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ASGE guidelines result in cost-saving in the management of choledocholithiasis

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Abstract

Background The goal of this study was to determine whether utilization of the ASGE guidelines for the evaluation of bile duct stones (BDS) would result in fewer imaging studies and in turn lead to a lower healthcare expenditure.

Methods This was a retrospective study set in an urban Teaching Hospital. Patients undergoing evaluation for BDS and who had their gallbladders *in situ* were included in the study. Data with regard to age, sex, clinical history, pain level, vital signs and laboratory studies as well as diagnostic tests performed were extracted from the hospital's electronic medical record. The ASGE guidelines were applied retrospectively to each patient in the study group and the group was divided into two cohorts: one that followed the ASGE guidelines and one which did not. Patients in the two cohorts were further stratified into high-, intermediate-, and low-risk categories.

Results Thirty-eight patients met the criteria and were included in the study. Of the 38 patients, 22 were managed as per the ASGE guidelines and 16 were not. Twenty-seven patients were categorized as high-risk (14 following the correct algorithm, 13 not) and 11 as intermediate-risk (8 following, 3 not). There were no low-risk patients. Twelve of the 27 patients in the high-risk group had stones (56%) while 6 of 11 (55%) had stones in the intermediate-risk group. Fourteen computed tomography scans and 12 magnetic resonance cholangiopancreatographies were deemed inappropriate resulting in unnecessary increased expenditure of $ 22,236.

Conclusion The application of ASGE guidelines can minimize redundant investigations and effect cost saving but need to be refined to produce a better yield.

Keywords ASGE guidelines, choledocholithiasis, ERCP

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Introduction

Choledocholithiasis, the occurrence of bile duct stones (BDS), is present in up to 15% of patients with gallstones [1,2]. Approximately 10% of patients undergoing laparoscopic cholecystectomy will also have common BDS [3,4]. The diagnosis of BDS requires a high degree of suspicion and is challenging because it cannot be made conclusively without invasive procedures like endoscopic retrograde cholangiopancreatography (ERCP). In 2010 the American Society of Gastrointestinal Endoscopy (ASGE) published guidelines [5] to assist in risk stratifying patients being evaluated for choledocholithiasis (Table 1). The guidelines stratify patients into high-, intermediate-, and low-risk categories based on clinical criteria, liver tests, and abdominal ultrasound (US). High risk is defined as the presence of any very strong predictor (BDS seen on US, clinical ascending cholangitis, and total bilirubin >4 mg/dL) or the presence of both strong predictors (CBD dilated more than 6 mm and bilirubin 1.8-4 mg/dL) confers a high probability (>50%) of BDS. In the low-risk category the probability of finding stones is <10% while in the intermediate category (any other abnormal liver test, age >55, clinical gallstone pancreatitis) the probability is 10-50%.

The goal of these guidelines is to evaluate patients safely and efficiently in an evidence-based manner. While patient safety is paramount, it is also critical to evaluate these guidelines from a cost-effectiveness perspective. The goal of the algorithm was also to minimize the number of unnecessary endoscopic and radiologic procedures performed. According to Medicare, data spending on imaging has been the fastest growing segment

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of healthcare expenditures [6-8]. Given the growing concern over deficits and the fact that entitlement spending is the largest driver of the national debt it is vital that these costs be controlled. Reigning in the costs of radiologic procedures will likely be an area of focus for policymakers especially since the number of Medicaid and Medicare beneficiaries is expected to rise rapidly in the coming years [9].

Materials and methods

The setting for the study was an urban teaching hospital with a diverse ethnic population. The hospital's CORI (Clinical Outcomes Research Initiative, Portland, Oregon) endoscopy database was retrospectively searched for all ERCPs performed from January 1 to December 31, 2009 - the year prior to the release of the ASGE guidelines for choledocholithiasis. Patients undergoing evaluation for BDS and who had their gallbladders *in situ* were included in the study; an intact gallbladder was the prerequisite for applying the ASGE guidelines. Exclusion criteria included prior cholecystectomy and patients evaluated for causes other than BDS like suspected tumors or strictures.

Data with regard to age, sex, clinical history, pain level, vital signs and laboratory studies (white blood cell count, aspartate aminotransferase, alanine aminotransferase, total bilirubin, alkaline phosphatase (ALP), γ-glutamyl transferase (GGT), amylase, and lipase) as well as diagnostic tests performed (abdominal US, CT scan, and magnetic resonance cholangiopancreatography (MRCP) were extracted from the hospital's electronic medical record (Quadramed. Reston, VA). MRCP, as opposed to endoscopic US (EUS), is the preferred modality to evaluate the biliary tree at our institution as it is easier to obtain. Each patient's length of stay was also determined. Radiologic and endoscopic charges were calculated based on third party payer reimbursement rates.

The ASGE guidelines were applied retrospectively to each patient in the study group and the group was divided into two cohorts: one that followed the ASGE guidelines and one that did not. Patients in the two cohorts were further stratified into high-, intermediate-, and low-risk categories (Table 1).

CT scans performed were deemed as appropriate or inappropriate based on the ASGE guidelines (Fig. 1). The number of unnecessary CT scans of the abdomen performed was determined based on the recommendation that abdominal US should be the initial modality of evaluation for biliary pain. CT scan was deemed as inappropriate if in addition to an US, a CT scan was done without appropriate additional justification.

It was assumed for the purpose of this study that both ERCP and MRCP are equally accurate in detecting stones. This has been substantiated in the literature [10-13].

Cost savings that would have been generated if the guidelines had been in place were then calculated. NY Medicare reimbursement rates were used to calculate these values. For 2013, the physician fee and technical fees for CT scan of the abdomen (with and without contrast (CPT 74170) were $344 and $274 respectively for a total amount of $618; the fee for MRCP (CPT 74183) was $622 (physician fee) plus $510 (technical component) for a total of $1132.

Table 1 Predictors of choledocholithiasis [5]

Predictors
Very strong
CBD stone on transabdominal US
Clinical ascending cholangitis
Bilirubin >4 mg/dL
Strong
Dilated CBD on US >6 mm (with gallbladder *in situ*)
Bilirubin level 1.8-4 mg/dL
Moderate
Abnormal liver biochemical test other than bilirubin
Age older than 55 years
Clinical gallstone pancreatitis
Risk stratification
High -Presence of any very strong predictor
Presence of both strong predictors
Low-No predictors present
Intermediate: All other patients

CBD, common bile duct; US, ultrasound

Paired Student's *t*-test was used to determine if there were any differences in age or gender between patients in the two cohorts. Other data points that were examined included difference in length of stay between the two groups.

Results

A total of 110 ERCPs were performed during the study period. Forty-eight cases were done for evaluation of strictures, masses or were repeat procedure. Sixty-two were done for the evaluation of choledocholithiasis. Of the sixty-two cases, thirty-eight had gallbladders intact while the remaining twenty-four did not. The 38 patients with gallbladders *in situ* were included in the study.

Age and sex

The age range of the 38 patients was 16 to 77 (median 43.5) years. There were 27 females and 11 males.

Adherence to guidelines

Of the 38 patients, 22 were managed as if the ASGE guidelines had been in place. Sixteen patients were managed in a manner not conforming to ASGE guidelines (Table 2).

Risk stratification and ERCP yield

Of the 22 patients managed as per the ASGE guidelines: 4 had two very strong predictors, 5 had one very strong

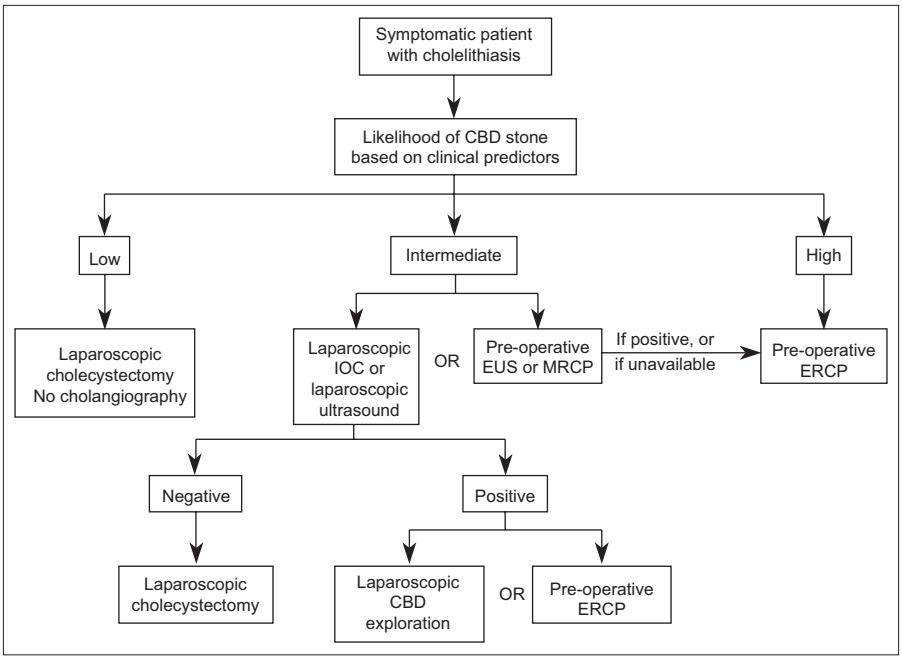

Figure 1 Algorithm for suggested management of patients with symptomatic cholelithiasis. (From ASGE guidelines [5])
CBD, common bile duct; EUS, endoscopic ultrasound; IOC, intraoperative cholangiogram; MRCP, magnetic resonance cholangiopancreatography; ERCP, endoscopic retrograde cholangiopancreatography

predictor, and 5 had two strong predictors for a total of 14 high-risk patients. The remaining 8 patients (7 with one strong predictor and 1 with a moderate predictor) were classified as intermediate-risk.

Of the 16 patients not adhering to guidelines, 13 were stratified as high-risk (7 with one very strong predictor and 6 with two strong predictors) and 3 were classified as intermediate-risk (1 with one strong predictor and 2 with moderate predictors). Five of the 13 patients in the high-risk category had stones (38%) and 1 of 3 patients in the intermediate category had stones (33%).

In total, 27 patients were at high risk (14 following the correct algorithm, 13 not) and eleven patients were of intermediate risk (8 following, 3 not). There were no patients in the entire study group at low risk. Twelve of the 27 patients in the high-risk group had stones (56%) while 6 of 11 (55%) had stones in the intermediate-risk group.

Liver enzymes

There were no significant differences in liver enzymes among the two cohorts (Table 3).

Comparison between the high-risk category and the intermediate-risk category did not reveal any significant difference in the liver enzymes save for total bilirubin levels (Table 4). The total bilirubin was significantly different between the two categories (4.74 vs. 1.48; P<0.001). The ALP and the GGT levels in the high-risk category were twice the levels in the intermediate-risk category (295 and 612 vs. 140 and 312) however these values did not reach statistical significance.

Imaging studies

All 38 patients included in the study had US, as recommended by the guidelines. Nine were normal, twenty-two showed a dilated common bile duct, and seven had BDS seen on US. Of those seven patients three were confirmed to have BDS on ERCP. Twenty-six patients had CT scan of the abdomen and pelvis. Sixteen were in patients where the guidelines were followed and 10 in those in which they were not. BDS were seen on CT in 8 patients, and 7 were confirmed by ERCP.

Fourteen CT scans of the abdomen/pelvis were deemed unnecessary, as these CT scans were done on otherwise healthy patients who had typical biliary pain.

MRCP was performed in 20 of the 38 of patients. Eight were in accordance with the guidelines and twelve were not. MRCP detected 7 of 18 patients who had stones extracted by ERCP. Of the 20 MRCPs, 12 were deemed as inappropriate as they were done in the high-risk category.

Of the total of 84 imaging studies performed (38 US, 26 CT scan and 20 MRCP) 26 studies (30%) were deemed to be unnecessary.

ERCP

Stones were removed in 18 of the 38 patients by ERCP. In three of the cases cannulation could not be achieved. There were no cases of post-ERCP pancreatitis, bleeding, perforation, or infection. There were no anesthesia related adverse events. In three instances ERCP was performed in patients at intermediate-risk MRCP should have been obtained prior. Only one of these patients had a stone.

Table 2 Patients adhering or not to ASGE guidelines

Age	Sex	US	CT	MRCP	ERCP	Risk
Patients adhering to ASGE guidelines						
70	F	DD	BDS-	ND	No stone	H
60	F	DD	BDS-	ND	No stone	H
39	F	DD, BDS+	ND	ND	No stone	H
25	F	DD, BDS+	ND	ND	Stone	H
29	F	NL	ND	FD-	Stone	I
77	F	DD	BDS+	ND	No stone	H
39	F	NL	ND	FD+	Stone	I
64	F	DD	BDS-	FD+	Stone	I
23	M	NL	BDS-	FD+	Stone	I
40	F	DD	ND	FD-	No stone	I
54	F	DD	BDS+	ND	Stone	H
50	M	DD	BDS+	ND	Stone	H
71	M	DD	BDS+	ND	Stone	H
71	F	NL	BDS-	FD-	No stone	I
48	M	DD	BDS-	ND	No stone	H
65	F	DD, BDS+	BDS-	ND	No stone	H
43	F	DD	BDS+	FD+	Stone	I
42	F	DD, BDS+	ND	ND	Stone	H
26	F	DD, BDS+	ND	ND	Stone	H
36	F	DD, BDS+	BDS-	ND	No stone	H
75	M	DD	BDS+	ND	Stone	H
47	F	DD	BDS-	FD+	No stone	I
Patients not adhering to ASGE algorithm						
36	F	DD	ND	FD-	Stone	H
44	F	DD, BDS+	ND	FD-	Unsuccessful	H
31	F	DD	BDS-	FD+	No stone	H
52	F	DD	BDS+	FD+	Stone	H
35	F	DD	ND	FD+	Stone	H
72	M	DD	BDS-	ND	Unsuccessful	I
42	M	NL	ND	FD-	Stone	H
60	M	DD	BDS-	ND	No stone	H
30	F	DD	BDS-	FD+	No stone	H
77	F	DD	BDS+	FD+	Stone	H
22	F	DD	BDS-	FD+	No stone	H
16	F	NL	BDS-	ND	Stone	I
43	M	NL	BDS-	FD-	No stone	H
48	M	NL	BDS-	FD-	Unsuccessful	H
30	M	NL	ND	ND	No stone	I
52	F	DD	BDS-	FD+	No stone	H

F, female; M, male; DD, dilated duct; BDS, bile duct stone; ND, not done; FD, filling defect; +, present, -, absent; H, high risk; I, intermediate risk

Table 3 Differences in liver tests and length of stay between groups following and not following the ASGE guidelines

	Group 1 (Y) n=22	Group 2 (N) n=16	P-value
T. bili (mg/dL)	3.76	3.83	0.94
ALP (IU/L)	275	213	0.44
GGT (IU/L)	540	501	0.8
AST (IU/L)	222	415	0.06
LOS (days)	7.11	6.86	0.84

T. bili, total bilirubin; ALP, alkaline phosphatase; GGT, γ-glutamyl transferase; AST, aspartate aminotransferase; ALT, alanine aminotransferase; LOS (in days), length of stay inpatient

Table 4 Difference in liver tests and length of stay between high- and intermediate-risk categories

	High-risk (27)	Intermediate-risk (11)	P-value
T. bili (mg/dL)	4.74	1.48	0.001
ALP (IU/L)	295	140	0.07
GGT (IU/L)	612	312	0.06
AST (IU/L)	334	220	0.30
ALT (IU/L)	411	207	0.06
LOS (days)	7.3	6	0.35

T. bili, total bilirubin; ALP, alkaline phosphatase; GGT, γ-glutamyl transferase; AST, aspartate aminotransferase; ALT, alanine aminotransferase; LOS (in days), length of stay inpatient

Table 5 Potential radiologic cost savings from following the guidelines

CT	(14×$618)	$8652
MRCP	(12×1,132)	$13,584
Total		$22,236

CT, computed tomography; MRCP, magnetic resonance cholangiopancreatography

Length of stay

There was no significant difference in the length on stay between patients following guidelines and those not following guidelines (7.11 vs. 6.84, P>0.84) and between the high- and intermediate-risk groups (7.3 vs 6, P>0.35).

Cost savings

Cost was calculated based on third party hospital reimbursement rates for the procedures that were not required per the guidelines. This included 14 CT scans of the abdomen/pelvis amounting to an unnecessary expenditure of $8,652. Twelve MRCP exams were done prior to ERCP on high-risk patients leading to $13,584 in hospital charges (12x $1132). Total costs for these unnecessary imaging procedures were calculated to be $22,236 (Table 5).

Discussion

The spiraling cost of healthcare is of great concern in the United States. It is not sustainable as healthcare expenditure is approximately 1/6 of the GDP [9]. This is significant as the debate over the national debt has moved to center stage. Increased scrutiny will fall upon invasive procedures and radiologic studies as these are seen as the largest drivers of these costs, especially in the fee for service model [14-16]. A large proportion of the imaging studies ordered by physicians are not of benefit to the patient or are done as a defensive practice [16,17]. Much of this is thought to be due to the fact that there are no firm guidelines for when to use imaging studies. The present study demonstrates that if such guidelines are developed and then utilized there can be a substantial reduction in the number of imaging studies and healthcare costs without a meaningful impact on patient outcomes.

The ASGE guidelines are a risk stratification algorithm that is based on an exhaustive literature search (Fig. 1). Several studies [18-20] including our own have attempted to validate these guidelines. Our yield of 56% in the high probability group is similar to what Adams *et al* found (56.3%) but much lower than the figure demonstrated by Sethi *et al* (75.8%). In the non-high-risk group our yield was 55% which was much higher than the yield in the other two studies, 48.9% and 34.8%. Both studies [19,20] found a statistically significant difference in the yield between the high-risk category and the non-high-risk category. Our study was not able to demonstrate this difference probably because of our small numbers.

The overall yield in both groups (high- and non-high-risk) was 47% in our study and 42% in the Adams study; the Sethi study demonstrated a yield of 68%. With 2 of these studies registering a less than 50% yield for the ASGE guidelines, the inference is that the guidelines need further refinement to effect a higher and more acceptable yield.

Our results substantiate the fact that there is no set pattern in the ordering of imaging studies by clinicians. The indiscriminate ordering of CT scans is of especial concern. Fourteen young and otherwise healthy patients who presented with a typical biliary pattern of pain received CT scans. In addition, the amount of ionizing radiation delivered during a CT scan is substantial and multiple recent reports have documented the rising rates of medical radiation exposure and its possible negative consequences [21]. Others have commented on the overuse of CT in the diagnosis of gallbladder disease and the fact that it adds little clinically beneficial information to right upper quadrant US [22]. In our study, only 3 of 7 stones detected on US were confirmed by ERCP as opposed to 7 of 8 BDS on CT scan. Despite this, because it is less invasive and cheaper than a CT scan, a US remains the imaging test of choice per the guidelines. Moreover, a US is primarily done to detect ductal dilation which is a strong predictor of BDS and not the detection of BDS *per se*.

In addition to the concerns associated with long-term radiation exposure, the costs associated with CT were found to be substantial in our study. We used very conservative criteria to determine if the CT was necessary. In patients above the age a certain degree of laxity was allowed and the CT was not deemed unnecessary on the assumption that alternate causes of abdominal pain were being ruled out. The average reimbursement rate to the hospital for each study, $618, was used and the figure of $8,652 was arrived at in unnecessary costs for the 14 CT scans. Had the guidelines been in place 12 MRCPs would have been prevented resulting in a cost savings of $13,584. This was determined using the average reimbursement rate of $1,132 per MRCP. The total savings from the two modalities was $22,236. In summary, of the 84 imaging studies performed on 38 patients, 30% or nearly one third had studies deemed as unnecessary and resulted in additional expenditure of $22,236.

The payer for most of these procedures was the New York Medicaid system, which has been under tremendous strain since the financial crisis began. The system has been targeted for budget cuts. One can speculate that, based on the potential cost savings achieved at one medical center over a one-year period, the cost savings could be quite extensive when extrapolated over a large geographic area encompassing many healthcare facilities. MRI, as a modality, stands out not only due the high cost it is associated with, but also due to the exponential rise in its use [16]. Using healthcare reimbursement figures as a method of assessing healthcare expenditures is constructive in this situation because the Government as a payer is feeling the direct effects of these spiraling costs.

The primary difficulty in the approach to patients with BDS is that there is no pathognomonic sign or symptom that patients present with. In addition, many of the modalities utilized in detecting BDS are newer such as EUS and MRCP. Even ERCP is a relatively new procedure. Thus, the data that has been accrued to this point is not as robust. BDS would then appear to be the ideal entity for which to have a more standardized approach; most importantly, because patient safety will be enhanced, and, second, because it will lead to a reduction in the use of costly procedures. Others have attempted to answer this question. One study using differing statistical probabilities of finding BDS and Medicare and Medicaid costs and lengths of stay data suggested that the most cost effective strategy was to perform lap cholecystectomy followed by intraoperative cholangiogram (IOC) [23]. Another group examined the use of EUS, MRCP, and IOC in the management of acute biliary pancreatitis and concluded that cost effectiveness was highly dependent on the probability of having BDS [24]. The publication of the ASGE guidelines will likely bring some uniformity to assessing patients with BDS and thus future studies on cost effectiveness maybe more feasible. It is also possible that if more studies are done to evaluate lab parameters and radiologic markers in patients with BDS the guidelines can be further refined and made more accurate.

The main weakness in our study was that it was retrospective and that the patient study population was small. Only a snap shot was provided by chart review and it is difficult to second guess the clinician's judgment in real time. Furthermore, there are pitfalls when trying to project these findings to a larger population. Different institutions may use protocols that differ from the ASGE guidelines. Clinicians may be hesitant to use or stick to suggestions provided in the guidelines if they are concerned about liability or do not have full confidence in their accuracy.

Summary Box

What is already known:

- Endoscopic retrograde cholangiopancreatography (ERCP) is highly effective in detecting and removing bile duct stones but carries a risk of post-ERCP pancreatitis of 2-8% and a 1-2% risk of post-endoscopic sphincterotomy bleeding
- Non-invasive tests like ultrasound, computed tomography and magnetic resonance cholangiopancreatography are used to identify patients who will require ERCP

What the new findings are:

- Adherence to ASGE guidelines result in cost-saving from unnecessary imaging studies
- The ASGE guidelines need to be refined to yield better results

The payor mix (revenue coming from private versus government insurances) at various institutions also differ, thus costs and savings will vary. There may particularly be little incentive to use such a system if a fee for service system is in place. Strengths of the study include the fact that even retrospectively there are defined objective parameters easily available to use in order to apply the guidelines. Using the third party payer perspective in assessing costs is also beneficial since these are the entities dictating the reimbursements and will demand that costs be held in check.

While patient safety is paramount, the current economic reality dictates that a more evidence-based and cost-effective approach will be needed in Medicine. Radiologic procedures are huge drivers of healthcare costs and expenditures on them have increased dramatically in recent years. Increased restriction on their use is a real possibility. BDS would seem to be an ideal disease to which to bring a more standardized approach, and the ASGE guidelines are a right step in that direction. This study demonstrated that application of the guidelines can result in a reduction in healthcare costs but the guidelines themselves require further refinement to increase the yield.

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