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1	Cystic Lymph Node Identification is More Reliable
2	Than Critical View of Safety in Difficult
3	Cholecystectomies
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42 43	design, collected data and edited manuscript, AP Wysocki contributed to concept, study design and editing, Z Ahmed analysed data and edited, and IC Gil edited manuscript
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44 Abstract

45

46 **Background:** The cystic lymph node (CLN) represents an anatomical safety marker and a

- 47 surrogate marker of technique during laparoscopic cholecystectomy (LC). We aim to
- 48 demonstrate the value of CLN in comparison to the critical view of safety (CVS) and study
- 49 the effects of increasing difficulty on the two approaches.
- 50
- 51 Methods: A prospective study of consecutive LC was conducted. Patient demographics, type
- 52 of admission, clinical presentation, operative difficulty grade, visualisation of CLN,
- 53 identification of CVS, operative time and complications were recorded and analysed.
- 54
- 55 **Results:** Of 393 LCs, half of the admissions were emergencies. 34% had obstructive jaundice
- 56 or acute cholecystitis. The CLN was visually identified in 81.7% with a small difference
- 57 between operative difficulty grades 1 to 3 versus 4 to 5. Although CVS was unachievable in
- 58 62 patients, 43 (69.4%) still had an identifiable CLN. The median operating time was 68
- 59 minutes with one mortality but no conversions or intraoperative complications.
- 60 **Conclusion:** Identifying the CLN during LC could compliment the CVS in avoiding major
- 61 ductal injury. Dissecting lateral to the CLN to commence the process of displaying the cystic
- 62 pedicle structures may be a strategy in safely achieving the CVS. During the more difficult
- 63 LC where displaying the CVS is impossible, the CLN may be the key anatomical landmark.

64 Introduction

- 65
- 66 The cholecystohepatic triangle, routinely referred to as Calot's triangle, refers to a tiny
- 67 anatomical region⁽¹⁾ of disproportionately high surgical importance during laparoscopic
- 68 cholecystectomy (LC). It was first described in 1891 by the French surgeon Jean-François
- 69 Calot as part of his thesis. He emphasised the identification of the borders of this triangle
- before any ligation or division of the exposed structures^(2, 3). In 1981, Rocko et al⁽⁴⁾ modified
- the borders of the triangle where the superior border was bounded by the inferior surface of
- the liver instead of the cystic artery as described by Calot. In current practice, when
- performing LC, many surgeons rely on target identification through displaying the critical
 view of safety (CVS)⁽⁵⁾. The CVS was first described by Strasberg in 1995, and re-written in
- 75 2010 applying the concept to LC. This simplified concept requires the identification of two
- and only two structures (cystic artery and duct) entering the gallbladder, opening a window
- between the gallbladder and lower third of the cystic plate and clearing all connective tissue
- in this area. However, it has been suggested that one third of the patients will have three
- 79 structures in Calot's triangle⁽⁶⁾.
- 80
- 81 Major bile duct injury (BDI) occurs in around 0.3 to 0.5% of LC and is a cause of major
- 82 morbidity and mortality. The recognition and identification of anatomical landmarks (e.g.
- 83 Rouviere's sulcus, quadrate lobe) during dissection is thought to reduce the risk of BDI.
- 84 Some surgeons employ operative imaging (e.g. intraoperative cholangiography or
- 85 laparoscopic ultrasound) to demonstrate biliary anatomy.
- 86

87 The cystic lymph node (CLN), also known as Calot's node, Lund's node or Mascagni's

- 88 lymph node, has been described as a content of the Calot's triangle^(2, 3, 7). Several studies ⁽⁸⁻¹²⁾
- have demonstrated that it is commonly found near the cystic artery. It was, therefore,
- 90 suggested that using CLN identification and ensuring all dissection is performed lateral to
- 91 this may reduce the risk of BDI. A lot remains unknown about this innocent lymph node,
- 92 namely whether it is uniformly present, can be identified during every cholecystectomy $^{(10, 11, 13)}$
- 93 ¹³⁾, and the frequency of multiple nodes.
- 94

95 We aim to evaluate the use of CLN as a safety marker, in addition to or instead of the CVS.

- We compared the efficacy of identification of CLN and CVS and evaluated the relationship
 between CLN identification, the operative difficulty of LC and the ability to demonstrate the
- 98 CVS.
- 99
- 100

101 Methods

- 102
- 103 Design:
- 104 A prospective study of consecutive patients undergoing LCs was conducted. We aimed to
- 105 identify and record the presence of CLN at the start of every procedure and the dissection of
- 106 the cystic pedicle lateral to the node, thus avoiding its excision. All cholecystectomies were
- 107 performed by a single surgeon (AHMN) or trainees under his direct on table supervision.
- 108
- 109 Patient demographics, type of admission, reason for admission, American Society of
- 110 Anaesthesiologists (ASA) physical status classification, operative difficulty grade, presence
- 111 of CLN, identification of CVS, operative time, conversion to open and pedicle-related and
- 112 perioperative complications were recorded prospectively. The operative difficulty grade was 112 based on the expended Nesser Scale^(14, 15) using a combination of features of the unit of the second second</sup>
- 113 based on the expanded Nassar Scale^(14, 15) using a combination of features of the gallbladder,

adhesions and cystic pedicle to classify LC into five grades: I-V ie. easy, normal, difficult,

- 115 very hard and complex. The senior author's biliary firm is dedicated to managing biliary
- 116 emergencies and receives great majority of patients admitted with gallstone complications
- 117 including those with suspected bile duct stones.
- 118
- 119 Technique:

120 A standard 4 port LC (one infraumbilical12mm by open access and three 5mm ports) was 121 performed with the patient in the supine position. Dissection of the cystic pedicle aimed to

- 122 display the CVS when possible. Dissection was carried out using a "duck-bill" dissector,
- 123 with swab or hydrosuction being used occasionally when a difficult pedicle is encountered
- 124 due to inflammation, impacted stones or other factors. Diathermy hooks were not a
- 125 component of dissection in any case. The CLN(s) was identified visually before or after
 126 opening the peritoneum between the gallbladder and liver (Figure 1). CLN appears as a
- 127 discrete shiny oval swelling immediately under the peritoneum. It is friable and becomes
- 128 haemorrhagic with minimal handling. There is variability in lymph node size but it is usually
- 129 solitary (duplicated CLN is shown in Figure 2). The CLN may be tiny or not identifiable
- 130 within the fibrofatty tissue of the hepatobiliary triangle. The subsequent dissection was
- 131 carried out lateral to the CLN, identifying and later ligating the cystic artery close to the
- gallbladder wall and sparing the node whenever possible. It was occasionally necessary to
- remove an enlarged CLN in order to secure the cystic artery as close to the gallbladder wall
- as possible. After displaying the CVS (Figure 2), the gallbladder neck was ligated as it joined
- the cystic duct with 2/0 absorbable suture. Endoclips were not used to secure the structures of the cystic pedicle in this unit. Intraoperative cholangiography was performed routinely
- 137 through a cystic duct incision using a size 5 French ureteric catheter within a
- 138 cholangiography cannula/clamp⁽¹⁶⁾ Patients who had common bile duct stones underwent
- 139 laparoscopic bile duct exploration either transcystically or via choledochotomy.
- 140
- 141 Informed consent was obtained from all patients with specific emphasis on the specialisation
- 142 of the unit with regard to the management of suspected bile duct stones. IRB approval was
- 143 not required as the management protocols were consistent with the recommendations of
- 144 national and international societies.
- 145
- 146
- 147 Statistics:
- 148 Continuous variables were evaluated using means and standard deviations and categorical
- 149 variables were analysed using frequencies and percentage. Chi Square test was performed on
- 150 categorical variables and student's t-test on continuous variables. In addition, logistic
- regression models for the predictors of achieving CVS and CLN identification were then
- 152 developed. All analyses were performed using stata version 16 software (StataCorp.
- 153 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC).
- 154

155 **Results**

- 156
- 157 393 patients underwent LCs between June 2018 and December 2019. The male to female
- ratio was 1:2.1 and the median age was 51 years. The split between elective and emergency
- 159 was essentially half (51% elective and 49 % emergency). The most common cause of
- 160 emergency admission was acute biliary pain (44.8%) followed by obstructive jaundice 161 (22.0%) source abala matrix (2.0\%) and (44.8%) followed by obstructive jaundice
- 161 (23.9%), acute cholecystitis (9.9%) and acute pancreatitis (7.9%)
- 162

- 163 The majority of the LCs in this series (n=314; 79.9%) were straightforward, while 20.1% 164 were classified as grades IV and V, reflecting the nature of referrals and workload of the unit. 165 The CLN was visually identified in 321 LC (81.7%) while in 72 cases (18.3%) the node was 166 not seen. The comparison of characteristics between operation where the CLN was identified 167 168 and not identified are shown in Table1. 169 170 The admission diagnosis did not affect the rate of CLN identification. Body Mass Index 171 above or below 30kg/m^2 did not affect the rate of CLN identification (p=0.206). The CVS 172 was achieved in 84.2% of the LC but did not affect the rate of CLN identification (p = 0.826). 173 Operative difficulty grades IV and V vs I to III demonstrated a trend towards a lower rate of 174 CLN identification (OR 0.75; 95% CI 0.50 –1.11). Fundus first dissection was performed in 175 16 LC (4.1%) and this also showed a trend towards a lower rate of CLN identification (43.8%) 176 vs 83.3%; p=0.161). 177 178 CLN was identified in 64.6% of the most difficult Grades IV and V LC. However, we were 179 able to visualise the CLN and use it as a guide to starting the cystic pedicle dissection in 180 69.4% of LC where the CVS was impossible to achieve. On the other hand only 30% of LC 181 with failed CVS also failed positive CLN identification, prompting the utilisation of 182 alternative approaches e.g fundus first dissection. 183 184 The median operating time in the whole series was 68 minutes. In patients with no CLN 185 identified, the median operative time was longer (90 min). The perioperative complication 186 rate was 4.4% (n=14) when CLN was identified vs 11.1% (n=8) with no CLN identification 187 (p=0.024).188 189 There were no operative complications related to pedicle dissection apart from one post 190 cholecystectomy bile leak (empyema of the gallbladder), contained by the subhepatic drain, 191 which ceased spontaneously within few days. In a few instances, special haemostatic 192 measures to the gallbladder bed were required e.g haemostatic gauze or foam. The source of 193 bleeding was not the cystic artery or its branches in any of these cholecystectomies. 194 195 The post operative median hospital stay was 1 day (range 0-20 days). However, as 50% of all 196 cases were emergency admissions and 77.4% were initially admitted to departments or firms 197 before they were referred to the biliary service, the median total length of hospital stay (from 198 day of admission to other team or specialty to discharge date) was 4 days (range 1- 46 days). 199 The perioperative complication rate was 5.6% (n=22), including twelve 30-day readmissions 200 (3.1%) with various symptoms. There were five reinterventions in this series: one 201 percutaneous drainage of an abdominal collection, two Endoscopic Retrograde 202 Cholangiopancreatography (ERCP) for retained stones following transcystic exploration, one 203 relaparoscopy to retrieve a retracted T-tube and one laparotomy for total small bowel 204 infarction (after uneventful LC) resulting in death. 205 206 There were no bile duct injuries or conversions to open in this series. Table 2 shows 207 postoperative complications, readmissions and their management. 208 209 210 Discussion
- 211

- 212 The CLN was identified in 4 out of 5 (81.7%) consecutive LC in this prospective single
- 213 surgeon series. The CVS was achievable with similar frequency (84.2%). Operative difficulty
- 214 grades IV and V and the need for fundus first dissection showed a trend towards a lower rate
- 215 of CLN identification (OR 0.75 and OR 0.53 respectively) suggesting a correlation between
- 216 increasing difficulty and the inability to identify CLN.
- 217

218 Displaying the CVS is widely recognised as the most important strategy of target

- 219 identification despite the lack of level 1 evidence. CVS represents the end point of dissection 220 and little emphasis has been placed on the technical details of how the surgeon should get to
- 221 this end point. Identification of CLN and dissection lateral to it is not a widely recognised
- 222 aspect of safe cholecystectomy. This could be due to lack of awareness or consistency of the presence of the lymph node as found by some. Torres et al⁽¹³⁾ identified 63.6% of CLN in
- 223 their 88 LC while Qamar et al⁽¹¹⁾ found 53.3% of CLN in their cohort of 300 LC. In our 224
- prospective series, the rate of CLN was much higher at 81.7%, possibly because the surgeon 225
- 226 actively looked for the node. Exposing and dividing the lateral lymphatic pedicle is usually
- 227 sufficient to display the underlying cystic artery because the node drops away. The entire CLN need not be dissected out as this is likely to result in its fracture and haemorrhage.
- 228 229
- A few $^{(8-12, 17)}$ have documented the relationship between CLN and the cystic artery. In a 230 study of 40 cadavers, Sonali et al⁽¹⁷⁾ found CLN in Calot's triangle along the cystic artery. 231 Qamar et al⁽¹¹⁾ found 59.4% of CLN were placed anterior-superior to the cystic artery and 232 40.6% were posterior-superior to the artery. Suzuki et al⁽¹⁸⁾ have shown a variety of cystic 233 234 artery patterns which could lead to injury and haemorrhage if the anatomical variant was not 235 recognised. The fixed relationship of CLN to the cystic artery is thus a useful landmark to the 236 artery location which may be especially useful if CVS is difficult to display.
- 237

The concept of identifying the CLN has been previously recommended ⁽⁸⁻¹²⁾ as a landmark to 238 help in displaying the CVS. Ferzli et al⁽⁸⁾ reviewed their dataset of 907 LC and found no bile 239 240 duct injury when they used the identification of CLN as an additional method. However the frequency of CLN identification was not reported in that paper. Kunasani et al⁽⁹⁾, Channa et 241 al⁽¹⁰⁾ and Singh et al⁽¹²⁾ also proposed keeping the dissection lateral to the CLN to avoid bile 242 243 duct injury.

244

Nawar⁽¹⁹⁾ has suggested an "artery first technique" as a modified infundibular approach 245 246 where the cystic artery is identified as it penetrates the gallbladder wall. In his series of 502 247 LC, this was recommended as being safer than the simple infundibular technique, although 248 that study did not mention the presence of CLN. Being aware of the fixed anatomical 249 relationship of CLN to its artery is a useful means of identifying the artery. The prevention of 250 arterial injury and bleeding is important. The author reported such an event in two cases 251 (0.4%) with one requiring Pringle manoeuvre to control the bleeding. However, care must be 252 taken when pursuing cystic artery dissection without achieving a complete CVS, due to the 253 risk of injury to posterior sectoral bile ducts or subvesical bile ducts, causing major bile leaks, 254 as reported by the author in 2 patients.

- 255
- 256 Guidelines suggest various approaches to performing a safe cholecystectomy in order to
- 257 minimize the rate of BDI. The Society of American Gastrointestinal and Endoscopic
- Surgeons (SAGES) proposed 6 strategies in their SAGES Safe Cholecystectomy Program⁽²⁰⁾, 258
- 259 'strategies for minimizing bile duct injuries: Adopting a universal culture of safety in
- cholecystectomy' (https://www.sages.org/safe-cholecystectomy-program). Connor et al⁽²¹⁾ 260 proposed a standardized 5-step method for safe laparoscopic cholecystectomy that includes 261

- 262 dissection close to the gallbladder and lateral to the CLN in order to display the CVS.
- 263 However, CLN identification was not specifically included in their 5-step final intraoperative
- 264 checklist. On the other hand, a few studies addressed the need for either excision or sparing
- of CLN in benign cholecystectomies. Habib et al⁽²²⁾ published their technique for widely opening Calot's triangle and described the excision of CLN as one of their steps in the
- 266 opening Calot's triangle and described the excision of CLN as one of their steps in the 267 dissection of cystic duct and artery. There were no bile duct injuries in their 220
- 268 cholecystectomies.
- 269
- 270 Nonetheless, the need for CLN excision in benign cases is not well established. Wysocki et 271 al⁽²³⁾ reviewed 1332 LC performed by a single surgeon and reported that only 10.4% of LC pathology specimens included the CLN irrespective of disease severity or surgical difficulty. 272 In another study published a year later by Wysocki et al⁽²⁴⁾, 2332 LCs performed by 27 273 surgeons in a single hospital were reviewed. A mean of 18.7% CLN were found in LC 274 275 pathology specimens with wide inter-surgeon variability around the mean of 18.7%: 0% (six 276 surgeons who together performed 59/2332 LCs) to 50.0% (one surgeon who performed 277 7/2332 LCs). The rate of spared CLN is thus very similar to the present series, although we 278 did not rely on histological confirmation of excision. The excision of CLN was therefore proposed as a surrogate marker of technique independent of disease severity and of operative difficulty on the Nassar Scale^(14, 15). Table 1 shows a trend towards a lower rate of CLN 279 280 281 identification with increasing operative difficulty (64.6% in grades IV & V vs 86.0% in 282 grades I-III; p=0.147) perhaps indicating that sometimes the node is shrunken/ fibrotic and 283 thus difficult to identify.
- 284

285 There seems to be a complimentary relationship between CLN and CVS. In this study,

- 286 positive identification of the CLN was possible in 43 (69.3%) of 62 LC where displaying the
- 287 CVS was unsuccessful. As CLN identification guides the commencement and progress of the
- dissection and displays the structures of the cystic pedicle, its adoption as a safety strategy
- during complex cholecystectomies is more reliable than the CVS. As the CVS is essentially the conclusion of a process of dissection it is more likely to be subject to the risk of
- 290 the conclusion of a process of dissection it is more likely to be subject to the risk of 291 complications before that conclusion is reached. In our study no incidents were recorded and
- the procedures were safely completed when the CVS was impossible to display, confirming
- the usefulness of CLN identification.
- 294 The multi-society consensus conference on preventing bile duct injury identified no direct
- comparative evidence to support the CVS over other methods for anatomic identification ⁽²⁵⁾.
- 296 The description of CVS does not address how and where to start and advance the dissection
- in order to achieve this end point. It would be inconceivable for injuries of the main bile ducts
- 298 to occur after displaying the $\text{CVS}^{(26)}$.
- 299
- There are limitations in our study. The data is based on a large series performed by a single surgeon with more than 30 years experience and a large biliary emergency workload.
- 302 However, the dataset also includes cases done by trainees performing the procedures under
- 303 direct supervision. Histological confirmation of CLN non-excision was not pursued. A
- 304 prospective multicentre study with a more traditional mix of diagnoses and with the
- 305 procedures performed by surgeons with a wider range of experience in biliary surgery is
- needed and can be easily conducted. The results may encourage more surgeons to apply the
- 307 concept of CLN identification to their practice, increasing the safety of LC.
- 308
- 309 Conclusion
- 310

- 311 The identification of CLN during LC can help minimize the rate of major bile duct injury.
- 312 This prospective study demonstrated the value of CLN in facilitating safe dissection and
- 313 completion of LC in a significant percentage of cases (69.4%) where the CVS was impossible
- to achieve. Using the CLN as a guide to commencing and progressing cystic pedicle
- 315 dissection during complex cholecystectomies may be a more helpful strategy than the end
- 316 point of attaining CVS.
- 317

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- 373
- 374

Characteristic	Number (%)	CLN identified (n=321)	CLN not identified (n=72)	p value	Odds Ratio (95% CI)
Admission diagnoses*					
Chronic biliary colic	192 (48.9%)	161 (50.2%)	31 (43.1%)	-	1
Acute biliary pain	176 (44.8%)	139 (43.3%)	37 (51.4%)	0.701	0.94 (0.69 – 1.28)
Obstructive jaundice	94 (23.9%)	74 (23.1%)	20 (27.8%)	0.738	$\begin{array}{c} (0.05 - 1.26) \\ 0.94 \\ (0.65 - 1.36) \end{array}$
Acute pancreatitis	31 (7.9%)	26 (8.1%)	5 (6.9%)	0.999	$ \begin{array}{c} (0.00 - 1.00) \\ 1.00 \\ (0.57 - 1.75) \end{array} $
Acute cholecystitis	39 (9.9%)	33 (10.3%)	6 (8.3%)	0.972	1.00 (0.61–1.68)
Acute cholangitis	9 (2.3%)	7 (2.18%)	2 (2.78%)	0.884	0.93 (0.34–2.55)
Type of presentation					
Emergency	193 (49%)	155 (48.3%)	38 (52.3%)	0.827	0.97 (0.72 – 1.30)
Elective	200 (51%)	166 (51.7%)	34 (47.2%)	-	1
Body Mass Index					
≤ 30	284 (72.3%)	218 (76.8%)	66 (23.2%)	-	1
> 30	109 (27.7%)	103 (94.5%)	6 (5.5%)	0.206	1.23 (0.89 – 1.70)
Operative difficulty grade (I/II/III v IV/V)					
I/II/III	314 (79.9%)	270 (86.0%)	44 (14%)	-	1
IV/V	79 (20.1%)	51 (64.6%)	28 (35.4%)	0.147	0.75 (0.50 – 1.11)
Critical view of safety identified					
Yes	331 (84.2%)	278 (84.0%)	53 (16.0%)	-	1
No	62 (15.8%)	43 (69.4%)	19 (30.6%)	0.826	0.83 (0.54 – 1.26)
Fundus first dissection					
Yes	16 (4.1%)	7 (43.8%)	9 (56.3%)	0.161	0.53 (0.21 – 1.30)
No	377 (95.9%)	314 (83.3%)	63 (16.7%)	-	1
Operative time median (SD) min	68 (43)	64 (37)	90 (57)	< 0.001	0.99 (0.98- 0.99)

 Table 1: Preoperative data and operative parameters.

 *Acute pain was recorded alone or in addition to another primary diagnosis

Causes	Number n= 22 (5.6%)	Management	Clavien Dindo Classification
Post operative			
complications			
Urinary retention	1	Urinary catheterisation	G1
Chest infection	2	IV antibiotic	G2
Post operative jaundice	1	Conservative management, MRCP showeed no retained stone, settled spontaneously	G1
Retained stone	1	Retained stone requiring ERCP for bile duct clearance	G3a
Bile leak	1	Transient, settled spontaneously	G1
Post operative anaemia	1	Blood transfusion	G2
Retracted T- tube	1	Relaparoscopy to remove T- tube	G3b
Bowel ischemia	1	Laparotomy. Total mesenteric infarction	G5
Pyrexial	1	Radiology investigations normal, self resolved.	G1
30 day readmission			
Nausea and vomiting	1	Conservative management, self resolved	G1
Chest infection	1	IV antibiotic	G2
Umbilical port haematoma	1	Conservative management, self resolved	G1
Non specific abdominal pain	2	Conservative management, self resolved	G1
Diarrhoea causing acute kidney injury	1	Conservative management, self resolved	G1
Retained stone	1	Retained stone requiring ERCP for bile duct clearance	G3a
Abdominal collection	2	 Conservative management, self resolved Radiologically guided percutaneous drainage 	G1, G3a
Post operative persistent pancreatitis	3 Conservative management, self resolved		G1

Table 2: Post operative complications and 30 day readmission and management. (MRCP: Magnetic Resonance Cholangiopancreatography, ERCP: Endoscopic Retrograde Cholangiopancreatography) Figure 1: Early identification of cystic lymph node.

Figure 2: Demonstration of critical view of safety and shows cystic artery ligation between 2 lymph nodes.