http://dx.doi.org/10.1016/j.hpb.2017.06.004 HPB

ORIGINAL ARTICLE

Routine intraoperative cholangiography during cholecystectomy is a cost-effective approach when analysing the cost of iatrogenic bile duct injuries

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Abstract

Background: The total cost of bile duct injuries (BDIs) in an unselected national cohort of patients undergoing cholecystectomy are unknown. The aim was to evaluate costs associated with treatment of cholecystectomy-related BDIs and to calculate cost effectiveness of routine vs. on-demand intraoperative cholangiography (IOC).

Methods: Data from Swedish patients suffering a BDI during a 5 year period were analysed. Questionnaires to investigate loss-of-production and health status (EQ-5D) were distributed to patients who suffered a BDI during cholecystectomy and who underwent uneventful cholecystectomy (matched control group). Costs per quality-adjusted-life-year (QALY) gained by intraoperative diagnosis were estimated for two strategies: routine versus on-demand IOC during cholecystectomy.

Results: Intraoperative diagnosis, immediate intraoperative repair, and minor BDI were all associated with reduced direct treatment costs compared to postoperative diagnosis, delayed repair, and major BDI (all $p < 0.001$). No difference was noted in loss-of-production for minor versus major BDIs or between different treatment strategies. The cost per QALY gained with routine intraoperative cholangiography (ICER-incremental cost-effectiveness ratio) to achieve intraoperative diagnosis was €50,000.

Conclusions: Intraoperative detection and immediate intraoperative repair is the superior strategy with less than half the cost and superior functional patient outcomes than postoperative diagnosis and delayed repair. The cost per QALY gained (ICER) using routine IOC was considered reasonable.

Received 5 March 2017; accepted 9 June 2017

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Introduction

Emergency and elective cholecystectomy is one of the most common procedures performed by general surgical services.[1,2] Serious complications associated with cholecystectomy are infrequent and iatrogenic bile duct injury (BDI) is reported to occur in 0.3–1.5%.[1,3–5] Major BDI can result in considerable short- and long-term morbidity and mortality, and are associated with high costs for the patient, health system and society as a whole.[6,7] Published studies on cost-analysis after BDI are either from referral centers, with a selection of major injuries and failures after primary repair, or theoretical models.[6–8]

Early recognition and treatment of BDI has been shown to reduce costs and improve patient quality-of-life (QoL). Specifically Savader et al. described significantly reduced costs (43–83%) for BDIs detected intraoperatively.[7] For these reasons Flum et al. has advocated routine intraoperative cholangiogram (IOC) in high-risk patients, complicated pathology or by less experienced surgeons to prevent BDI.[9] The reported frequency for intraoperative detection and diagnosis of BDI varies in a wide range from 19 to 90%.[10–13] A high frequency of intraoperative detection (90%) is reported from centers performing IOC on a routine basis.[5,12] Studies on QoL after BDI have shown diverging results, but postoperative diagnosis and prolonged treatment have proven to be factors associated with poor outcome.[14,15] In a cost-effectiveness analysis of early versus late reconstruction of BDIs, early repair by a hepatobiliary surgeon was the superior strategy.[8]

Please cite this article in press as: Rystedt JML, et al., Routine intraoperative cholangiography during cholecystectomy is a cost-effective approach when analysing the cost of iatrogenic bile duct injuries, HPB (2017), http://dx.doi.org/10.1016/j.hpb.2017.06.004

In Sweden, approximately 12,500 cholecystectomies are performed annually and registered in GallRiks, a national quality register for all gallstone surgery. This includes patients undergoing open and laparoscopic cholecystectomy as well as endoscopic interventions of the bile ducts. One third of cholecystectomies are performed as an emergency procedure; IOC is considered a routine procedure, attempted in over 90% of cholecystectomies, and laparoscopy is the preferred technique in both elective (94%) and emergency (82%) procedures.[2] The register is validated and 100% of BDIs were included in the register when compared to the National Patient Insurance Register (LÖF).[16] Treatment and clinical outcome as well as QoL measured by SF-36 for the cohort of patients with BDI reported in this paper, have previously been published.[5,14]

The aim of this study was to evaluate the direct and indirect costs associated with the treatment of cholecystectomy-related BDIs in relation to when the injury was diagnosed and treated. The cost effectiveness for routine versus on-demand intraoperative cholangiography at cholecystectomy was also estimated (ICER-incremental cost effectiveness ratio).

Methods

GallRiks

All patients with a BDI registered in the national quality register GallRiks between 2007 and 2011 from 76 participating hospitals were included. Exclusion criteria were bile leakage from the cystic duct or liver bed (Hannover classification Grade A), planned choledochotomy, malignancy in the hepatopancreaticobiliary (HPB) area, and planned liver resections.

Perioperative data in GallRiks are registered prospectively by the operating surgeon or endoscopist on a secure website and postoperative data are collected at 30 days. GallRiks data included were: age, gender, ASA-score (American Society of Anesthesiologists physical status classification system), indication for cholecystectomy, surgical technique, intraoperative cholangiography (IOC), and intra- and post-operatively detected complications. Administrative data included: planned or emergency admission, type of hospital (local, regional, or university), and referrals.

A control group without BDI (1:2) frequency-matched for age, gender, ASA-score, date of treatment (± 2 years), indication for cholecystectomy (uncomplicated gallstone disease or complicated by cholecystitis, pancreatitis, or biliary obstruction), planned or emergency procedure, and surgical technique (laparoscopic/converted/open procedure) was recruited from GallRiks.

National survey

In a national follow-up survey, all hospitals reporting BDIs were contacted. Medical records were reviewed and injuries were recorded according to the Hannover-classification and grouped into minor BDI (Hannover C1, i.e. lesion <5 mm) or major BDI (Hannover C2-D).[17] Protocol included when the injury was diagnosed (intraoperatively/postoperatively), intraoperative cholangiography (IOC) (no/attempted/performed) and if performed any diagnosed pathology, referrals, and when the definitive procedure was performed (intraoperatively or a delayed repair).[5]

Cost analysis

Total treatment costs for patients suffering BDI were calculated by adding direct treatment costs (healthcare costs) and indirect costs (loss-of-production). Direct treatment costs were calculated by summation of six main groups: radiology, interventional radiology, endoscopy, surgery, hospitalization, and out-patient clinic. Unit costs for all radiological procedures, interventional radiology, anaesthesia, operation/re-operation, endoscopy, hospitalization, and out-patient clinic visits were retrieved from a regional debit price list and are listed in Table 1S.[18,19] A price in Euro was achieved by using the average exchange rate over three years, 2013–2015, from the Riksbank, Sweden's central bank.[20]

Indirect costs were calculated from a follow-up questionnaire which was distributed by mail to all participants. Parameters included were: sick leave, income, employment, and control-questions related to follow-up and monitoring. Written reminders as well as telephone calls from a specially trained administrator were conducted over a period of four months to increase the responder frequency. Data on mortality were retrieved from SPAR (Swedish: Statens PersonAdressRegister), which includes all persons registered as a resident in Sweden. SPAR is updated daily and data presented in this report were retrieved through October 2013, the same month the questionnaires were distributed by mail to the participants.[14] Missing data for yearly sick leave and monthly income for patients with BDI up to the age of 65 were imputed by performing calculations on official Swedish statistics for the year 2013 when mean yearly sick-leave in Sweden was 10.0 days for women and 5.2 days for men.[21]

Health status (EQ-5D)

The EuroQol Group is an international network of multidisciplinary researchers that developed EQ-5D as a standardized measure (utility value) of health status, i.e. outcome, enabling studies on cost-effectiveness. EQ-5D evaluates health in five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D index expresses 243 possible health states (3^5), where 1 is perfect health and 0 is death.[22–25] Health status measured by the EQ-5D Index, during a defined time-period, can be expressed as a quality-adjusted-life-year (QALY). QALYs incorporate changes in both quantity (longevity/mortality) and quality (morbidity, psychological, functional, social, and other factors) of life.

EQ-5D forms were sent to all BDI and control patients (1:2) as long-term follow-up. The EQ-5D questionnaires were distributed simultaneously with the study-specific forms as described above. Written reminders and telephone calls were used to

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