



Acute biliary pancreatitis – focus on recurrence rate and costs when current guidelines are not complied

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TITLE PAGE

ORIGINAL ARTICLE

Title: Acute biliary pancreatitis – focus on recurrence rate and costs when current guidelines are not complied

Short title: Acute biliary pancreatitis – costs related to recurrence

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Abstract

Background: International guidelines recommend cholecystectomy within 2-4 weeks after mild-moderate acute biliary pancreatitis (ABP) to prevent recurrence. We aimed to investigate the compliance to guidelines concerning early cholecystectomy and the associated costs.

Methods: Admissions for ABP 2011-2013 were retrospectively reviewed. Classification was made according to the revised Atlanta classification. Treatment, time to surgery and recurrence, as well as cost analysis for both in-hospital costs and loss of production was performed.

Results: In total 254 patients were included. Some 202 of the ABP patients (80%) underwent definitive treatment during their first attack of ABP (68% cholecystectomy, 17% ERCP, 15% both interventions) and 186 (73%) were treated within one month of discharge. Patients with ERCP alone were significantly older than cholecystectomy cases ($p < 0.001$), but no significant difference was observed between those who underwent ERCP or no treatment ($p = 0.071$). Mild ABP had intervention earlier ($p < 0.001$). Fifty-two patients (20%) had no intervention, out of which 15 were readmitted due to pancreatitis, compared to 3 patients of those treated at the initial admission ($p < 0.001$).

The mean cost for hospital care and loss of production in mild ABP was € 6,882±3,010 and € 9,580±7,047 for moderate ABP ($p=0.001$). The cost for a recurrent episode was € 16,412±22,367.

Conclusion: By improved compliance to current guidelines concerning the management of ABP, recurrence rate and associated costs can potentially be reduced.

Introduction

Acute pancreatitis (AP) is an inflammatory condition of the pancreas. The incidence of AP is exceeding 30 per 100,000 and year in Sweden [1, 2]. The majority of the episodes are mild and self-limiting. Acute biliary pancreatitis (ABP) accounts for 38–47% of episodes [2-4]. Numerous international and national guidelines on the management of AP have been published, varying in quality [5]. Hence, there is no clear international consensus on the management of AP

Whilst there is a clear consensus among the major guidelines that patients with mild ABP should undergo laparoscopic or open cholecystectomy as definitive treatment [6-8], the timing of surgery is an on-going debate. Endoscopic retrograde cholangiopancreatography with sphincterotomy (ERCP/ES) do not prevent recurrence of other gallstone-related conditions (i.e. cholecystitis, biliary colic), however some guidelines [6-8] accept ERCP/ES as a definitive treatment, limited for patients deemed unfit for surgery.

However, several studies have shown that adherence to guidelines varies greatly [3, 9-14]. Pure conservative treatment increases the risk of recurrent ABP to about 15% as compared with about 4% when patients received definitive treatment. [15]. Up to 31% of the attacks occur within 2 weeks [16], carrying a reported mortality rate of 2.5% [1], implying that delayed surgery may render unnecessary recurrences and associated risks.

A limited number of studies have been made on health economical aspects on ABP. Fagenholz et al. [17] have previously estimated the cost for AP hospitalization to be about \$ 2.2 billion annually in the US. In a Swedish study, we estimated the annual costs for handling AP to € 38,500 000 [18], corresponding to € 4,1 million per 10⁶ inhabitants.

The aim of the current study was to investigate compliance to guidelines concerning early cholecystectomy after mild to moderate ABP and the costs associated with the disease, with extra focus on recurrent disease.

Methods

Medical records of patients admitted to the Department of Surgery at Skåne University Hospital, Lund and Malmö, from January 1st 2011 through December 31st 2013 were reviewed retrospectively. The last follow up date was December 1st 2014. Patients were identified using the International Classification of Diseases, tenth revision (ICD-10) code K85 for acute pancreatitis. Patients 15 years of age were excluded, as they are treated at the Department of Pediatric Surgery. The medical charts were reviewed between September and December 2014; consequently the follow-up period was varying for each patient.

For each patient, aetiology and severity were evaluated. The severity classification authorized by the modified Atlanta classification [19] was used. Once a biliary aetiology, of either mild or moderate severity, was considered, the patient's medical record was examined thoroughly and the following data were extracted: patient demographics, laboratory parameters, radiological examinations, length of stay (LOS), time to surgery, type of surgery, anaesthetic and surgical time, readmissions for AP, follow-up and sick leave. Follow-up included radiological examinations and admission to surgical ward for ambulatory care e.g. radiological examinations and additional surgery. All recurrent episodes, regardless of severity were included. To the largest extent, time spent at the ward was summarized and approximated to the nearest full day. If the patient was transferred to another ward owing to another disease not related to the AP, only the days spent at the surgical ward were included. An independent reviewer settled difficulties regarding classification of the patients.

Definition of acute pancreatitis

Acute pancreatitis was defined according to the modified Atlanta classification [19], thus requiring two of the following three characteristics: (1) abdominal pain, (2) increase in serum amylase at least three times the upper normal limit, (3) characteristic findings of AP on contrast-enhanced computed tomography (CT), magnetic resonance imaging (MRI) or transabdominal ultrasonography (US).

Definition of biliary aetiology

Biliary aetiology was defined as documentation of gallstones on US, magnetic resonance cholangiopancreatography (MRCP) or ERCP, or two of the three following laboratory abnormalities: serum bilirubin level > 40 mmol/l, alanine aminotransferase (ALT) level greater than 1.7 ukat/l with ALT level greater than the aspartate aminotransferase level and alkaline phosphatase level greater than 3.3 ukat/l with a γ -glutamyltransferase level greater than 0.75 ukat/l [20]. If the patient were included by the biochemical definition, no other obvious aetiology should be observed.

Definition of definitive treatment

The guidelines commissioned by the British Society of Gastroenterology (BSG) [7], American Gastroenterological Association (AGA) [8] and the International Association of Pancreatology (IAP) [6] were used as they are frequently used in studies that have been published. All guidelines recommend cholecystectomy as definitive treatment. In the present study ERCP/ES were also considered as definitive treatment as it is accepted if the patient is unfit for surgery. All guidelines advocate definitive treatment at index admission, however both BSG and AGA guidelines accept a delay of 2 - 4 weeks from discharge.

Approximation of health care costs

The direct medical costs for an episode of ABP were calculated as total hospital costs per patient. This included expenses at the surgical ward, surgical emergency ward, anaesthesia and operating costs, main radiological costs and costs for follow-up.

The internal price list [21, 22] was used to convert resource use to medical costs. Costs for ICU consist of a complex pricing, adjusted three times a day, and not a definite unit price. Each patient's individual ICU cost was collected from the economy department at the hospital. Unit costs for each item are displayed in Table 1. Subsequent hospitalization for a further bout of ABP was calculated. Pharmaceutical, nutritional and fluids are incorporated in the unit costs for the ward.

The indirect costs reflect the loss of production (LOP) for absence from work due to morbidity and mortality. The human capital approach is the standard methodology used in Sweden. No direct information on the patients' income was available. LOP was based on statistics from Statistics Sweden (<http://www.scb.se>) on age- and sex-dependent average annual earnings. Sick leave was retrieved from the patients' medical records. Statutory social security contributions (31.42%) and an average cost of contracts of insurance (9.41%) of employed men and women in Sweden were added. The median age of retirement in Sweden is 65 years, hence no LOP was calculated for patients older than 65 years.

All costs are given in the average price levels for 2015, inflated using the Swedish consumer price index. The costs have been converted from Swedish krona (SEK) to Euro (€) using the average exchange rate for 2015 (9,3562 SEK to € 1).

Statistics

Continuous variables are given as median and range. Economic calculations are given in mean and standard deviation. Categorical data are displayed as absolute numbers and percentages. Categorical variables were analysed by Chi-square-test. Non-parametric data was analysed using Mann-Whitney U-test, and parametric data was analysed using student's T-test. A probability level of < 0.05 was considered significant. The statistical analyses were performed with SPSS version 22.0 (IBM Corporation, Armonk, NY, USA) and GraphPad Prism 6 (GraphPad Software, San Diego, CA, USA).

At index admission, missing values regarding sick leave was predicted using a linear regression model. Since only a few patients were younger than 65 years at a recurrent episode, missing values were replaced with the median value of registered sick leave (22 days).

Ethics were approved by the Regional Ethical Committee in Lund.

Results

A total of 286 patients presented with their first episode of ABP of whom 268 patients had either mild or moderately severe ABP. Sixteen patients were included by the biochemical definition. There was only one in-hospital death, which occurred during the index admission. The patient died from complications after surgical intervention. Fourteen patients had cholecystectomy performed prior to the AP and were consequently excluded from further analysis, leaving 254 patients eligible for definitive treatment. Demographics and clinical characteristics for these patients are displayed in Table 2.

Figure 1 display the overall management of the included patients. In total, 217 patients (85%) underwent definitive treatment either in association with the initial admission or after a recurrent attack. In total 37 patients (15%) did not receive any definitive treatment during the follow-up period. Patients with mild ABP had a significantly shorter interval prior to intervention (table 3).

A total of 202 patients (80%) underwent definitive treatment following their first attack of ABP; 137 patients (68%) had a cholecystectomy; 35 had an ERCP (17%); and 30 (15%) underwent both procedures. 180 patients (89%) were treated at index admission and a total of 186 (92%) were treated within one month of discharge. 52 (20%) did not receive any definitive treatment following their first attack of ABP.

Patients treated with ERCP alone were significantly older than patients treated with cholecystectomy, 82 (38-97) years versus 58 (16-88) years ($p < 0.0001$). However, there was no difference between patients that did not receive any definitive treatment and patients receiving ERCP alone, 78 (25-93) years versus 82 (38-97) years ($p = 0.071$).

A total of 18 patients suffered from ≥ 1 recurrent episode of ABP, rendering a recurrence rate for the entire study population of 7.1%. One patient suffered from two recurrences and another one from three

recurrences. The second episode occurred in median after an interval of 46 days (6–650) after the index AP episode.

Three patients (1.5%) who underwent any biliary procedure following their first attack suffered from one further episode of ABP compared with 15 patients (29%) not receiving definitive treatment ($p < 0.001$). All patients presenting with recurrent ABP were treated except for one patient who underwent cholecystectomy and ERCP at index admission and did not undertake any measures. The time until treatment from initial admission to hospital was 5 (1-232) days in mild AP and 8 (0-179) days in moderate AP ($p = 0.001$).

Costs for healthcare and loss of production

The costs for index admission, including LOP, was in mean € 6,882 ± 3,010 for mild ABP and € 9,580 ± 7,047 for moderate ABP ($p = 0.001$), as shown in Figure 2. Hospital ward costs accounted for the majority of the total cost of the index admission. In the group with mild AP, ward costs were 40 % higher than costs for interventions. In the moderate group, however, ward costs were 2.5 times higher than intervention costs.

Costs for recurrent ABP

The costs for a further bout of ABP, including LOP, was in mean € 16,412 ± 22,367. When excluding costs for surgery the costs for hospitalization, radiology, follow-up and LOP was in mean € 13,010 ± 21,281. Table 4 display the different costs in detail. One patient suffered from severe pancreatitis rendering a total cost of € 103 609 (figure 3).

Discussion

This study adds new knowledge by analysing the direct medical and indirect medical costs of a recurrent episode of biliary pancreatitis, demonstrating that conservative treatment not only puts patient at an high risk of recurrences (29 % vs. 1.5 %) but also comes with additional costs.

Only a few studies have previously estimated the costs for managing AP. One study conducted at our institution [18] analysed indirect and direct medical costs of mild and severe AP in general. According to this study, the overall cost including cost for loss of production was in mean € 5,300 ± 2,400 for mild AP regardless of aetiology.

Monkhouse et al calculated the costs for recurrent AP [23]. The total cost for 21 patients, requiring total 40 readmissions, was £ 172,170, converted to € 268,531, suggesting an average cost of € 6,713 per patient with recurrent AP, compared to € 16,412 ± 22,367 in the present study. However, in the present study severity was evaluated for every readmitted patient, including one severe case costing €103,609, as opposed to Monkhouse et al not reporting severity grade for each case.

Current guidelines recommend cholecystectomy within 2–4 weeks as definitive treatment of ABP, whereas ERCP/ES is recommended for patients deemed unfit for surgery. In the present study 80% underwent any definitive treatment following their first attack and 73% were treated within the recommended interval. Some patients may have been rejected surgery due to comorbidities. Interestingly, 15 patients initially deemed unfit for surgery were subsequently treated after a relapse, suggesting that compliance could be further improved. A possible explanation why not adhering to guidelines, besides the possible hesitation due to patient's comorbidity, is that patients awaiting surgery have a lower priority than more acute cases. In the present study, recurrent AP occurred after a median of 46 days. Previous studies indicates that 31 % of recurrent AP occurs within 2 weeks of discharge [16]. Consequently, though the patient is clinically improved, cholecystectomy following ABP should have high priority to prevent recurrent events. It is also important to realise that a mild to

moderate AP can be followed by a recurrence with severe AP, as was the case for one patient in our study.

Recently the PONCHO-trial implied that same admission cholecystectomy reduces the risk of recurrent gallstone-related events without any obvious impact on difficulty or complications related to the cholecystectomy [24]. Also, cholecystectomy within 3 days of admission is probably the most cost-efficient option in mild cases [25]. In the present study, the majority of the medical costs were derived from the ward. A small prospective, randomized study showed a significantly shorter length of stay for those who underwent laparoscopic cholecystectomy within 48 hours of admission, compared with those who had surgery after abdominal pain and laboratory parameters were normalized [26]. Hence, same-admission cholecystectomy seems safe and would reduce the costs for managing ABP.

Future research should investigate the optimal timing of cholecystectomy during the initial admission and management of patients with severe illness and co-morbidity should be further investigated.

The current study has some limitations. In a retrospective design, the clinical considerations of the clinical decision-making process cannot be evaluated. Consequently, some patients may have been rejected for surgery due to comorbidities; also comorbidities were not evaluated for each patient. The revised Atlanta classification assess organ failure using the modified Marshall score, requiring testing for blood gases which is not taken routinely at our institution. Some patients may therefore have been classified incorrectly. The indirect medical costs for recurrent ABP might be overestimated as LOP are based on median sick leave.

Conclusion

This study demonstrates that compliance concerning definitive treatment in mild to moderate ABP is about 80%. The cost for managing ABP is € 6,882 ± 3,010 and € 9,580 ± 7,047 for mild and moderate, respectively. Conservative treatment, not dealing with the underlying biliary disease, is associated with a 29 % recurrence rate. Furthermore, recurrent ABP is associated with an additional cost of €

16,412 ± 22,367 per patient. By improving implementation of current guidelines, recurrence rates following ABP could be reduced even more, consequently improving cost-efficiency.

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Table 1. Units' costs of items used for calculation of total direct medical costs.

Item	Unit cost €
Hospitalization	
Emergency visit	273
Admission to surgical emergency ward	216 ^a
Admission to surgical ward	134
Surgical emergency ward (per day)	445
Surgical ward (per day)	350
Radiology	
Ultrasonography	202
Computed tomography	281
Magnetic resonance cholangiopancreatography	359
Perioperative cholangiography	34
Endoscopy	
Endoscopic retrograde cholangiography	1,188
Endoscopic ultrasonography	1,968
Surgery	
Operation (per min)	10
Anaesthesia (per min)	8
Anaesthetic induction	95

^a Based on the Skane University hospital (2012) internal debit price list [22]

Table 2. Patient demographics, index admission.

	Mild (n=172)	Moderate (n = 82)	p Value
Age	66 (19 - 92)	71 (27 - 97)	0.175
Male sex	85 (49%)	44 (54%)	0.527
Body mass index (BMI)	26.7 (17.1 - 67.9) ¹	27.6 (15.3 - 43.1) ²	0.064
CRP*	90 (0.65 - 345)	244 (17 - 471)	< 0,001
Bilirubin*	37 (3 - 308)	40 (6 - 217)	0.446
Amylase*	20 (0.7 – 101)	25 (1.2 – 153)	0.055
Ward (total), days	7 (2-26)	11 (5-69)	< 0.001
Surgical emergency ward, days	2 (0-10)	3 (0-18)	< 0.001
Surgical ward, days	5 (0-23)	7 (0-60)	0.003
ICU, days	0 (0-0)	0 (0-4)	0.001
Sickleave, days	16 (4-58)	29 (11-153)	< 0.001

* The peak value

ICU=intensive care unit

¹ 14 patients missing

² 3 patients missing

JUST ACCEPTED

Table 3. Diagnostic work up and interventions during index admission.

	Mild	Moderate	p Value
Procedures	n = 172	n = 82	
Ultrasonography, numbers of	1 (0-2)	1 (0-4)	0.051
Computed tomography, numbers of	0 (0-3)	1 (0-7)	<0.001
MRCP, numbers of	0 (0-1)	0 (0-1)	0.509
EUS, numbers of	0 (0-0)	0 (0-1)	0.148
Definitive treatment	140 (81%)	62 (76 %)	0.285
Surgery	n = 140	n = 62	
Post-operative days	3 (0-15)	4 (0-33)	0.026
Day of enlistment to day of surgery, difference	1 (0-191)	2 (0-69)	0.516
Operative time, minutes	107 (12–319)	106 (20 – 489)	0.863
Anaesthetic time, minutes	178 (27–465)	170 (31 – 567)	0.821
Numbers of surgeries	1 (1-4)	1 (1-3)	0.464
Type of treatment	n = 140	n = 62	
Laparoscopic	88 (63%)	34 (55%)	0.282
Open	0 (0%)	2 (3%)	0.093**
Conversion	7 (5%)	6 (10%)	0.225**
Cholecystectomy and ERCP	23 (16%)	7 (11%)	0.344
ERCP alone	22 (16%)	13 (21%)	0.363
Cholecystectomy, use of IOC	103 (74%)	46 (74%)	0.211
Cholecystectomy, common bile duct management	n = 118	n = 49	
Per-operative ERCP	11 (9%)	2 (4%)	0.349**
Transcystic bile duct exploration	10 (8%)	2 (4%)	0.512**
None	5 (4%)	2 (4%)	1.00**

** Fishers exact test

Endoscopic ultrasonography; EUS, Magnetic resonance cholangiopancreatography; MRCP, Endoscopic retrograde cholangiography; ERCP, intraoperative cholangiography; IOC

Table 4. Additional hospital costs associated with patients readmitted with ABP.

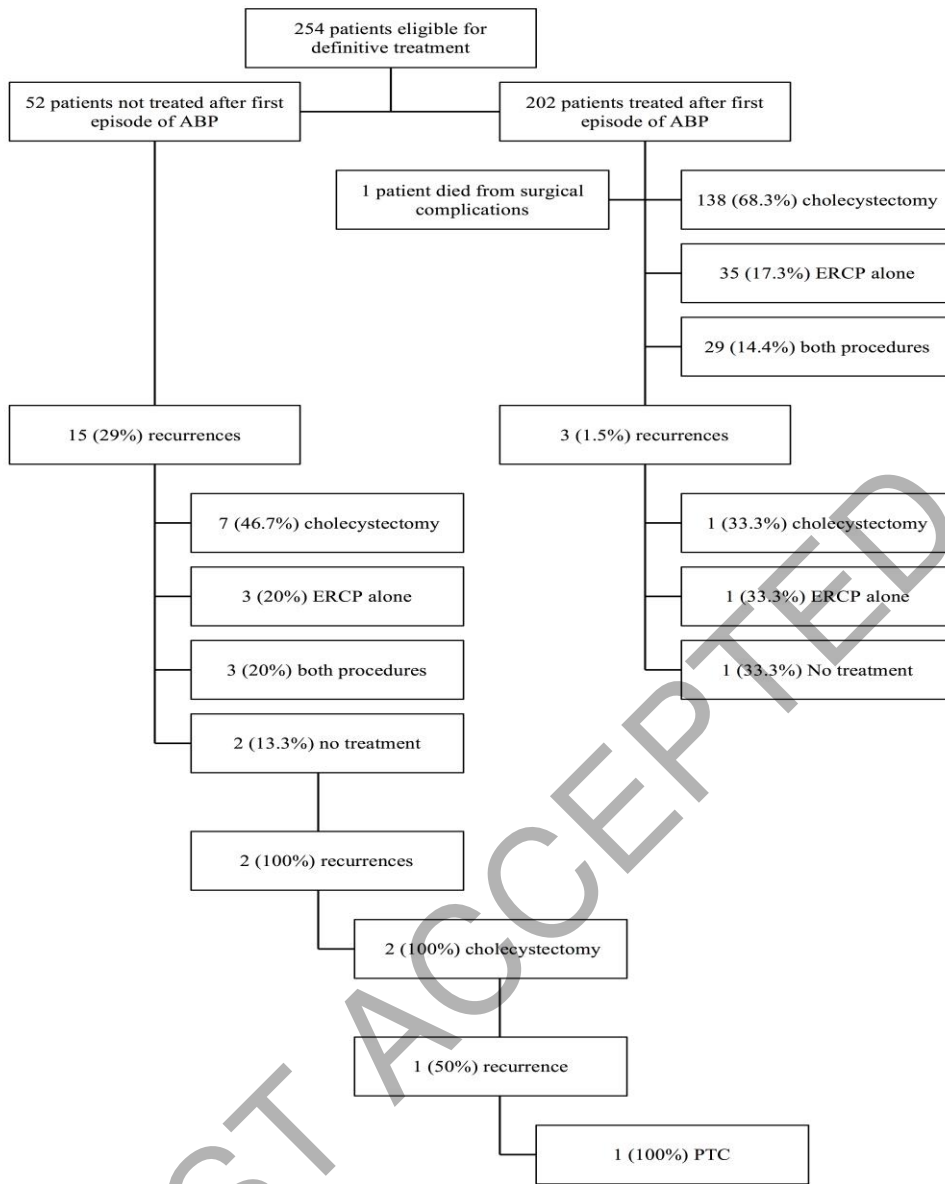
Resource use	All episodes (n=21)
	Costs (EUR)
Ward, total	9,093 ± 11,725
Surgery, total*	3,968 ± 2,478
Radiology, total	480 ± 1,320
Follow-up, total	1,152 ± 4,104
Loss of production**	7,336 ± 12,427
Total	16,412 ± 22,367

* n = 18

** n = 6

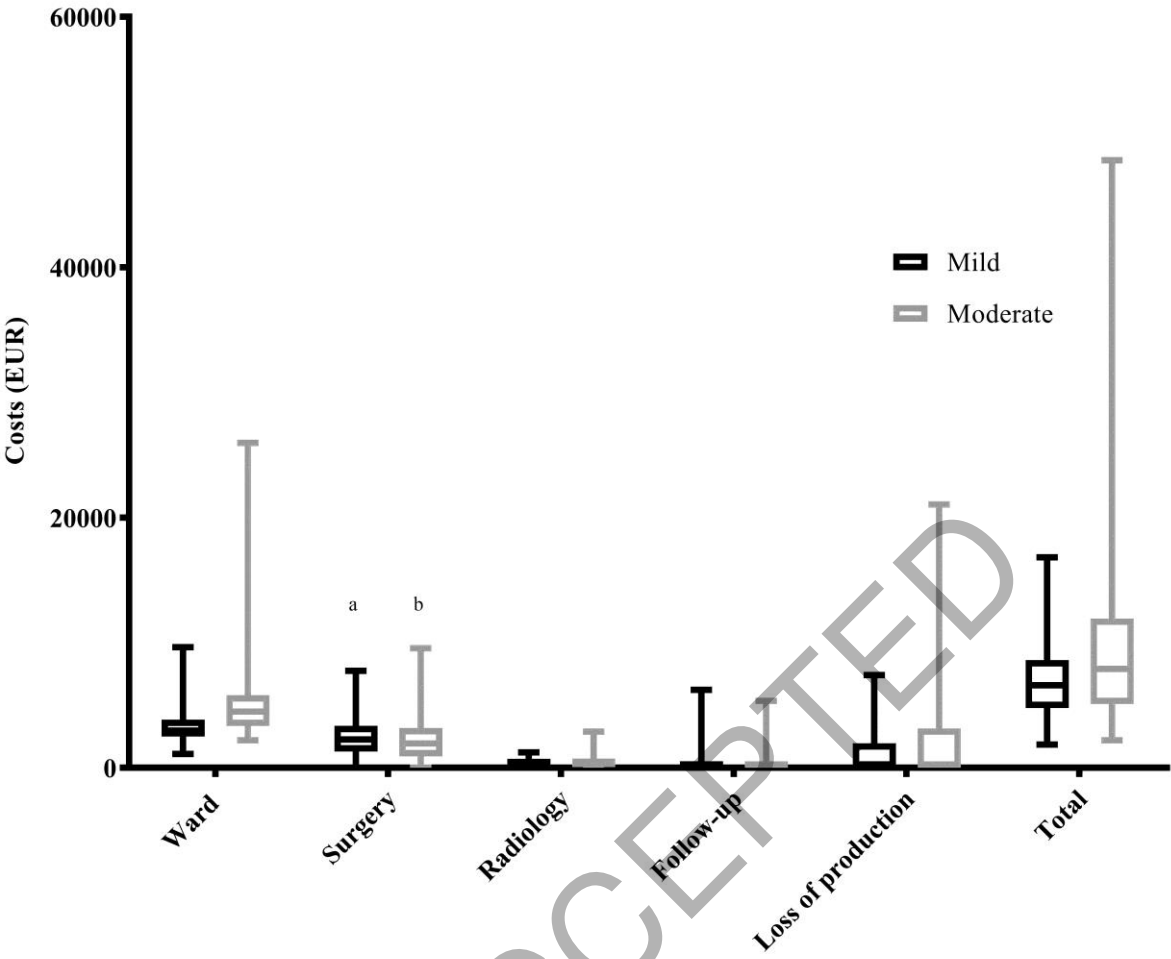
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Figure 1. Management flowchart of patients with ABP.



PTC = Percutaneous transhepatic cholangiography.

Figure 2. Hospital costs for patients with mild and moderate ABP at index admission.



^a n = 140
^b n = 62

Figure 3. Hospital costs for patients readmitted with ABP.

