers, mortality rates after PC are compared with historical cholecystectomy mortality rates, but advances in anaesthesiology and perioperative care seem to have improved the high mortality rates after acute cholecystectomy.

The comparison in this review between PC studies published prior to 1995 and those reported later shows that the total mortality rate has fallen over time (22.1% vs. 13.3%; $P < 0.001$). A similar improvement in mortality rates is seen in the cholecystectomy series. The combined mortality rate in cholecystectomy series published prior to 1995 is 12.0%, whereas it falls to 4.0% for series published after 1995 ($P < 0.001$).

Most of the prospective studies and all but three[35,49,50] of the retrospective studies in this review failed to declare whether patients admitted for cholecystitis represented consecutive cases with acute cholecystitis. Only one study[26] reported outcomes in patients who were not included.

These biases and shortcomings in study design make any comparison between outcomes of PC and acute cholecystectomy hazardous. Despite that, we have intentionally made a statistical calculation. This review indicates that 30-day or in-hospital (whichever is reported) mortality after PC is high (15.4%), but that procedure-related mortality is low (0.36%). If we compare the 15.4% mortality rate after PC with the 4.5% rate after acute cholecystectomy, we find a significant difference ($P < 0.001$) in favour of acute cholecystectomy. However, we would like to stress again that this comparison is not appropriate.

Conclusions

Given the data at hand, it is not possible to make decisive recommendations regarding treatment by PC or cholecystectomy in elderly or critically ill patients with acute cholecystitis. It is possible that cholecystectomy is a better alternative for treating acute cholecystitis in the elderly and/or critically ill population than PC. Low mortality rates after cholecystectomy in elderly patients with acute cholecystitis have been reported in recent years and therefore we believe it is time launch an RCT to address this issue. This would necessitate strict inclusion criteria and would require a multicentre design in order to achieve sufficient power. Elderly septic patients (e.g. ASA grade >2, age >80 years, with septic symptoms, but fit for general anaesthesia) with acute cholecystitis, diagnosed with ultrasonography, could be randomized to PC or acute cholecystectomy.

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Conflicts of interest

None declared.

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