DIAGNOSTIC ACCURACY OF GALL BLADDER WALL THICKNESS ON ULTRASONOGRAPHY IN DETECTING THE CONVERSION FROM LAPAROSCOPIC TO OPEN CHOLECYSTECTOMY

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ABSTRACT

INTRODUCTION: It is reported that increased gall bladder wall thickness on preoperative ultrasonography can predict difficulties during laparoscopic cholecystectomy. The rationale of this study is to determine the predictive accuracy of preoperative ultrasound which if found good, could be a recommended as a standard practice in preoperative evaluation of these patients in our settings as it is readily available, cost effective can give on spot results. **OBJECTIVES:** To determine diagnostic accuracy of gallbladder wall thickness on preoperative ultrasonography in detecting the conversion from laparoscopic to open cholecystectomy, keeping surgical conversion as gold standard. **MAIN OUTCOME MEASURES:** Sensitivity, specificity, positive predictive value (PPV), negative predictive values (NPV) and Accuracy. **STUDY DESIGN:** Cross-sectional (validation) study **DURATION OF STUDY:** Six months (20-06-2013 to 31-10-2013) & (01-05-2014 to 30-06-2014). **SETTINGS:** Department of Radiology, KRL Hospital Islamabad. **SUBJECTS:** 110 patients of either gender with age >20 years who had recurrent pain in right hypochondrium radiating to right shoulder with gallstones on ultrasonography. **METHODS:** Thickness of the gallbladder wall was measured in each patient through ultrasound a day before the surgery. Information about conversion of planned laparoscopic cholecystectomy to open cholecystectomy was also recorded for every patient. **RESULTS:** Sensitivity, specificity, PPV, NPV and accuracy were found to be 85.71%, 37.86%, 8.57%, 97.5% and 43.67% respectively in this study. **CONCLUSIONS:** Thickened gall bladder walls on preoperative ultrasonography can predict the possibility of conversion of planned laproscopic cholecystectomy to open surgery. However, further large scale studies are needed for its validation of its use in routine clinical practice.

Key words: Gall stones, Laproscopic cholecystectomy, pre-operative ultrasonography, Laproscopic ultrasonography, Cholelithiasis

Introduction

Gall stone disease known as cholelithiasis is one of the most common gastrointestinal disorder leading to surgical intervention. Its incidence increases with age from 21 years to 90 years.[1] In Pakistan the estimated prevalence of gall stone disease is 15% which is responsible for 22% admissions in a surgical unit.[2]

Laparoscopic cholecystectomy (LC), since its intro-duction in 1989, has remained the procedure of choice in the treatment of symptomatic gall stones.[3] In Finland, during 2008, 85% of cholecystectomies were performed through laparoscopic procedure.[4] It has gradually replaced the open cholecystectomy in almost all major hospitals in Pakistan.[5] However, of all laparoscopic cholecystectomies 1-13%[3] requires conversion to an open procedure due to difficulties faced during surgery like adhesions around the gall bladder, unclear Calot's anatomy and uncontrolled bleeding.

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Gall bladder wall thickness on preoperative ultrasonography (USG) is related to inflammation or fibrosis that follows previous attacks of cholecystitis.[3] Increased gall bladder wall thickness can cause conversion from laparoscopic to open cholecystomy in 40.1% of patients.[6] Sensitivity, specificity, positive predictive value and accuracy of gall bladder wall thickness on preoperative ultrasonography as an indicator of surgical conversion to open cholecystectomy is 80.0%, 78.6%, 21.1% and 78.7% respectively.[7] Thus identifying increased gall bladder wall thickness on preoperative ultrasonography can predict difficulties during laparoscopic cholecystectomy and need to convert to open surgery. So on the basis of preoperative ultrasonography surgeons will know in advance the problems faced during laparoscopic surgery and can be prepared for the risk of conversion.[8] It also helps in improving preoperative counselling and allows better organization of operating room schedule ultimately leading to reduction in procedure related costs. It also helps in increasing safety by limiting delay in conversion to open procedure; this may shorten duration of surgery and improves patient outcome.[9]

The importance of pre-operative ultrasonographic detection of gall bladder wall thickness should be emphasized upon as it is beneficial for the operating surgeon and helps in improvement of patient care and management.

Objectives

To determine diagnostic accuracy of gallbladder wall thickness on preoperative ultrasonography in predicting the conversion from laparoscopic to open cholecystectomy, keeping surgical conversion as gold standard.

Operational Definitions

Thickened gallbladder wall: Gallbladder with wall thickness more than 3 mm on ultrasound. Thickness of the gallbladder wall will be measured orthogonally to the liver surface at the anterior wall adjacent to the liver.

STUDY DESIGN:
Cross sectional validation study

SETTING:
Department of Radiology, KRL Hospital Islamabad

DURATION:
Six months (20-06-2013 to 31-10-2013) & (01-05-2014 to 30-06-2014)

SAMPLE SIZE: Using WHO calculator
Sensitivity = 80%[10] Specificity = 78.6%
Prevalence = 40.1%[11] Prevalence = 40.1%
Absolute precision = 10%   Absolute precision = 10%
Sample size = 108 patients Sample size = 77 patients
Sample Size is approximately 110 patients.

SAMPLE TECHNIQUE:
Consecutive non-probability sampling technique

SAMPLE SELECTION:

INCLUSION CRITERIA:

Patients of both genders above 20 years of age Patients with symptomatic cholelithiasisie recurrent pain in right hypochondrium radiating to right shoulder with gallstones on ultrasonography will be included in the study.

EXCLUSION CRITERIA:

Patients with previous upper abdominal surgery Patients with suspected biliary malignancy

Data Collection Procedure

Informed consent from patient was taken. The data was collected with the help of attached proforma (Annexure I). 3rd year post graduate resident of Radiology department performed the ultrasound of patient a day before the surgery after 6 hours of fasting and the findings were confirmed by senior registrar. The equipment used was Voluson 730 PRO V ultrasound machine having curved array probe with frequency of 3.5 MHz. Patients were examined in supine and left decubitus positions Thickness of

the gallbladder wall was measured orthogonally to the liver surface at the anterior wall adjacent to the liver. The upper limit of normal wall thickness would be 3 mm. The consultant surgeon performing the surgery provided information if there was need to convert planned laparoscopic cholecystectomy to open cholecystectomy in patients having increased gall bladder wall thickness on preoperative ultrasonography

Data Analysis Procedure

All the data was entered and analyzed by using SPSS version 10. For continuous variables like age and gallbladder wall thickness in millimetres mean with standard deviation were calculated. However for categorical variables (like gender and true positives) frequencies along with percentages were calculated. 2X2 table was constructed to calculate the sensitivity, specificity, positive predictive value, negative predictive value and accuracy.

Following parameters were determined for validation of the test:

1. Sensitivity $= \dfrac{\text{True Positive}}{\text{True Positives+False Negatives}} \times 100$

Equation 1: Formula for Sensitivity

2. Specificity $= \dfrac{\text{True Negative}}{\text{True Negatives+False Positives}} \times 100$

Equation 2: Formula for Specificity

3. Positive Predictive Value $= \dfrac{\text{True Positive}}{\text{True Positives+False Positives}} \times 100$

Equation 3: Formula for Positive Predictive Value

4. Negative Predictive Value $= \dfrac{\text{True Negative}}{\text{True Negatives+False Negatives}} \times 100$

Equation 4: Formula for Negative Predictive Value

5. Accuracy $= \dfrac{\text{True Positives+True Negatives}}{\text{True Positives+True Negatives+False Positives+False Negatives}} \times 100$

Equation 5: Formula for Accuracy

Results

DEMOGRAPHY OF THE SELECTED POPULATION
45 (41 %) patients were males with the mean age of 52.73 years ± 11.54 SD and 65 (59%) were females with mean age of 48.26 years ± 10.88 SD. Cumulative mean age was 50.1 years ± 11. 44 SD.

RESULTS OF ULTRASONOGRAPHY AND SURGERY
On pre-operative ultrasonography, there were 63.6% (n=70) of patients who showed gall bladder thickness of greater than 3 mm and 36.4% (n=40) showed thickness less than 3 mm (Tab. 1) During the laproscopic surgery, there were 6.4% (n=7) of patients

GB-THICKNESS	FREQUENCY	PERCENT
> 3 mm	70	63.6
< 3 mm	40	36.4
TOTAL	110	100.0

Table 1: Gall Bladder thickness measured on pre-operative ultrasonography

who required conversion to open surgery (Tab. 2) The results were analyzed by creating 2 x 2 contingency tables which displayed the numbers of subjects

OPEN SURGERY	FREQUENCY	PERCENT
CONVERSION +	7	6.4
CONVERSION -	103	93.6
TOTAL	110	100.0

Table 2: Percentage of patients converted to open surgery

who had gall bladder thickness > 3 mm and who were conversion positive (true positives), who had gall bladder thickness > 3 mm but were conversion nega-tive (false positives), who had gall bladder thickness < 3 mm and who were conversion positive (false negatives)andwho had gall bladder thickness < 3 mm and were also conversion negative (true negatives) The table allows us to see at a glance the proportion of true positives, false positives, true negatives and false negatives Our study results showed that in overall study population, 6 were true positives, 39 were true negatives, 64 were false

positives and 0 were false negatives. The diagnostic value of gall bladder thickness measured at pre-operative ultraso-nography was evaluated by measuring the following parameters:
1. Sensitivity (By using Equation1)
2. Specificity (By using Equation 2)
3. Positive Predictive Value (By using Equation 3)
4. Negative Predictive Value (By using Equation 4)
5. Accuracy (By using Equation 5)

For the validation purpose, we calculated four parameters; sensitivity, specificity, positive predictive value and negative predictive value for overall study population Our study results showed that sensitivity, specificity, positive predictive value, negative predictive value and accuracy of 85.71%, 37.86, 8.57%, 97.5% and 43.67% respectively. Results are shown in (Tab. 3).

GB Thickness	Conversion positive	Conversion negative	Total
> 3 mm	6 (True Positives)	64 (False Positives)	70
< 3 mm	1 (False Negatives)	39 (True Negatives)	40
Total	7	103	110

Table 3: Cross-tabulation of ultrasonography and surgical conversion results

Discussion

Gallstone disease is one of the most common and abdominal disorder. The third National Health and Nutrition Examination Survey estimated that 6.3 million men and 14.2 million women aged 20 to 74 in the United States had gallbladder disease.[12] Incidence of this disease from age of 21 years upto 90 years.[13] In Pakistan the estimated prevalence of gall stone disease is 5% which is responsible for 22% admissions in a surgical unit.[14] Prior to the availability of ultrasound, most studies relied on highly selective autopsy data and limited oral chole-cystography Laparoscopic cholecystectomy is considered the "gold standard" for the surgical treatment of gallstone disease. This procedure results in less postoperative pain, better cosmesis, shorter hospital stays and disability from work than open cholecystectomy.[15] However, the overall serious com-plication rate in laparoscopic cholecystectomy remains higher than that seen in open cholecystec-tomy.[16] Increased gall bladder wall thickness can cause conversion from laparoscopic to open cholecys-tectomy in 40.1% of patients.[17] Thus identifying increased gall bladder wall thickness on preoperative ultrasonography can predict difficulties during laparos-copic cholecystectomy and need to convert to open surgery. So on the basis of preoperative ultrasono-graphy surgeons would be aware of the potential problems during laparoscopic cholecystectomy and can maintain reasonable threshold of conversion if technical difficulties are faced.[18] It also helps in improving preoperative counselling and helps in increasing safety by limiting delay in conversion to open procedure; this may shorten duration of surgery and improves patient outcome.[19] The rationale of this study was to determine the predictive accuracy of pre-operative ultrasound which if found good, could be a recommended as a standard practice in preoperative evaluation of these patients in our settings as it is readily available, cost effective can give on spot results in patients of either gender with age > 20 years who had recurrent pain in right hypochondrium radiating to right shoulder with gallstones on ultrasonography.

Our results are in quite concordance with the already published data on the subject. Dinkel HP[20] assessed the value of sonography in predicting intraoperative difficulties for patients undergoing laparoscopic chole-cystectomy and in identifying indicators for conversion to conventional cholecystectomy. Upper abdominal sonography was performedin 75 consecutive patients before laparoscopic cholecystectomy. Sonographic findings were verified by the surgeon in the operating room. Their results showed that conversion from laparoscopic surgery to laparotomy was performed in five patients (6.7%). Of 75 patients, 19 had sono-grams revealing gallbladder wall thickening (> 4 mm); surgical preparation difficulties in 16 of these patients led to laparotomy in four patients. Sensitivity, speci-ficity, positive predictive value and accuracy of wall thickening as an indicator of technical difficulties were 66.7%, 94.1%, 84.2% and 85.3% respectively. Sensitivity, specificity, positive predictive value and accuracy of wall thickening as an indicator of surgical

conversion were 80.0%, 78.6%, 21.1% and 78.7% respectively.

Liu CL et al[21] in their study aimed to identify the risk factors predictive of conversion of laparoscopic cholecystectomy to open surgery in five hundred patients. Factors affecting conversion to open surgery were identified with statistical analysis. Their main outcome measure was conversion of laparoscopic cholecystectomy to open surgery for management of technical difficulties or intraoperative complications. They found that increased risk of conversion with statistical significance was found in patients with ultrasonographic findings of thickened gallbladder wall. They concluded that thickened gall bladder walls on preoperative ultrasonography along with other factors contributed to the possibility of conversion to open surgery.

Fried GM et al[22] in their single institutional study of 1,676 consecutive patients in whom LC was attempted and performed aimed to predict conversion to OC Factors evaluated were age, sex, history of acute cholecystitis, pancreatitis, or jaundice, previous abdominal surgery, abnormalities of liver function tests, thickened gallbladder wall identified by preoperative ultrasound. They found that conversion to OC was required in 90 of 1,676 (5.4%) patients. One of the significant preoperative predictors of conversion was thickened gallbladder wall found by ultrasound.

Rosen M[23] et al in their retrospective analysis on total of 1,347 laparoscopic cholecystectomies performed at the Cleveland Clinic Foundation from January 1996 to January 2000 aimed to identify risk factors that may predict conversion from a laparoscopic to an open procedure. A total of 34 parameters including patient demographics, clinical history, laboratory data, ultrasound results, and intraoperative details were analyzed. Stepwise, multivariate logistic regression was used to determine those variables predicting conversion of laparoscopic cholecystectomy. They found that seventy one (5.3%) laparoscopic cholecystectomies required conversion. Multivariate analysis revealed that for all cases showed a gallbladder wall thickness > 0.4 cm (7.2 OR, P < 0.001) predicted conversion to open cholecystectomy. They concluded that along with other factors a thickened gallbladder wall is also an independent predictor with regards to the probability of conversion to an open procedure.

Daradkeh SSet al[24] carried out a prospective study to investigate the value of preoperative ultrasound findings for predicting difficulties encountered during laparoscopic cholecystectomy. They recruited 160 consecutive patients with symptomatic gallbladder disease (130 females, 30 males) referred to the Jordan University Hospital. All patients underwent detailed ultrasound examination 24 hours prior to LC. The overall difficulty score (ODS), as a dependent variable, was based on the following operative parameters: duration of surgery, bleeding, dissection of Calot's triangle, dissection of gallbladder wall, adhesions, spillage of bile, spillage of stone, and difficulty of gallbladder extraction. Multiple regression analysis was used to assess the significance of the following preoperative ultrasound variables (independent) for predicting the variation in the ODS: size of the GB, number of GB stones, size of stones, location of GB stones, thickness of GB wall, common bile duct (CBD) diameter, and liver size. They found that only thickness of GB wall and CBD diameter were found to be significant predictors of the variation in the ODS (adjusted R2 = 0.25). They concluded that preoperative ultrasound examination is of value for predicting difficulties encountered during LC, but it is not the sole predictor.

Kama NA[25] in his study prospectively analyzed 1,000 laparoscopic cholecystectomies from March 1992 to July 1999. The patients studied included 804 women (80.4%) and 196 men (19.6%) with a mean age of 43.8 years (range, 30-80 years). From the data collected, only factors available to the surgeon preoperatively were considered for analysis. These factors included age, gender, history of acute cholecystitis, jaundice or pancreatitis, previous abdominal surgery, obesity and concomitant disease, white blood cell (WBC) count, preoperative liver function tests, ultrasound findings of the gallbladder, preoperative endoscopic retrograde cholangiopancreatography (ERCP), and suspicion of common bile duct stones. They found that of the 1,000 patients in whom laparoscopic cholecystectomy was attempted, 48 (4.8%) required conversion to open surgery. Thickened gallbladder wall on preoperative ultrasonography was found to be an independent predictive factor for conversion to open surgery.

Santambrogio R[26] et al evaluated ultrasound findings as predictors of potential operative difficulties and

complications during laparoscopic cholecystectomy (LC). From October 1993 to June 1995 a total of 143 patients with symptomatic cholelithiasis (50 males, 93 females, mean age 49.5 ± 15 years) were evaluated by ultrasound (US) the day before LC. The US examination assessed six parameters: gallbladder (GB) volume, GB wall thickness, GB neck position, GB stone mobility, stone maximum size, and GB adhesions. On the basis of these US findings, a predictive judgment of technical difficulties was expressed by degree: easy, difficult, and very difficult. Altogether 101 patients presented with uncomplicated symptomatic cholelithiasis, and 42 had acute cholecystitis. The operation was predicted to be easy in 38% of cases, difficult in 49%, and very difficult in 13% with a good correlation with the surgeon's intraoperative judgment (r = 0.66). A significant association was found between US findings and intraoperative difficulties. Their results suggested that preoperative US is a useful screening test for patients undergoing LC, and it can help predict technical difficulties.

Conclusions

Thickened gall bladder walls on preoperative ultrasonography can predict the possibility of conversion of planned laproscopic cholecystectomy to open surgery with a sensitivity, specificity, positive predictive value, negative predictive value and accuracy of 85.71%, 37.86%, 8.57%, 97.5% and 43.67% respectively. However, further large scale studies are needed for its validation and its use in routine clinical practice.

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