



Research Article

A Resource Tailored Right Upper Quadrant Pathway - Systematic Review and Critical Appraisal of International Guidelines for Acute Calculus Biliary Disease

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Abstract

Background: The acute management of calculus biliary disease is a major component of emergency general surgery care. Multiple international guidelines exist describing best practice management, however significant variation exists regarding aspects of management. Design of local clinical pathways needs to be based on up-to-date evidence based guidelines, and translated to account for locally available resources.

Methods: A systematic review and critical appraisal of international guidelines for the management of gallstone disease was performed. A search of Pubmed, EMBASE, and Cochrane databases and web search was performed. Identified guidelines were critically appraised using the AGREE II Instrument. The resulting scores were used by a multidisciplinary team in the design of a local clinical pathway for patients presenting with right upper quadrant pain, as well as establishing key outcome indicators.

Results: Literature search yielded 2,892 articles for screening, of which nine were identified as guidelines meeting inclusion criteria. Six of these were deemed high quality. A simple, concise, single page clinical pathway was designed based on locally available resources. Six key performance indicators were established under the categories of care process, surgical outcomes, and adverse events.

Conclusions: Multiple high quality international guidelines exist for the management of acute calculus biliary disease. The process of critical appraisal guided a multidisciplinary team in the successful design of a resource tailored clinical pathway for use by surgical and emergency department staff in the triaging, diagnosis and definitive management of patients presenting with right upper quadrant pain. The pathway serves an additional purpose as a data collection and quality improvement tool for ongoing audit and analysis of key outcome indicators through implementation into a digital emergency general surgery registry with the goal of development of AI algorithms and machine learning processes to further identify presentation, disease, and management patterns.

Keywords: Cholecystectomy; Clinical pathway; Gallstones; Index surgery; Quality improvement; Surgical outcomes

Introduction

Acute calculus biliary disease presents a significant burden for health care provision in particular for acute surgical services. In the US, an estimated 6% of men, and 9% of women have gallstones leading to symptoms in 25% [1]. Calculus biliary disease typically presents with the cardinal symptom of Right Upper Quadrant (RUQ) pain. The RUQ is the second most common site of abdominal pain for patients presenting to the emergency department, accounting for almost 20% of patients with acute abdominal pain [2]. Whereas acute cholecystitis (45.6%) is the most common underlying pathology in calculus biliary disease, choledocholithiasis (32% - of whom 43.5% had cholangitis), and biliary pancreatitis (21%) should not be overlooked, nor should the importance of index cholecystectomy in these patient cohorts [3-5]. An early, accurate clinical diagnosis aids and guides appropriate, prompt investigation and management of calculus biliary disease. The mixture of RUQ pain with or without the presence of jaundice, fever, and/or rigors will indicate where a patient lies on the spectrum of biliary disease from simple cholecystitis to complex cholangitis. Inflammatory markers, liver function tests, and ultrasound findings will further solidify the specific diagnosis and leading to early definitive treatment such as an index admission cholecystectomy, or in more complex cases the need for more costly investigations such as Magnetic Resonance Cholangiopancreatography (MRCP) or Endoscopic Retrograde Cholangiopancreatography (ERCP).

Over 1,000,000 cholecystectomies are performed in the US per annum [6]. However, despite this index cholecystectomy rates remain low internationally with significant heterogeneity between countries [3,7], contributing to readmission rates for biliary disease of up to 30% in the absence of index surgery [6]. This in turn has consequences as patients with two or more admissions with biliary disease prior to cholecystectomy have a higher complication rate (18%) and readmission rate (13%) when compared to index cholecystectomy (15.3% and 9.5% respectively) [8]. Current care in patients with gallstone pancreatitis is suboptimal and could be improved by reducing the variation that exist in the delivery of care [9]. Pathways supported by evidence based strategies will improve this. The evidence supporting pathway driven care and enhanced recovery protocols has been long established in elective surgery [10,11]. The literature demonstrates significant improvements in mortality, morbidity, and length of stay following implementation of pathways [12-14]. Emergency General Surgery (EGS) is estimated to account for 11% of hospital admissions with almost 30% requiring surgery [15]. This complex cohort accounts for the majority of surgical mortality despite making up a fraction of admissions when compared to elective surgery [16]. There is an urgent need to translate the lessons learnt from optimisation and

standardisation of elective care into EGS to tackle excessive associated morbidity and mortality (Sherratt, Allin et al. 2020) [17-19]. Optimal outcomes have been identified, but real world application in any care pathway must be tempered by the locally available resources and skill mix [20]. This paper describes the development of a clinical pathway with key outcome indicators for patients presenting with RUQ pain supported by a systematic review and critical appraisal of international guidelines.

Methods

A systemic review of the literature was performed in accordance with the PRISMA statement [21] to identify national and international guidelines and consensus statements on the management of gallstones. A literature search was performed using PubMed, EMBASE and Cochrane databases during March 2021. Key words of “cholecystitis”, “choledocholithiasis”, “cholangitis”, “guidelines” and “consensus” were used to interrogate each database. Searches were limited to literature published after 2011 to ensure current relevance. A web search for guidelines was also performed. The full details of each search are included in the appendix. To be eligible for inclusion guidelines needed to be published in English, deal with generality of gallstone disease, and be compiled based on critical appraisal of the literature.

The Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument was used to critically appraise these guidelines [22]. AGREE II provides a framework to assess quality, inform development and reporting of information in guidelines. It assesses guidelines under 6 domains - scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability, and editorial independence - using 23 items. An overall score is also assigned to each guideline. Though no defined criterion for what consists a “good” or “acceptable” guideline exists, studies have previously used a score of 70 as good quality [23]. Two authors (IS, HH) independently scored each guideline, combined scores were calculated. The statements and recommendations put forward in these guidelines were then used to design a right upper quadrant pathway tailored to local resource availability and expertise based on the strength of the supporting evidence. This pathway was designed for a 350-bed regional university hospital serving a population of 160,000. The department of surgery includes 6 consultant surgeons covering a 24 hour, 7 days a week emergency general surgery call through a surgeon of the week system. The hospital annual load of approximately 3000 EGS admissions is managed without an acute surgical assessment unit [2]. Patients self-present, are brought in by ambulance or are referred to the emergency department by their GP. On arrival they are triaged by nursing staff using the Manchester Triage System [24], then assessed by emergency department doctors who refer to the surgical service if warranted. Typically, patients are then assessed by resident surgical staff prior to admission or consultant review.

Access to ultrasound and MRI is limited to daytime only (9am to 5pm), with CT available out of hours. ERCP is not locally available and necessitates transfer to a Level 4 tertiary hospital 250km away by ambulance. A single emergency operating theatre is available 24hours a day, with access shared between general surgery, orthopaedics and gynaecology/obstetrics. A Multidisciplinary Team (MDT) consisting of surgical consultants and trainees, Emergency Department (ED) consultant physicians, senior nursing staff, information systems experts, and research fellows used a process mapping approach to design this clinical pathway for patients presenting with undifferentiated right upper quadrant pain. Further expert input was provided by surgeons from a neighbouring hospital. An iterative process was used in the development of the pathway and key outcome indicators. Designs for the pathway and key outcome indicators were reviewed on a weekly basis for 3 months until final drafts were agreed upon by the team members. Established best practices for pathway development were adhered to, namely 1) multidisciplinary team implementation, 2) local consensus, 3) evidence based practice and 4) educational outreach [14].

Local availability of resources including MRCP, ERCP and theatre access was accounted for in its design. Key Outcome Indicators (KOIs) [25] including pathway compliance, time to ultrasound, ERCP and surgery, length of stay, index cholecystectomy rates, and readmission rates were established for assessing implementation and clinical impact of the pathway. Following the implementation of the pathway an ongoing weekly feedback system remained in place for the first stages of application allowing for a robust troubleshooting system.

The statements were assessed on basis of AGREE II scores, levels of evidence (LoE), grade of recommendation (GoR), clinical applicability, availability of local resources and practicality by an MDT working group. Following this assessment, the international guidelines were used to develop an easily applicable, short, approachable right upper quadrant triage system and pathway for use by junior emergency department physicians and surgeons in the emergency department to aid in the prompt recognition of severity of gallstone disease, and initiation of appropriate first steps in management, with an emphasis on early consultant guidance and input (Figure 2). KOIs were developed as part of this process to

allow for robust audit following implementation (Table 3). These had to be readily measurable, collectable, reproducible, and easily validated to allow for use in quality improvement [26, 27].

Results

Systematic Review and Scoring of Guidelines

Database searches yielded 2,892 articles (Figure 1). Following the screening of article abstracts, 13 articles were further assessed for suitability of inclusion. Of these, 4 were excluded due to lack of English language text [28], not being a guideline or consensus statement [29], or covering topics with scope outside of calculus biliary disease (specific to the management of post ERCP pancreatitis and severe pancreatitis) [30,31]. 9 articles were identified as guidelines for the management of calculus biliary disease (Table 1). Breakdown of scores are shown in Table 2.

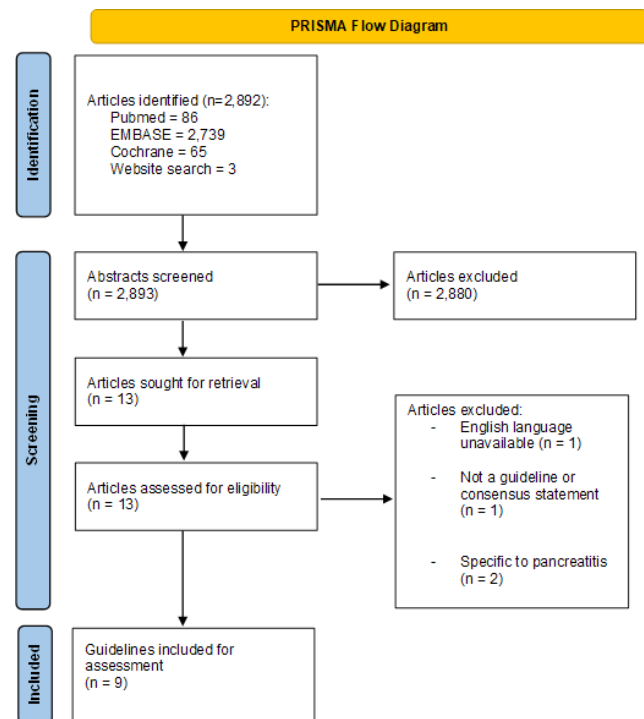


Figure 1: Literature Search.

Organisation	Guideline	Publication Site	Abbreviation	Year
World Society of Emergency Surgery	2020 World Society of Emergency Surgery updated guidelines for the diagnosis and treatment of acute calculus cholecystitis (44)	World Journal of Emergency Surgery	WSES	2020
The American Society for Gastrointestinal Endoscopy (ASGE)	ASGE guideline on the role of endoscopy in the evaluation and management of choledocholithiasis (41)	Gastrointestinal Endoscopy	ASGE	2019
European Society of Gastrointestinal Endoscopy	Endoscopic management of common bile duct stones: European Society of Gastrointestinal Endoscopy (ESGE) guideline (34)	Endoscopy	ESGE	2019
World Society of Emergency Surgery and the Italian Surgical Society for Elderly People	2017 WSES and SICG guidelines on acute calculous cholecystitis in elderly population (37)	World Journal of Emergency Surgery	WSES/SICG	2019
Japanese Society of Hepato-Biliary-Pancreatic Surgery	Toyko Guidelines 2018: updated Tokyo Guidelines for the management of acute cholangitis/acute cholecystitis (45)	Journal of Hepato-Biliary-Pancreatic Sciences	TG18	2018
The Japanese Society of Gastroenterology	Evidence-based clinical practice guidelines for cholelithiasis 2016 (32)	Journal of Gastroenterology	JSG	2017
European Association for the Study of the Liver	EASL Clinical Practice Guidelines on the prevention, diagnosis and treatment of gallstones (33)	Journal of Hepatology	EASL	2016
Italian Surgical Societies Working Group	Laparoscopic cholecystectomy: consensus conference-based guidelines (38)	Langenbeck's Archive of Surgery	ISSWG	2015
National Institute for Health and Care Excellence	Gallstone disease - Diagnosis and management of cholelithiasis, cholecystitis and choledocholithiasis (35)	National Institute for Health and Care Excellence	NICE	2014

Table 1: Included Guidelines.

Guideline	Scope and Purpose	Stakeholder Involvement	Rigour of Development	Clarity of Presentation	Applicability	Editorial Independence	Overall Assessment	Recommend for use
WSES	69.5	44.4	77	69	47.9	83.3	75	Yes
ASGE	91.7	66.7	77.1	83.3	47.9	58.3	83.3	Yes
ESGE	52.7	38.9	79.1	80.5	37.5	87.5	66.7	Yes
WSES/SICG	89	52.8	66.7	77.8	41.7	83.3	75	Yes
TG18	91.6	41.7	77.1	77.8	56.25	79.1	83.3	Yes
JSG	61.1	44.4	50	66.7	27	79.1	50	with modifications
EASL	77.8	41.7	43.8	55.6	29.2	54.2	50	with modifications
ISSWG	72.2	61.1	64.4	72.2	39.6	83.3	75	Yes
NICE	91.7	72.2	79.2	94.4	68.8	50	83	Yes

Table 2: AGREE II Scores.

Six of guidelines were considered high quality, achieving overall assessment scores of over 70. Three guidelines did not achieve the threshold of 70 - The Japanese Society of Gastroenterology Evidence based practice guidelines for cholelithiasis 2016 [32] (JSG - score 50), European Association for the Study of the Liver Clinical Practice Guidelines on the prevention, diagnosis and treatment of gallstones [33] (EASL - score 50), and Endoscopic management of common bile duct stones: European Society of Gastrointestinal Endoscopy (ESGE) guideline [34] (score 66.7),

Stakeholder involvement and applicability were the lowest scored domains with average scores of 51.5 and 44 respectively, with only one guideline - the National Institute for Health and Care Excellence Gallstone disease - Diagnosis and management of

cholelithiasis, cholecystitis and choledocholithiasis [35] (NICE) - received a score above, or approaching 70 for either domain (72.2 Stakeholder Involvement, 68.8 Applicability). Scope and Purpose (mean 77.4), Rigour of Development (mean 68.2), Clarity of Presentation (mean 75.2) and Editorial Independence (mean 73.1) were all scored consistently high across all papers.

Development of Right Upper Quadrant Pain Pathway and Outcome Indicators

Statements from the scored guidelines were tabulated, with corresponding levels of evidence and grades of recommendation. The majority of articles scored used GRADE [36] criteria for assessing the quality literature on which they based their guidelines and recommendations. The 2017 WSES and SICG guidelines on acute calculus in the elderly population (WSES/SICG) [37], and Laparoscopic Cholecystectomy: consensus conference-based guidelines (ISSWG) [38] used the 2011 Oxford Levels of Evidence [39], whereas the Tokyo Guidelines 2018: Guidelines for the management of acute cholangitis/acute cholecystitis (TG18) [40] and NICE guidelines [35] used Modified GRADE framework. Following extensive review, discussion and iteration through a multidisciplinary working group, these statements were used to the Key Outcome Indicators and Right Upper Quadrant Pain Pathway shown in Figure 2 and Tables 3.

- Care process
1. Abdominal US should be completed with 24 hours of admission (Target 90%)
- Surgical Outcomes
1. Index cholecystectomy performed within <72hrs of admission for acute cholecystitis (Target 60%)
 2. Time to ERCP or definitive duct clearance <72hrs for choledocholithiasis (Target 75%)
 3. Index cholecystectomy performed with <72hrs of duct clearance for choledocholithiasis (Target 60%).
- Adverse events
1. Re-admission <90 days with recurrent biliary pathology (Target <10%)
 2. Post-operative bile leak < 2%. Defined as an intraoperatively, clinically, or radiologically identified biliary leak within 30 days of surgery regardless of whether it required radiological, endoscopic, or surgical intervention. (Target <2%)

Table 3: Key Outcome Indicators.

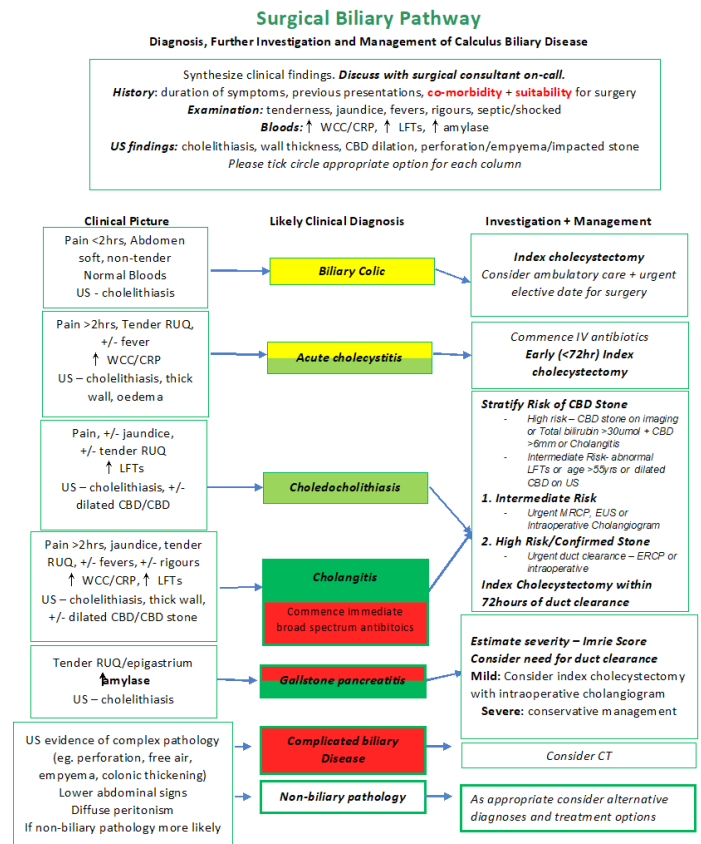


Figure 2: Right Upper Quadrant Pain Pathway.

Discussion

This study identified 9 papers, 6 of which were classified as high quality. These papers were used to develop a unique RUQ pain pathway. While most of these articles score highly on scope and purpose, rigour of development and clarity of presentation the tools for clinical implementation and ease of use of these guidelines were not routinely provided. In addition, means of auditing and accessing the impact of their use were not reported, resulting in low average scores for applicability. Some of the guidelines provided excellent decision tools, such as the NICE algorithm for diagnosis and management [35], the ASGE risk stratification for CBD stones [41], and the TG18 electronic forms [40]. Access and visibility of these assets is challenging and access during busy clinical practice difficult without distilling them down to readily accessible local policies or pathways. The AGREE II score, while a useful tool for critically appraising the quality of guidelines, does not comment explicitly on the content of those guidelines and guidance on threshold scores for “high-quality” are not provided by the tool itself [42]. There are multiple topics of ongoing research highlighted by these articles, some of which are still being hotly debated amongst the surgical community - namely the use of cholecystectomy and precise timing of index cholecystectomy, particularly in the critically ill - randomized trials such as CHOCOLATE have tried to address some of these questions [43-45]. All the articles examined here advocate the use of early laparoscopic cholecystectomy, however, the exact timing of this varies - with a range of 72hrs from presentation to “as soon as patient factors allow” regardless of elapse of time. Optimal management strategies for critically ill and/or elderly patients with biliary pathology with regards to appropriateness of surgery, use of cholecystectomy, and timing of intervention vary significantly across the guidelines.

The right upper quadrant pain pathway developed here is tailored to local expertise in this institute and is designed as a single page triage tool and clinical aid to streamline patient access to definitive diagnosis and management. It doubles as a data capture sheet, which will be fed automatically into a digital emergency general surgical registry as we transition to a digital format, with an opportunity for further introduction of AI algorithms and machine learning. Clinical history, examination, laboratory investigation and ultrasound are universally accepted as low cost first steps in management of biliary disease across all guidelines examined. The critical steps in patient management are identification and management of septic focus and biliary obstruction, and ensuring that biliary pancreatitis is not overlooked. Following, or as part of, the management of the acute complications of cholelithiasis, timely access to cholecystectomy ensures reservoir elimination and prevention of recurrent biliary disease. The focus of this pathway is on early identification of critically unwell patients with critical care involvement, initiation of antibiotic therapy where appropriate,

and screening for patients with biliary obstruction to ensure urgent ductal clearance either through ERCP or intraoperatively when required. It is aimed towards junior staff, with an emphasis on early consultant involvement to ensure appropriate decision making for critically unwell or complex comorbid patients. Decisions around timing of surgery, use of cholecystectomy, and need for patient transfer due to lack of local resource, must involve senior clinicians. The design of the pathway is such that routine clinical audit can be easily performed based on the data captured.

Conclusion

The result of systematic review and critical appraisal is a pathway designed to aid in streamlining accurate diagnosis, guide efficient investigation, and increase timely surgery with index cholecystectomy while improving patient outcomes and reducing readmission rates for biliary disease. Through the process of developing this pathway, the abundance of high-quality guidelines for calculus gallbladder disease has been demonstrated and highlighted. However, short falls in their applicability and guidance on the audit of practice limit the ease of use in the clinical setting without localised adaptation. Transforming guidelines into local practice requires an understanding of local resources, expertise, and limitations as well as critical appraisal of evidence behind best practice guidelines. High quality patient care relies on basic principles being completed to high standards. The processes used to develop this pathway provide an example of how to translate international guidelines into locally adapted clinical pathways or aids for clinicians to streamline patient care. An emphasis on key outcome indicators and audit ensures robustness and provides means of assessing impact and outcomes.

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