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2

3 **TITLE:** Clinical value of elevated gamma glutamyl transferase and/or alkaline
4 phosphatase in non-jaundiced symptomatic gallstone disease

5

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EARLY VIEW

65 **ABSTRACT**

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67 **Aims**

68 To evaluate the importance of elevated gamma glutamyl transferase (GGT) and
69 alkaline phosphatase (ALP) as predictor factors for choledocholithiasis in non-
70 jaundiced symptomatic gallstone disease.

71

72 **Methods**

73 This study was carried out in the Department of General Surgery, Zagazig University
74 Hospitals in the period between February 2016 and February 2017. This study was
75 carried out upon 20 patients diagnosed as symptomatic cholecystitis and met the
76 inclusion criteria i.e. elevated GGT and/or ALP levels with normal bilirubin level and
77 normal common bile duct (CBD) by ultrasonography.

78

79 **Results**

80 We found that 20 diagnosed cases of symptomatic gallstone disease in the study
81 and they were predominantly females (80%). In pre-operative liver function tests,
82 serum bilirubin was normal and ranged from 0.1 to 1 mg/dl. All cases had GGT level
83 above 60 IU/L and ranged from 82 to 609 IU/L with mean standard deviation was
84 (mean \pm SD: 298.3 \pm 184.08 IU/L). ALP level ranged from 57 to 520 IU/L with mean
85 standard deviation was (mean \pm SD: 210.9 \pm 132.82 IU/L) and 30% of these cases
86 had normal level (\leq 130 IU/L). Magnetic resonance cholangiopancreatography
87 (MRCP) was done for all the cases of the study. 85% of the cases were normal and
88 15% of the cases were narrow. Statistically, there was highly significant difference
89 decreasing in GGT and ALP levels among post-operative ($p < 0.001$).

90

91 **Conclusion**

92 GGT and ALP are sensitive but not specific to choledocholithiasis because of their
93 multiple sources. The value of their estimation pre-operatively is that their elevation
94 increase the suspicious of CBD stone or pathology. Their elevation provoke the
95 surgeon to assess the state of CBD by more accurate diagnostic tool as MRCP.
96 Most of cases (85%) with elevated GGT and/or ALP but with normal bilirubin and

97 ultrasound findings of CBD had no stones at CBD at time of their evaluation. But the
98 small sector (15%) had pathology indicated intervention by endoscopic retrograde
99 cholangiopancreatography (ERCP) and if neglected before laparoscopic
100 cholecystectomy, there would be morbidity on the patient.

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102 **Keywords:**Gamma-glutamyl transferase, Akaline phosphatase, Gallstones

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EARLY VIEW

129 INTRODUCTION

130 The majority of patients with gallstones are asymptomatic. Acute cholecystitis occurs
131 when the cystic duct becomes obstructed by a gallstone, leading to unresolving right
132 upper quadrant pain, nausea, vomiting, anorexia, and fever [1]. Patients with
133 gallstones undergo ultrasonography examination and hepatobiliary biochemical
134 serum analysis (bilirubin, alkaline phosphatase, etc.) as routine preoperative
135 screening for common bile duct (CBD) stones [2].

136 Alkaline phosphatase (ALP) is markedly elevated in persons with biliary obstruction.
137 However, high levels of this enzyme are not specific to cholestasis. To determine
138 whether the enzyme is likely to be of hepatic origin, measure gamma-glutamyl
139 transferase (GGT). GGT is used most commonly and is elevated in patients with
140 diseases of the liver, biliary tract, and pancreas [3].

141 In numerous preoperative imaging investigations, endoscopic retrograde
142 cholangiopancreatography (ERCP) showed the highest accuracy in the diagnosis of
143 choledocholithiasis. As this approach is invasive and expensive, it is generally not a
144 preferred option [4]. However, magnetic resonance cholangiopancreatography
145 (MRCP) showed a high accuracy in the diagnosis of choledocholithiasis [5]. Its
146 accuracy is comparable to that of ERCP, and its sensitivity and specificity were
147 shown to reach 95 % and 90 %, respectively [6].

148

149 MATERIALS AND METHODS

150 This was a prospective study upon 20 patients who were admitted to the hospital as
151 they had symptomatic gallstone disease with elevation in GGT and/or ALP, normal
152 bilirubin, and normal CBD by ultrasonography. This study was conducted in the GIT
153 surgical unit in the department of general surgery, Zagazig University Hospitals from
154 February 2016 till February 2017. Routine pre-operative laboratory investigations
155 including GGT and ALP were done for all patients. Also imaging studies carried out
156 for all patients include abdominal ultrasonography and MRCP. All patients admitted
157 with symptomatic gall bladder stones for lap cholecystectomy will be included in the
158 study and their ages between 20 to 67 years. Their lab investigations showed normal
159 bilirubin, elevated GGT and/or ALP. Also, their imaging studies (Abdominal
160 Ultrasonography) showed Gall Bladder stones with no stones or pathology in CBD.

161 **TECHNIQUES**

162 Those patients whose MRCP detected CBD pathology were managed by ERCP then
163 after 1 week, laproscopic cholecystectomy was performed and followed up in surgery
164 outpatient department. But those patients whose MRCP showed normal CBD were
165 managed by laproscopic cholecystectomy and followed up in surgery outpatient
166 department.

167

168 **The ERCP Technique**

169 Under General anaesthesia with endotracheal intubation, The endoscope was
170 passed gently down through the mouth into the oropharynx then through esophagus
171 into the stomach then advanced toward the pylorus. Gentle rotation and pressure
172 was used to pass the endoscope through the pylorus into the proximal duodenum.
173 Here the patient was turned to prone position. Visualization of the papilla was done
174 and selective cannulation of the common bile duct was performed. After an adequate
175 sphincterotomy or papillary balloon dilatation, we used either ordinary balloon or
176 basket extraction to retrieve the CBD stone and plastic stent was inserted (Figure 1).
177 In case of CBD stricture, plastic stent was inserted.

178

179 **The laparoscopic cholecystectomy technique**

180 The patient is placed in a supine position. Under General anaesthesia with
181 endotracheal intubation, Pneumoperitoneum was created by blind puncture with a
182 Veress needle through a subumbilical incision using carbon dioxide. Four-port
183 technique was used. 0 Degree viewing laparoscope was used. The gall bladder
184 fundus is grasped and retracted cranially toward the right shoulder. The cystic duct
185 and the cystic artery were identified, clipped with tiny titanium clips and divided. Then
186 the gallbladder was dissected away from the liver bed and removed through one of
187 the ports (Figure 2,3).

188 We informed all patients before discharging for follow up at surgery outpatient
189 department after 2 weeks, 1 month and 3 months.

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193 **RESULTS**

194 In this study, the age of the patients ranged from 20 to 67 years with mean age of
195 42.6 ± 14.77 years and median 46.5 years. Regarding sex, it shows highly proportion
196 in female sex (80%). GGT level is elevated in all cases of the study, However ALP
197 level is elevated in 70% of the cases only (Table 1). About the liver condition of the
198 cases included in the study, There were 20% of the cases had enlarged liver and
199 50% had bright fatty liver. Also all cases had no intrahepatic biliary radicle dilatation
200 (IHBRD). 50% of the cases had thick wall gall bladder. Also 80% of the cases had
201 multiple stones and 30% had stones smaller than 4 mm in size (Table 2). 85% of the
202 cases were normal by MRCP and managed by Lap cholecystectomy.

203 Only 1 case (5%) had short smooth narrowing at distal part of CBD detected by
204 MRCP (Figure 4) and was managed by ERCP which required stenting only, and 2
205 cases (10%) had small stone in CBD detected by MRCP (figure 5) and was
206 managed by ERCP for stone extraction and stenting. Then lap cholecystectomy was
207 done for those three cases after one week (Table 3). 47% of the cases managed by
208 cholecystectomy had straight forward operation. While in 12% of the cases, there
209 were acute inflammation and edema in GB during operation and 41% had wide
210 cystic duct which required clipping by large sized clips.

211 The operation time ranged from 30 to 90 min with mean 43 min.

212 There were decreasing in GGT and ALP levels in post-operative comparing to pre-
213 operative. Also, all cases showed normal levels of (GGT level ≤ 60 IU/L and ALP
214 level ≤ 130 IU/L) (Table 4). Statistically, there was highly significant difference
215 decreasing in GGT and ALP levels among post-operative ($p < 0.001$). While there
216 was no statistical significance difference between cases pre and post-operative in
217 level of bilirubin. All cases needed 2 weeks for ALP to return to normal. While in
218 GGT, 90% of the cases needed 2 weeks and 10% needed 1 month to return to
219 normal level of GGT (Table 5).

220 All cases, either managed by cholecystectomy or ERCP followed by
221 cholecystectomy, had no abnormality detected by clinical examination at the follow
222 up i.e., no pain, no fever and even no jaundice.

223

224

225 **DISCUSSION**

226 CBD stones assessment by biochemical testing of liver enzymes is a common
227 clinical practice with a high sensitivity [7]. When a stone becomes impacted in the
228 CBD, obstructive jaundice results. Bile stasis triggers release of liver enzymes e.g.,
229 serum ALP and GGT [8]. Thus, this study was to evaluate the clinical value of
230 elevated GGT and ALP as predictor factors for choledocholithiasis in non-jaundiced
231 symptomatic gallstone disease. In our study, the age of adult population ranged
232 from 20 to 67 years; median age was 46.5 years with a mean age of
233 42.6 ± 14.77 years. Regarding the patient sex; there was higher frequency of
234 gallstone in females (80%). That was in agreement with the study done by
235 Reshetnyak et al., that revealed gallstone is more common in women than in men [9].
236 In our study, pre-operative liver function tests results for all patients showed normal
237 serum bilirubin which ranged from 0.1 to 1 mg/dl. And also, 100% of the cases had
238 GGT serum level above 60 IU/L and ranged from 82 to 609 IU/L. Peng et al., found
239 that the serum level of GGT was more than 90 IU/l is considered being high risk to
240 have stone in common bile duct [10].

241 In study done by Fikry et al., found that serum levels of GGT were elevated in
242 patients with acute and chronic calcular cholecystitis with the highest level was 130
243 IU/L without elevation in serum level of bilirubin [11]. If the serum ALP is
244 persistently elevated for a long period of time, it suggests prolonged cholestasis [12].
245 In our study, the serum ALP level was elevated in patients ranged from 57 to 520
246 IU/L and 30% of the cases had normal level (≤ 130 IU/L).

247 Fikry et al., found that serum ALP was elevated in patients with acute calcular
248 cholecystitis with the highest level up to 250 IU/L [11]. And also, this correlated with
249 a study done by Thapa et al., stated that, the serum level of ALP was raised in
250 patients with acute cholecystitis by 1.69 ± 0.118 fold [13].

251 In the present study, 20% of the patients had enlarged liver and 50% had bright fatty
252 liver discovered by preoperative ultrasonography. All patients had no IHBRD. These
253 findings were in agreement with that study of Gupta et al., [7]. Also, 50% of the
254 cases had thick wall gall bladder. And 80% of the cases had multiple stones and
255 30% had stones smaller than 4mm in size. That also was in agreement with the
256 study of Gupta et al., [7].

257 MRCP is a reliable and noninvasive procedure for detecting or excluding the
258 presence of CBD stones [14]. It also has the potential to reduce the number of
259 invasive preoperative diagnostic procedures [15].

260 All our cases with the inclusion criteria underwent MRCP preoperatively and 85% of
261 the results of MRCP were negative for CBD stones or tumor i.e there were no
262 obstruction in CBD. One case (5%) had smooth narrowing at distal part of CBD and
263 also 2 cases (10%) had small stone in CBD. Based upon our MRCP results, the
264 patients with normal CBD (85%) were managed by laparoscopic cholecystectomy
265 without any need for ERCP preoperatively and the other 3 cases (15%) underwent
266 ERCP. Between the 3 cases managed by ERCP, 2 cases had stone extraction and
267 stenting and 1 case showed narrowing at distal CBD which required stenting only.
268 After one weak from ERCP, lap cholecystectomy was done for those three cases.

269 This was in agreement with the study of Dalton et al., which showed that 80% of their
270 results of MRCP were normal CBD and 20% had small stones in CBD and so the
271 same decisions of our study were taken in the cases of their study [14].

272 In the cases which underwent laparoscopic cholecystectomy, we found
273 intraoperatively that 47% of the cases had straight forward cholecystectomy
274 operation. While in 12% of the cases, there were acute inflammation and edema in
275 GB during operation and 41% had wide cystic duct which required clipping by large
276 sized clips. These findings were nearly in agreement with the study of Dalton et al,
277 Which revealed that 53% of his cases had wide cystic duct [14].

278 In our study, the average time needed for cholecystectomy operation ranged from 30
279 to 90 min with mean 43 min, while the mean time needed in the study of Dalton et
280 al., was 39 min [14]. In the study, we found highly significant difference decreasing in
281 GGT and ALP levels among post-operative ($p < 0.001$) which was consistent with
282 past studies of Habib et al., and Zare et al., [16, 17].

283 All cases of the study needed 2 weeks for ALP to return to normal. While 90% of the
284 cases needed 2 weeks and 10% needed 1 month to return to normal level of GGT
285 and these findings were in agreement with the study of Zare et al., [17]. There was
286 no statistical significance difference in bilirubin level among patients before and after
287 surgery ($p > 0.33$). These findings were in accordance with the study done by Wong
288 et al., [18].

289 CONCLUSION

290 GGT and ALP are sensitive but not specific to choledocholithiasis because of their
291 multiple sources. The value of their estimation pre-operatively is that their elevation
292 increase the suspicious of CBD stone or pathology. Their elevation provoke the
293 surgeon to assess the state of CBD by more accurate diagnostic tool as MRCP.
294 Most of cases (85%) with elevated GGT and/or ALP but with normal bilirubin and
295 ultrasound findings of CBD had no stones at CBD at time of evaluation. But the
296 small sector (15%) had pathology indicated intervention by ERCP and if neglected
297 before laparoscopic cholecystectomy, there would be morbidity on the patient. All
298 patients with non-jaundiced symptomatic gallstone disease and normal CBD by
299 ultrasonography with elevation in GGT and/or ALP must be managed by either
300 doing MRCP as a mandatory investigation pre-operatively or undergoing intra-
301 operative cholangiogram during laparoscopic cholecystectomy to avoid missing CBD
302 stone or pathology necessitate post-operative intervention by ERCP or open surgery.

303

304 ABBREVIATIONS

305 GGT: gamma glutamyl transferase

306 ALP: alkaline phosphatase

307 CBD: common bile duct

308 MRCP: magnetic resonance cholangiopancreatography

309 ERCP: endoscopic retrograde cholangiopancreatography

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311 CONFLICT OF INTEREST

312 Authors declare no conflict of interest.

313

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417 **TABLES**

418

419 Table 1: Laboratory findings pre-operative among the studied group

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Variable			Number of Patients
Total Bilirubin (mg/dL)	X±SD		0.41 ± 0.21
	Median		0.40
	Range		(0.1 - 1)
GGT (IU/L)	X±SD		298.3 ± 184.08
	Median		252
	Range		(82 – 609)
	≤ 60 N (%)		0 (0%)
	> 60 N (%)		20 (100%)
ALP (IU/L)	X±SD		210.9 ± 132.82
	Median		168
	Range		(57 – 520)
	≤ 130 N (%)		6 (30%)
	> 130 N (%)		14 (70%)

421

422 (**GGT**): Gamma-glutamyl-transferase (N: 8-60)423 (**ALP**): Alkaline phosphatase (N:40-130)424 (**X ± SD**): mean standard deviation425 (**IU/L**): International unit per litre

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434 Table 2: Gall bladder condition among the studied group by ultrasonography

435

Variable		Number of Patients
Wall	Normal	10 (50%)
	Thick	10 (50%)
Number of Stones	Single	4 (20%)
	Multiple	16 (80%)
Size of Stones	< 4 mm	6 (30%)
	> 4 mm	14 (70%)

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458 Table 3: MRCP results and decisions among the studied group

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Variable		Number of Patients
MRCP	Normal	17 (85%)
	Short smooth narrowing at distal part of CBD	1 (5%)
	Small stone in CBD	2 (10%)
Decision	Lap cholecystectomy	17 (85%)
	ERCP and stenting then lap cholecystectomy	1 (5%)
	ERCP , stone extraction and stenting then lap cholecystectomy	2 (10%)

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461 MRCP: Magnetic Resonance Cholangiopancreatography

462 CBD: Common Bile Duct

463 ERCP: Endoscopic Retrograde Cholangiopancreatography lap:Laprosopic

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480 Table 4: Comparison between Laboratory findings pre- and post-operative among
 481 the studied group

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Variable		Pre-operative (n = 20)	Post-operative (n = 20)	Paired Wilcoxon	P - value
GGT (IU/L)	X±SD	298.3 ± 184.08	36.35 ± 14.62	3.92	< 0.001 (HS)
	Median	252	37.5		
	Range	(82 – 609)	(11 – 60)		
ALP (IU/L)	X±SD	210.9 ± 132.82	94.3 ± 19.59	3.47	< 0.001 (HS)
	Median	168	90		
	Range	(57 – 520)	(70 – 130)		
Bilirubin (mg/dL)	X ± SD	0.41 ± 0.21	0.35 ± 0.11	0.97	0.33 (NS)
	Median	0.40	0.35		
	Range	0.1 - 1	0.1 – 0.8		

483

484 (**GGT**): Gammaglutamyl-transferase(N:8-60)

485 (**ALP**): Alkaline phosphatase(N:40-130)

486 (**IU/L**): International unit / litre

487 (**HS**): Highly significance (p < 0.001)

488 (**X ± SD**): mean standard deviation

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500 Table 5: Time needed for GGT and ALP to return to normal level among the studied
 501 group

502

Variable	Time	Number of Patients
ALP: (IU/L)	2 weeks	20 (100%)
GGT: (IU/L)	2 weeks	18 (90%)
	1 month	2 (10%)

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504 (**GGT**): Gammaglutamyl-transferase

505 (**ALP**): Alkaline phosphatase

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527 **FIGURE LEGENDS**

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529 Figure 1: CBD stone removal with a Dormia basket.

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531 Figure 2: Cystic duct dissection.

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533 Figure 3: Clipping of cystic duct by titanium clips.

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535 Figure 4: MRCP showing smooth narrowing at distal part of CBD.

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537 Figure 5: MRCP showing small stone at CBD.

538

539 **FIGURES**



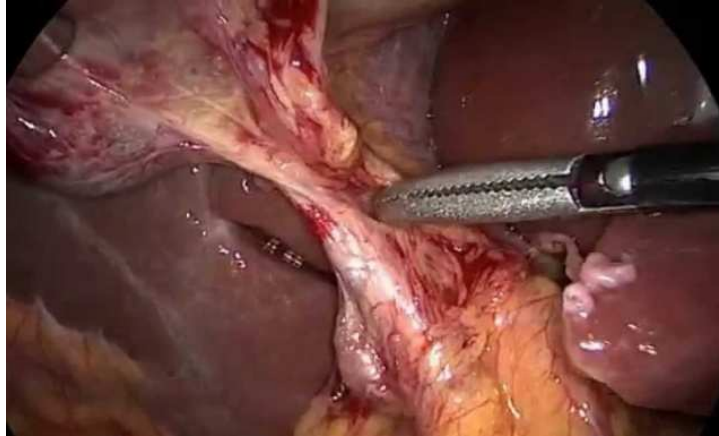
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542 Figure 1: CBD stone removal with a Dormia basket.

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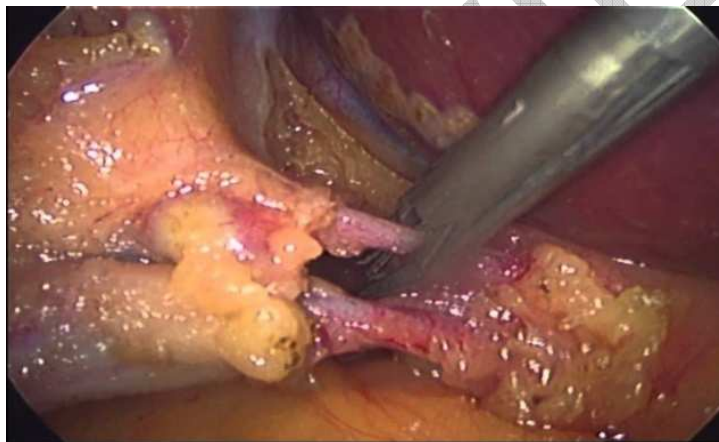


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547 Figure 2: Cystic duct dissection.

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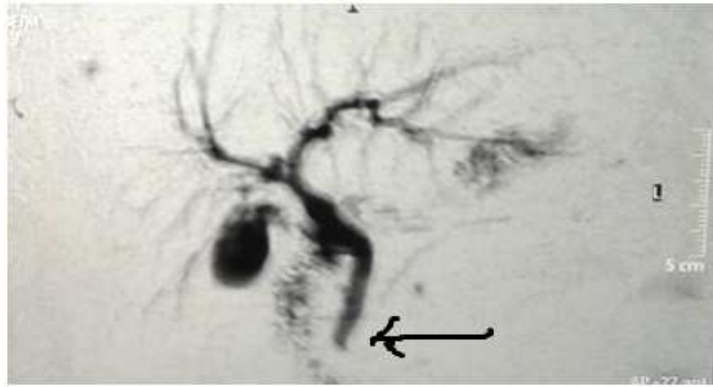
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551 Figure 3: Clipping of cystic duct by titanium clips.

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557 Figure 4: MRCP showing smooth narrowing at distal part of CBD.

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561 Figure 5: MRCP showing small stone at CBD.