COMPARISON OF ULTRASONOGRAPHY FINDINGS WITH INTRAOPERATIVE FINDINGS IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY FOR GALL STONE DISEASE

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METHODOLOGY

Study Design

A hospital based observational cross-sectional study conducted to compare preoperative USG with intraoperative findings in LC for gallstone disease. The study was conducted in Department of General Surgery in Nepal Medical College and Teaching Hospital, Jorpati, Kathmandu (NMCTH) from September 2021 to August 2022, a one year period.

Sampling Design

Sampling Technique

A consecutive sampling technique was applied.

Sample Size

To select the appropriate sample size, a prevalence of 10 % of cholelithiasis[29] was taken at a confidence interval of 95% (Z = 1.96), and a precision (d) of 6%. Based on these calculations, the sample size obtained was 96.

Prevalence of cholelithiasis worldwide[29]: 10% -15%

Prevalence of cholelithiasis in USA[17]: 6%-9%

Prevalence of cholelithiasis in Brazil[34]: 1.29%

Prevalence of cholelithiasis in standard textbooks like Sabiston's Textbook of Surgery 21st edition[5] and Schwartz's Principles of Surgery 11th edition[6]: 10% -15%

We obtained the sample size using the following formula:

For large population (infinite population)

$$n = \frac{z^2 pq}{d^2} = 3.84*0.10*0.90/ (0.06*0.06) = 96$$

n = Sample size

$Z^2 = 1.96*1.96 = 3.84$

p = Prevalence value = 10% = 0.10

q = 1-p = 1-0.10 = 0.90

d = desirable error or precision level (5% to 10%) = 6% = 0.06 (pre-set value)

To prevent loss in follow-up, 10% was added to the above calculated sample size

Total sample size = 96 + 10% of 96 = 105.6 = 106

Hence the minimum sample size was 106 patients.

Inclusion Criteria

1. All patients with findings of gallstone disease in USG who underwent LC.

Exclusion Criteria

1. Patient refused to participate.
2. Suspected or histological diagnosis of gallbladder carcinoma.
3. All patients with dilated CBD and stones in CBD.

Ethical Consideration:

All patients enrolled in the study were explained about the enrollment, and verbal and written consent were obtained from the patient. Patients were counseled about the strict confidentiality that would be maintained throughout their participation in this study, and that their name would not be disclosed in the proforma or after the completion of study until voluntarily disclosed by the patient. Ethical approval was obtained from the Institutional Review Committee (IRC) of Nepal Medical College and Teaching Hospital. The reference is ThesisProp 35-078/79. All precautions were taken so as not to harm the patients during the study and standard protocol of the department was never breached.

Data Collection Tools and Technique

The primary sample data was collected by filling a preformed proforma developed after a thorough research of literature and based on the objectives of the study and the study variables.

Study Procedure

Consent

After obtaining ethical clearance from the IRC, those patients that fulfil the inclusion criteria were offered detailed printed information about the proposed study. Patients agreeing to take part in the study were requested to sign the consent form. After signing the consent, the patient were recruited to the study. There was no discrimination of sex, race, religion and geography.

Preoperative data collection

Preliminary diagnosis was based on clinical suspicions and patients were sent for imaging study by USG. USG was performed by a single specialist consultant radiologist. XARIO100 ultrasound scan, made by TOSHIBA, with a 3.5MHz convex probe was used for imaging studies. USG was used to comment on GB appearance of whether normal or distended or contracted, GB wall thickness of more than 3cm or less, number of stones either single or multiple. Size of largest stone in cm, location of stone within GB, mobility of stone with respect to change in position and presence or absence of pericholecystic fluid were mentioned. Size of CBD and stones in CBD was also mentioned. All of these data were filled in the proforma at the same time.

Intraoperative data collection

After obtaining appropriate laboratory investigations patients were electively planned for LC. Following which all patients underwent a standard four port LC. All LCs was performed by a team of single surgical unit to maintain uniformity throughout the study process. The standard ports were the infraumbilical camera port of 10mm made with Hasson's method and the remaining 3 ports made under direct vision. A 30° viewing laparoscope with camera was used as the standard viewing scope.

After all the ports were made, anatomy of GB was studied. GB anatomy, status of CBD and adhesions were recorded in proforma. After dissection had started, anatomic variations of Calot's triangle were noted down. Operating times were recorded at three stages: from port entry to achievement of Critical view of safety, from achievement of critical view to dissecting GB out of fossa and from dissection of GB out of fossa to the removal of GB and closure of ports. Intraoperative finding of bleeding, bile leakage and total duration of surgery was recorded in the proforma. After removal of GB, it was cut open and we measured the maximum thickness of the gallbladder wall by a caliper adjusted to a standard ruler. The number of stones whether single or multiple was checked and the size of largest stone was measured by the same caliper. All of these findings were noted in the proforma under the supervision of the same operating surgeon.

Postoperative data collection

After surgery patients were kept in a postoperative ward. Their postoperative events until discharge from hospital was filled in relevant sections of the proforma and length of hospital stay was recorded. Patients were asked to follow-up with histopathology reports. Reports that did not show GB carcinoma were considered as study sample and their data was included in study. All of these data were finally analyzed when adequate sample size was met.

Data Management and Analysis Technique

Data Processing

Data collected on a hard copy proforma was regularly entered in Microsoft excel sheet and into IBM- Statistical Package for the Social Sciences (SPSS) version 16.0 respectively. Classification and tabulation of data were done to make analysis further easier.

Data Analysis and representation

Continuous variables are expressed as the mean value + or - standard deviation (SD) and range, while categorical variables are expressed as proportions. We used chi-square test and Fisher's exact test for analysis of categorical data and parametric tests (independent t-test) for continuous data depending upon the sample size distribution.[34] All data showing p value of less

than 0.05 ($p<0.05$) was considered significant. The data, after analysis, was reported with descriptive statistics, with all data reported as mean $\pm$ SD. Various frequency tables, charts, graphs, trends, plots and bar diagrams were used to present the data.

Validity and reliability

For reliability of study extensive literature review was done and standard tools (proforma) was adopted. Data entry was done regularly for each patient. Single radiologist was used for every USG. At the same time, single unit with two experienced surgeons were taken for intraoperative findings. The researcher himself was actively involved in data collection and intervention. This was further regularly assessed by investigator and on-duty doctors.

Terminology:

Intraoperative dilated CBD: subjectively decided by the operating surgeon at the time

Length of hospital stay: calculated as day of admission to day of discharge, day of admission was considered as day 1 and 12 AM was the defining period for beginning of another day

Bleeding: any amount of blood loss requiring blood transfusion was considered as heavy bleeding

INFORMED CONSENT FORM

I…….……..Age/Sex……... resident of .....give my consent for my participation in the research study on "**COMPARISON OF ULTRASONOGRAPHY FINDINGS WITH INTRAOPERATIVE FINDINGS IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY FOR GALL STONE DISEASE"** being performed by Dr. Bineet Thapa. I have been well explained about the details of research study and am fully aware of the practicalities of this research.

This is my voluntary participation and I understand that I can quit anytime with my own wish without any questions being asked. I have no objection in getting myself enrolled in the study.

Name of Participant: Witness Dr.:

Signature: Signature:

Date:

Finger print:

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