

## ORIGINAL ARTICLE

## Colicky pain and related complications after cholecystectomy for mild gallstone pancreatitis

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### Abstract

**Background:** Same-admission cholecystectomy is advised after gallstone pancreatitis to prevent recurrent pancreatitis, colicky pain and other complications, but data on the incidence of symptoms and complications after cholecystectomy are lacking.

**Methods:** This was a prospective cohort study during the previously published randomized controlled PONCHO trial on timing of cholecystectomy after mild gallstone pancreatitis. Data on healthcare consumption and questionnaires focusing on colicky pain and biliary complications were obtained during 6 months after cholecystectomy. Main outcomes were (i) postoperative colicky pain as reported in questionnaires and (ii) medical treatment for postoperative symptoms and gallstone related complications.

**Results:** Among 262 patients who underwent cholecystectomy after mild gallstone pancreatitis, 28 of 191 patients (14.7%) reported postoperative colicky pain. The majority of these were reported within 2 months after surgery and were single events. Overall, 25 patients (9.5%) required medical treatment for symptoms or gallstone related complications. Acute readmission was required in seven patients (2.7%). No predictors for the development of postoperative colicky pain were identified.

**Discussion:** Some 15% of patients experienced colicky pain after cholecystectomy for mild gallstone pancreatitis, which were mostly single events and rarely required readmission. These data may be used to better inform patients undergoing cholecystectomy for mild gallstone pancreatitis.

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### Introduction

Cholecystectomy is among the most common surgical procedures in the Western World.<sup>1</sup> A recent systematic review reported that up to one third of patients who undergo this procedure for symptomatic gallbladder stones have persisting or new abdominal symptoms, such as upper abdominal pain.<sup>2</sup> These findings have raised concerns about the appropriateness of cholecystectomy in uncomplicated symptomatic gallstone disease.<sup>3,4</sup>

In patients with complicated gallstone disease such as gallstone pancreatitis or acute cholecystitis, the risk of these gallstone related complications outweighs the risk of persisting symptoms.<sup>5–7</sup> Several studies have demonstrated that cholecystectomy following gallstone pancreatitis does not completely eliminate the risk of recurrent disease, as this may occur in 5% of patients.<sup>8–12</sup> Detailed data on the frequency and natural history of these recurrent symptoms after cholecystectomy for gallstone pancreatitis are lacking.<sup>13</sup>

To this end, we prospectively investigated the risk of colicky pain and related complications after cholecystectomy for mild gallstone pancreatitis, both from a patient and healthcare perspective. Furthermore, we explored potential risk factors for postoperative colic in these patients.

## Methods

### Study design

This was a prospective analysis of patients enrolled in the randomized controlled multicenter PONCHO trial on timing of cholecystectomy after mild gallstone pancreatitis.<sup>11,15</sup> Patients were enrolled in the trial between December 2010 and August 2013 in 23 Dutch hospitals, including 7 university medical centers and 16 teaching hospitals. Adult patients admitted with a first episode of gallstone pancreatitis were screened for eligibility, excluding those with severe gallstone pancreatitis (*i.e.* organ failure for more than 48 h, pancreatic necrosis or peripancreatic fluid collections on imaging), chronic pancreatitis, pregnancy or *a priori* high risk of perioperative complications (American Society of Anesthesiologists [ASA] class III *and* age over 75 and all those with ASA class IV or V).<sup>16,17</sup> Pancreatitis was diagnosed according to the Atlanta guidelines.<sup>16</sup> At least two of the following three items had to be present: (i) epigastric pain, (ii) serum amylase or lipase levels exceeding three times the upper limit normal and (iii) if performed, characteristic findings of acute pancreatitis on cross-sectional imaging. Once discharge was foreseen within 48 h, participants were randomized to cholecystectomy within 3 days (*i.e.* same-admission cholecystectomy) or interval cholecystectomy after 25–30 days. Intraoperative cholangiography was not part of the study protocol, as very few Dutch surgeons perform this procedure routinely. The primary endpoint of the trial was mortality or acute readmission for gallstone-related complications during a 6-month follow-up period. In the present study, outcomes after cholecystectomy with a time horizon of 6 months were investigated from the perspective of both healthcare providers and patients.

### Patient-reported postoperative colicky pain

Upon inclusion in the PONCHO trial, all patients were given questionnaires with instructions to prospectively document what they considered to be colicky pain during a 6-month period. Events were rated on a 0–10 numeric rating scale (NRS), with 0 representing ‘no pain’ and 10 ‘the worst pain imaginable’. Duration of the event was documented dichotomously as either under or over 30 min. We defined postoperative colicky pain as (i) persisting hypochondriac or epigastric pain of at least 30 min, corresponding with the Rome criteria, and (ii) pain with an NRS score of 5 or higher, which we considered a reasonable cut-off value.<sup>18</sup> The trial study nurse contacted all participants by telephone approximately every 2 months and at the end of the 6-month follow-up period.

### Healthcare based outcomes

Health care utilization of all participants was prospectively registered during the 6-month follow-up period. The following healthcare components were included in this study: hospital visits for gallstone-related disease (e.g. recurrent gallstone pancreatitis), diagnostics for suspected persisting common bile duct stones (e.g. ultrasound, endoscopic retrograde cholangiopancreatography). The focus of this study was postoperative gallstone-related complications. Therefore, hospital visits for surgical complications (such as wound infections) were excluded, as were patients in whom diagnostics revealed an unrelated cause of symptoms.

### Risk factors for colicky pain

The following variables were examined for a potential effect on the development of colicky pain: age, sex, body mass index (BMI), overall health status based on ASA classification, a history of biliary colic, endoscopic sphincterotomy prior to surgery, the number of days between onset of pancreatitis and cholecystectomy, conversion to open cholecystectomy and difficulty of cholecystectomy according to the surgeon. This last variable was included as a difficult cholecystectomy, with much manipulation of the gallbladder, could theoretically increase the risk of gallbladder stones being forced into the common bile duct. Difficulty of cholecystectomy was assessed by the surgeon on a 0–10 NRS (10 being most difficult). Also, logistic regression analyses including those patients in whom cholecystectomy was performed per the PONCHO trial study protocol (*i.e.* same admission or interval cholecystectomy). Additionally, risk factors for common bile duct stones were assessed using the guidelines of the American Society for Gastrointestinal Endoscopy (ASGE).<sup>19</sup> According to this stratification system, factors associated with high risk (*i.e.* >50%) for choledocholithiasis are (i) gallstones in the common bile duct on imaging, (ii) serum bilirubin levels exceeding 70  $\mu\text{mol/l}$ , (iii) dilatation of the common bile duct  $\geq 7$  mm AND serum bilirubin levels between 30 and 70  $\mu\text{mol/l}$  or (iv) signs of cholangitis. Finally, the findings of patients who underwent intraoperative cholangiography (IOC) were evaluated.

### Statistical analysis

Only investigations or hospital visits for (suspected) colic and related complications were included in this study. Patients were dichotomized based on post-cholecystectomy healthcare resource utilization. Patients who made a completely uneventful recovery were grouped as ‘no additional care’; those with postoperative symptoms needing additional medical care through diagnostics or treatment were grouped as ‘additional care’. In the latter category, all diagnostics and treatment for direct surgical complications such as bleeding or wound infections were excluded.

All continuous data was non-normally distributed and therefore reported as median with interquartile range (IQR). For

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