AUDIT ARTICLE

Clinical audit: Reviewing management of gallbladder and common bile duct stones at a public sector tertiary care hospital in Karachi, Pakistan

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Abstract

Objective: To evaluate adherence to the guidelines for the management of gallstones in a tertiary care setting.

Methods: The clinical audit was conducted at the General Surgical Unit VI, Civil Hospital, Karachi, and comprised data of laparoscopic cholecystectomy from October 1 to November 1, 2023. Management practices were assessed using the guidelines published by the National Institute of Health and Care Excellence. The audit conformed to the Standards for Quality Improvement Reporting Excellence 2.0 guidelines for quality improvement projects. Data was analysed using SPSS 20.

Result: Of the 62 patients, 49(79%) were females, 12(21%) were males, 18(29%) were aged 40-50 years and 17(27.4%) were aged 30-49 years. All the 62(100%) patients underwent liver function tests and an ultrasound of the abdomen. There were 26(41.9%) patients with acute cholecystitis, and 6(23%) underwent surgery within a week of diagnosis as recommended. There were 48(77.4%) symptomatic patients, and the recommended day-care admission was employed for 15(31,3%).

Conclusion: The delay in surgical intervention for acute cholecystitis warranted attention. Balancing this with resource limitations underscored the need for effective adaptive strategies to optimise patient care.

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Introduction

Gallstone disease is a significant contributor to gastrointestinal disorders globally.[1] According to the European Association for the Study of the Liver (EASL),[2] it affects 20% of Europeans. Cholelithiasis is the most dominant cause of hospital admission compared to other gastroenterological conditions, and it has a significant impact on public health and socioeconomics.[3]

The National Institute of Health and Care Excellence (NICE), United Kingdom, provides comprehensive guidelines for the management of gallstones to address adequate diagnosis, symptomatic relief, and timely cholecystectomy, endoscopic retrograde cholangiopancreatography (ERCP) or medical dissolution therapy for symptomatic patients to prevent complications, such as choledocholithiasis.[4] The NICE aimed at optimising patient outcomes and resource utilisation, but adherence to the guidelines poses a challenge considering resource limitations. For both gallstones and common bile duct stones, treatment is only advised when accompanied by symptomology since symptomatic patients with common bile duct stones have the highest evidence of benefit.[4,5]

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The current study was planned to audit and evaluate adherence to the NIC guidelines for the management of gallstones in a public-sector, tertiary care setting.

Materials and Methods

The clinical audit was conducted at the General Surgical Unit VI, Civil Hospital, Karachi (CHK), and comprised data of laparoscopic cholecystectomy from October 1 to November 1, 2023. The audit conformed to the Standards for Quality Improvement Reporting Excellence for quality improvement projects.[6]

CHK is a tertiary care hospital with a 1,900-bed capacity. General surgical wards are divided into six units, each operating independently. The operation theatres are well-equipped with facilities of advanced infrastructure, modern surgical equipment and instruments, sterilisation and infection control, operating theatre staff, and documentation for elective procedures adhering to the World Health Organisation (WHO) guidelines for surgical care to perform open, laparoscopic and robotic cholecystectomy.[5] According to 2018 data, the operation theatres are equipped to entertain 14 surgical wards, resulting in 7,733 operations.[7] Additionally, emergency cases are operated at the Shaheed Mohtarma Benazir Bhutto Institute of Trauma (SMBBIT) centre equipped with modern facilities and an operation theatre capable of managing 12,000 patients annually.[8] However, the availability of the general ward and hospital resources is a significant limitation in providing standard care.

After exemption from the ethics review committee of Dow University of Health Sciences (DUHS), Karachi, a set of clinical criteria extracted from the NICE 2014 guidelines was identified for the audit.[4]

Adult inpatients aged 18-80 years were included if they were planned for elective laparoscopic cholecystectomy. Informed consent was obtained from each patient.

Patients who were diagnosed with gallbladder stones and were managed conservatively were excluded. Patients with acute cholelithiasis resulting in emergency surgery were also excluded, and so were those with incomplete medical records and those not willing to participate.

Instead of using a pre-set sample size, all patients who met the inclusion criteria were included.

Data was collected through medical records using a pre-designed proforma. Data included age, gender, co-morbidities, investigative imaging modalities, referral for other conditions, patient reassurance, the proposal of laparoscopic cholecystectomy, the proposal of day-case procedure, the proposal of surgery in case of acute cholecystitis, bile duct clearance and the methodology applied, and patient education.

Laparoscopic cholecystectomy was planned under general anaesthesia (GA) by experienced laparoscopic surgeons having at least five years of experience. The 4-port laparoscopic approach was employed in all the surgeries. ERCP was performed by experienced gastroenterologists under GA, sedation or topical anaesthesia, depending on the patient's clinical condition and preferences.

Data was analysed using SPSS 20. Data was reported as frequencies and percentages.

Results

Of the 62 patients, 49(79%) were females, 12(21%) were males, 18(29%) were aged 40-50 years and 17(27.4%) were aged 30-49 years. There were 22(35.5%) patients with known comorbidities. Overall, 26(41.9%) patients presented as acute cholecystitis, 25(40.3%) with chronic cholecystitis and 11(17.7%) with choledocholithiasis (Table 1).

All the 62(100%) patients underwent liver function tests (LFTs) and an ultrasound of the abdomen. There were 8(13%) patients with no common bile duct (CBD) stone on ultrasound with deranged LFTs or dilated bile ducts, and 5(62.5%) of them were offered magnetic resonance cholangiopancreatography (MRCP). The rest of the patients were only offered ERCP, showing the dilation to be secondary to bile strictures resulting from stones. They were managed by placing stents. The patients were asymptomatic following the stent placement, and were discharged without surgery.

Among the 32(51.6%) patients with comorbidities, 30(93.7%) received coordinated care through multidisciplinary management.

Table-1: Baseline characteristics.

Characteristic	n (%)
Age Range	
20-30 years	13 (21)
30-40 years	17 (27.4)
40-50 years	18 (29)
50-60 years	11 (17.7)
60-70 years	3 (4.8)
Gender	
Female	49 (79)
Male	13 (21)
Comorbidities	
Hypertension	22 (35.5)
Diabetes Mellitus	3 (4.84)
Hepatitis B	1 (1.61)
Diagnosis	
Chronic Cholecystitis	(40.3)
Acute Cholecystitis	(41.9)
Choledocholithiasis	(17.7)

Table-2: Findings of the audit.

	NICE Recommendations	Results of Audit n (%)
	1.1. Diagnosing Gallstone Disease	
1.1.1	LFTs and ultrasound to people with suspected gallstone disease	62/62 (100)
1.1.2	MRCP if ultrasound has not detected common bile duct stones, but the bile duct is dilated, and LFT results are abnormal	5/8 (62.5)
1.1.3	EUS if MRCP does not allow a diagnosis to be made	0/3 (0)*
1.1.4	Refer people for further investigations if conditions other than gallstone disease are suspected	30/32 (93.7)
	1.2. Managing Gallbladder Stones	
1.2.1	No treatment for asymptomatic gallstone	22/22 (100)
1.2.2	Lap. Chole in symptomatic gallbladder stones	45/48 (93.7)
1.2.3	Day-care elective lap. Chole, if not contraindicated	15/48 (31.3)*
1.2.4	Lap. Chole within a week in acute cholecystitis	6/26 (23.1)*
1.2.5	Percutaneous cholecystostomy for gallbladder empyema	NA
1.2.6	Reconsider lap. Chole following percutaneous cholecystostomy	NA
	1.3. Managing Common Bile Duct Stones	
1.3.1	Bile duct clearance in case of common bile duct stone	24/24 (100)
1.3.2	Lap. chole or ERCP for bile duct stone clearance	24/24 (100)
1.3.3	Stent with ERCP if ERCP failed	12/12 (100)
1.3.4	Low-cost option utilization	NA
	1.4. Patient, Family Member, and Carer Information	
1.4.1	Advice avoidance of triggering food before surgery	32/62 (51.6)*
1.4.2	Advice not to avid triggering food following surgery	34/62 (53.1)*
1.4.3	GP advice for new symptoms	60/62 (96.7)

*: Area of Improvement; NA: Data not available, LFTs: Liver function tests, MRCP: Magnetic resonance cholangiopancreatography, EUS: Endoscopic ultrasound, Lap. Chole: Laparoscopic cholecystectomy, ERCP: Endoscopic retrograde cholangiopancreatography.

There were 48(77.4%) patients who were diagnosed with gallbladder stones, and 22(45.8%) of them reported that they had previously been diagnosed with gallstones during outpatient evaluations and were advised that no surgical intervention was necessary at that time due to the absence of symptoms. They were admitted later once symptoms developed.

Of these 48(77.4%) symptomatic patients, 45(93.7%) were scheduled for elective laparoscopic cholecystectomy. However, surgery was postponed in 3(6.25%) cases due to acute cardiac events, and those patients were discharged for further medical optimisation. Further, 15(31.3%) symptomatic patients received surgery as a day-case procedure, primarily due to limitations in operating room availability. There were 26(41.9%) patients with acute cholecystitis, and 6(23%) underwent surgery within a week of diagnosis as recommended. Delays were largely attributed to limited theatre time, staffing constraints, and the prioritisation of more urgent emergency surgeries. The delay was considered secondary to the lack of availability of medical staff, operation theatres, and patient load.

The 11(17.7%) patients with symptomatic choledocholithiasis were included in the clinical audit. Among the 26(41.9%) patients with acute cholecystitis, 13(50%) also had CBD stones. These stones were not considered the primary cause of their presenting symptoms, which were consistent with cholecystitis. The diagnosis of bile duct stones was based on imaging and/or deranged LFTs rather than distinct symptoms of biliary obstruction or cholangitis. Bile duct clearance was offered to all such patients regardless of the symptoms, adhering to the guidelines, while ERCP or laparoscopic cholecystectomy employment was decided based on the surgeon's clinical experience and preference.

In 13(21%) acute cholecystitis patients with CBD stones, bile duct was cleared in 11(84.6%), and 2(15.4%) patients were offered ERCP before the surgery to clear the bile stones. In 11(17.7%) patients with choledocholithiasis, 10(90.9%) were managed with ERCP and stenting, and 1(9.1%) patient underwent laparoscopic bile duct exploration during laparoscopic cholecystectomy.

Before the intervention, 32(51.6%) patients were advised on foods and drinks that triggered their symptoms, and 34(53.1%) were told that they would not need to avoid food or drink that triggered their symptoms following the procedure. Moreover, 60(96.7%) patients were educated about contacting their general physicians if any food or drink triggered their symptoms following the surgery (Table 2).

Discussion

The current audit revealed inconsistent adherence to the NICE guidelines 4, primarily resulting from the lack of resources available in the hospital and the lack of pre-surgical and post-surgical counselling sessions for the patients. The audit also identified a significantly smaller percentage of patients with acute cholecystitis, managed in 1 week against the recommendations. However, the discrepancy in the patient-to-operation theatre ratio in the emergency and elective setting was relatively unremarkable. Therefore, prioritising trauma surgeries occasionally results in negligence towards the lesser life-threatening conditions. Additionally, a lesser percentage of day-care admissions for elective cholecystectomy was identified.

According to the results, counselling the patients regarding preoperative food triggers and postoperative food administration was also identified as an area for improvement. However, almost all the patients were counselled regarding the reappearance of the symptoms, and were advised to have a general physician's assessment.

The audit showed consistent demographic distribution in relation to previous studies, having a higher incidence of gallstones in females aged 40-50 years.[9]

The audit showed that the clinical practice only lacked the ability to provide MRCP to a fraction of patients with non-visualised gallstones on ultrasound. Despite the unavailability of MRCP, the patients were offered ERCP, which has therapeutic benefits that improve clinical symptoms.

The reluctance of the patients, loss to follow-up, and limited resources have been noted as leading causes of non-adherence to clinical management in the country.[9,10] Despite the challenges, the current results showed adherence towards gallstone diagnostic and initial management. Standardising protocols for managing asymptomatic gallstones and providing clear guidelines and patient education materials have a consistent role in patient care.[11]

Following the audit, the surgical team and department faculty were invited to a brainstorming session to identify the problems and solutions with the aim of improving patient care. The meeting decided to improve the practice by constantly educating and reminding the doctors and nursing staff through verbal reminders and individual verbal feedback. Standardising patient education protocols can improve patient satisfaction, treatment plan adherence, and overall healthcare outcomes.[11,12]

The meeting also emphasised the need of timely

intervention in day-care settings to improve the patient flow and address adequate operation theatre scheduling. However, the major drawback identified was that the clinical practice needed to be improved within the means available.

The current study has limitations as the audit related to a single, public-sector, tertiary care hospital in Pakistan, indicating that the findings were not generalisable. Besides, the manual data recording method at the CHK resulted in a significant loss of patient data.

Conclusion

Despite adequate adherence to the NICE guidelines, delayed surgical intervention in the management of acute cholecystitis was a drawback in clinical practice.

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AA & SI: Design, data analysis, drafting, revision, final approval and agreement to be accountable for all aspects of the work.