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Financial Aspects of Bile Duct Injuries

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Background: Major bile duct injury is the most worrisome complication of cholecystectomy. There is no detailed data about the incidence or treatment-related costs of bile duct injuries in Turkey. We aimed to determine prevalence and therapeutic costs of patients with major biliary duct injuries managed in our department, and further estimate a projection of these parameters at the national level.

Material/Methods: All patients admitted due to bile duct injury during cholecystectomy from 2011 to 2014 were included. Healthcare costs were calculated by summing of their all treatment-related costs in Istanbul Medical Faculty. We collected 2014–2015 data on number of patients diagnosed with cholecystitis in Turkey, the number of cholecystectomies, and the number of the interventions performed following these initial surgeries, which were obtained from the Turkish Social Security Institution.

Results: Forty-nine patients were enrolled and bilioenteric diversion was performed in 39 patients: 20.4% of patients had Bismuth II, 38.8% had Bismuth III, and 40.8% had Bismuth IV biliary stricture. Comparison of stricture types with total costs, days of hospitalization, and outpatient clinic costs revealed significant differences. Mean total cost of corrective surgeries was 9199 TRY. We estimated that 1.5% to 2.4% of patients who underwent cholecystectomy in Turkey have bile duct injury (including 0.3% with major bile duct injury).

Conclusions: New preventive strategies should be used to avoid bile duct injuries, which have a huge financial impact on the national economy.

MeSH Keywords: Bile Ducts, Extrahepatic • Cholecystectomy • Cholecystectomy, Laparoscopic • Health Care Costs

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Background

Gallstone disease occurs throughout the world, being common in Europe and North America and rare in Africa. Epidemiological studies reported its prevalence to range from 3.1% to 24.5% (Table 1) [1,2]. Despite the absence of definite current data, the prevalence is thought to be around 10%. Gallstone disease is treated with cholecystectomy, in which major biliary duct injuries are one of the most worrisome complications. After being applied for the first time by Philip Mouret in 1987, laparoscopic cholecystectomy became more popular and even regarded as the standard of care. However, this led to an increase in biliary duct injuries, in which no marked decline has been achieved yet despite technological advancements and improved surgical techniques [3–5]. With an annual cost of more than $6.5 billion United States dollars (USD), gallstone disease is thought to be the most expensive digestive tract disorder in the United States [6]. Depending on the criteria used for the definition of injury, the incidence of biliary duct injuries during laparoscopic cholecystectomy are reported to be between 0.3% and 1.4% [1,3]. To the best of our knowledge, there is no data about the incidence or treatment-related costs of major biliary duct injuries in Turkey. Here, we aimed to determine prevalence and therapeutic costs of patients with major biliary duct injuries managed in our department, obtain statistical data about management and progress of cholecystitis cases, and to further estimate a projection of these parameters at the national level.

Material and Methods

A total of 49 patients admitted to the Hepatopancreatobiliary (HPB) Surgery and Liver Transplantation Unit of the General Surgery Department in Istanbul Medical Faculty of Istanbul University between 2011 and 2015 due to biliary duct injury after cholecystectomy were included in the study. Our study was performed in a retrospective fashion by screening medical records. Healthcare costs of the patients with post-cholecystectomy biliary duct injury were calculated by summing of their all treatment-related costs in Istanbul Medical Faculty, which was further compared with those of the patients who did not develop biliary duct injury after standard cholecystectomy. Then, we collected 2014–2015 data on the number of patients diagnosed with acute cholecystitis and cholecystolithiasis in Turkey, the number of cholecystectomies (open and laparoscopic), and the number and approximate costs of the interventions performed following these initial cholecystectomy, which were obtained from the Turkish Social Security Institution (TSSI) according to the Right to Information Act.

The study protocol was approved by the Ethics Committee of Istanbul Medical Faculty. The relevant study data were requested from TSSI.

Patient sex, age, height, weight, body mass index, Bismuth injury type, date of surgery, time to surgery from index injury, and time from index outpatient presentation until surgery were determined from the registries of Istanbul Medical Faculty and HPB Surgery and Liver Transplantation Unit of Istanbul Medical Faculty. The cost of each hospitalization, total cost of hospitalization, cost of each outpatient application, total cost of outpatient applications, cost of surgery, and total cost of patient treatment were all determined from billing records of the hospital administration. The costs are given in Turkish lira (TRY) and in USD. The mean TRY: USD exchange rate between 2011 and 2016 was used for all currency conversions; 1 USD=2.22 TRY.

Data analyses were performed with SPSS 17.0 statistics software (SPSS Inc., Chicago, IL, USA, Licensed to Istanbul University). Mean costs and mean days of hospitalization, standard deviations, and frequencies were calculated. The differences between groups were analyzed with the chi-square test for categorical variables and the Mann-Whitney U test for continuous variables. The comparison of the costs and mean days of hospitalizations by Bismuth stricture type was performed with Kruskal-Wallis test and Spearman's correlation. An overall 5% type I error level was used to infer statistical significance with a confidence interval of 95%.

Results

Our study included 49 patients who were diagnosed with biliary duct stenosis secondary to iatrogenic bile duct injury in our department from 2011 to 2015. The mean age of the patients was 51 years (range: 21–79 years). Female subjects comprised 77.6% (n=38) of the study population.

Bilioenteric diversion (Roux-en-Y hepaticojejunostomy) was performed in 39 patients (9 males; 23.1%, 30 females; 76.9%), among which 1 male patient with additional injury of hepatic artery and right branch of portal vein further underwent right hepatectomy with bilioenteric diversion. The remaining 10 patients could not be operated on due to being lost to follow-up for unknown reasons or medical reasons. Bismuth classification of biliary injury showed that 10 patients (20.4%) had Bismuth II stricture, 19 patients (38.8%) had Bismuth III, and the remaining 20 patients (40.8%) had Bismuth IV biliary stricture.

Comparison of Bismuth stricture types by the total costs, days of hospitalization, costs of hospitalization, and outpatient clinic costs showed a significant difference (Table 2), which was detected to be driven by the difference between Bismuth type II and type IV groups (p=0.029). Bismuth type III and IV groups did not differ in terms of these parameters (p=0.056).

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Table 1. Geographic Prevalence of Gallstones according to different ultrasonograpic studies (1–3).

Study	Area & population	Male (%)	Female (%)
Everhart et al.	American Indians	64.1	29.5
	Hispanic	8.9	27
Shaffer	Non-Hispanic White	8.6	16.6
	Non-Hispanic Black	5.3	13.9
Miguel et al., Covarrubias et al., Moro et al.	Chilean Indians	12.6	49.4
Palermo et al.	Argentina	18.2	25
Glambek et al.	Norway	17	21
Loria et al.	Italy	2.7	8.4
Mellström et al.	Sweden	–	27
Kratzer et al.	Germany	5.8	6.3
Martinez et al.	Spain	7.8	11.5
Beyler et al.	Turkey	Mean	5.25
Ozutemiz et al.	Turkey (Agean region)	Mean	7.5
Khuroo et al.	Kashmir	3.07	9.6
Unisa et al.	India	2	5.6
Chen et al.	Taiwan	5.3	2.4
Shen et al.	China	9.3	9.8
Kono et al.	Japan	3.6	–
Chapman et al.	New Zealand	18.1	23.1
Walker et al.	South Africa	–	10
Bagi Abdel	Sudan	5.6	5.1

The difference of total days of hospitalization between groups was found to arise from the statistically significant difference between Bismuth type II and type IV groups (p=0.021). The difference in total outpatient clinic costs between groups was shown to originate from the significant difference between Bismuth type III and type IV groups (p=0.043). These groups also significantly differed in terms of total costs (p=0.05).

Kruskal-Wallis one-way variance analysis did not detect any significant difference between Bismuth injury type groups in terms of the time elapsed from index injury to the surgery.

There was also no difference between Bismuth injury type groups in terms of the time from index outpatient presentation until the surgery, as analyzed by Kruskal-Wallis one-way variance test.

No significant associations were found between total length of stay and either the time from index injury to the surgery or the time from index outpatient presentation to the surgery.

Spearman's correlation showed a weak association between age and outpatient cost (rs=0.47, p=0.001). Other parameters, including total hospitalization cost, total length of hospital stay, and total costs, were not significantly correlated with age.

Body mass indices of 49 patients were calculated using height and weight parameters. No statistically significant association was found between body mass index and each of the total cost, total hospitalization cost, total outpatient cost, and total length of hospital stay.

No statistically significant associations were found between body mass index and either the time from index injury to the

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Table 2. Biliary injury types, length of hospitalization, and treatment costs.

		Bismuth injury type			p
		II	III	IV	
Total cost of hospitalization TRY (USD)	Patient n	10	19	20	0.049
	Mean	5131 (2311)	5840 (2631)	7579 (3414)	
	Minimum	1123 (505)	3339 (1504)	4728 (2129)	
	Maximum	27248 (12273)	14604 (6578)	22089 (9950)	
Total length of hospital stay days	Patient n	10	19	20	0.026
	Mean	23	32	36	
	Minimum	4	10	20	
	Maximum	65	82	111	
Mean total costs of outpatient clinic TRY (USD)	Patient n	10	19	20	0.046
		835 (376)	443 (199)	978 (440)	
Total cost TRY (USD)	Patient n	10	19	20	0.030
	Mean	6590 (2968)	6168 (2778)	9220 (4153)	
	Minimum	1142 (514)	3459 (1558)	4829 (2175)	
	Maximum	27908 (12571)	15694 (7069)	23272 (10482)	

TRY – Turkish Lira; USD – US Dollar; n – number.

Table 3. Total costs of 49 patients with biliary duct injury.

Mean total cost of hospitalization TRY (USD)	7971 (3590)
Mean total costs of outpatient clinic TRY (USD)	958 (431)
Mean total length of hospital stay days	36
Mean total cost TRY (USD)	8929 (4022)

TRY – Turkish Lira; USD – US Dollar.

surgery or the time from index outpatient presentation to the surgery.

Mean length of hospital stay was 36 days (range: 4–111).

Mean total cost of the study population was 8929 TRY (range: 1142–27908) [4022 USD; range: 514–12571] (Table 3). This only included the cost of the healthcare provided in our faculty, excluding those costs of surgery and hospitalization at the index surgery, of tests performed in other facilities, and of healthcare services provided by other centers while being hospitalized in our faculty.

The mean total cost of the subjects operated on due to bile duct injury was 9199 TRY (range: 3459–27908) [4143 USD; range 1558–12571] (Table 4). The mean total cost of the subjects that were not operated on was 7878 TRY (range: 1142–17991) [3548 USD; range 514–8104].

Mean postoperative stay after correction surgery was 11 days (range: 4–35 days). Mean cost of the hospitalization during which this corrective surgery was performed was 4988 TRY (range: 2973–11933) [2246 USD; range: 1339–5375].

The mean interval between index injury and the surgery, which is an important assessment tool for the management and follow-up of patients with biliary duct injury, was 506 days (range: 4–4317) for the 39 patients operated on.

Mean time from index presentation to surgery among the patients operated on was 120 days (range: 1–555). In fact, the patient who underwent surgical intervention had also right portal vein and right hepatic artery injury in addition to biliary duct injury, where right hepatectomy was performed in emergency settings.

Data from TSSI showed that a total of 308 481 cholecystectomies were performed in Turkey in 2014 and 2015, yielding 154–240 TSSI-paid cholecystectomies per year. Among all these

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Table 4. Total costs and hospital stay of the patients who underwent biliary reconstruction.

	Min.	Max.	Mean
Total cost of hopitalization TRY (USD)	3339 (1504)	27248 (12273)	8298 (3737)
Total length of hospital stay	10	111	37
Total cost TRY (USD)	3459 (1558)	27908 (12571)	9199 (4143)

TRY – Turkish Lira; USD – US Dollar; Min – Minimum; Max – Maximum.

operations, 277 292 interventions (89.9%) were performed laparoscopically, while the others were open (n=31 189). TSSI data on patients with cholecystitis (acute and chronic) revealed 175 990 and 183 412 cases for years 2014 and 2015, respectively.

Among patients who had TSSI-paid cholecystectomy within 2014–2015, the number of patients who further underwent endoscopic or surgical procedure related to biliary duct following initial cholecystectomy surgery (open or laparoscopic) was 7802, giving a 2.5% rate of secondary biliary procedures among cholecystectomized patients. Nevertheless, the available data did not allow us to conclude that all these interventions were performed due to bile duct injury. In order to reach more plausible results, the data of these secondary procedures were further grouped as: "interventions for biliary stricture and cysts", "choledochoenterostomy", "uncomplicated interventions for biliary fistula", "complicated interventions for biliary fistula", "interventions for gallbladder and biliary duct injuries", "biliary intestinal diversions", "endoscopic biliary dilation", "endoscopic biliary endoprosthesis insertion", "endoscopic biliary stent implantation", "endoscopic retrograde cholangiopancreatography", "cholecystectomy", and "laparoscopic cholecystectomy". The latter 2 procedures were probably performed due to prior partial cholecystectomy. When we excluded these 2 procedures, the rate of secondary biliary duct intervention was reduced to 2.4%. Moreover, when we also removed endoscopic sphincterotomy, which we assumed to be performed partly for residual choledochal stones, the rate of post-cholecystectomy intervention was further reduced to 1.5%. Though the definite rate could not be achieved due to the diversity of diagnostic spectrum, we suggest that 1.5% to 2.4% of TSSI-paid cholecystectomy patients could have biliary duct injury. Using the same method, we estimated individual rates of the bile duct injury as 5.6–7% and 1.1–1.8% during open and laparoscopic cholecystectomy, respectively. In order to estimate the rate of major bile duct injuries which eventually require reconstructive biliary surgery, we excluded all of the endoscopic interventions following initial cholecystectomy, and found a total of 920 cases for the years 2014 and 2015. We calculated that major bile duct injury occurred in 0.3% of cholecystectomy cases.

Discussion

Bile duct injuries are the most serious and fearsome complication of cholecystectomy. While it ranged between 0.2% to 0.3% in the past, iatrogenic bile duct injuries were reported to increase to 0.3% to 1.4% after laparoscopic cholecystectomy gained popularity and widespread use [1,3,4]. Bile duct injuries cause different short- and long-term problems. Financial considerations of the bile duct injuries, which also had higher morbidity and mortality, have received little research attention. The aim of the present study was to discover the financial burden of these bile duct injuries on the national economy and to build awareness of this problem.

It is obvious that data from TSSI are not only relatively heterogeneous, but also probably contain physician-related erroneous records. However, by obtaining total numbers of subsequent biliary endoscopic or surgical procedures reimbursed by TSSI for patients who previously underwent cholecystectomy during the study period, we estimated the rate of bile duct injuries to range between 1.5% and 2.4%. About 2.5% of cholecystectomized patients had further endoscopic or surgical intervention to the biliary tract, which was 5.6–7% for open cholecystectomies and 1.1–1.8% for laparoscopic cholecystectomies. We thought that the unexpectedly high rate of injury after open cholecystectomy probably was primarily due to the conversion from laparoscopic to open cholecystectomy, where the suspected injury was the reason for conversion or occurred after conversion, followed by the reporting of the procedure with the code of open cholecystectomy. While there was a defined procedure code for bile duct injury in the notice of health practices, the relatively wide spectrum of secondary biliary procedure codes of previously cholecystectomized patients implied that bile duct injury complications were recorded with inadequately or thoroughly erroneous codes. Incorporation of a detailed coding system for health practices for bile duct injuries is essential for both documentation and for faster and more serious evaluation and therapeutic decisions about the patients' conditions. Biliary enteric diversion surgeries that are performed for other reasons and corrective surgical interventions should be separately evaluated and scored. Corrective

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operations after bile duct injury, which are technically very difficult to perform, should clearly be performed only by experienced hepatobiliary surgeons in order to increase therapeutic success and reduce treatment-related costs.

The relative number of cholecystectomies has increased as laparoscopic cholecystectomy has become widespread, which in turn has increased rates of bile duct injuries [7–9]. In fact, bile duct injuries were 2-fold higher in laparoscopic cholecystectomies compared to in open technique [10]. We attributed the inconsistency of our findings compared with the literature to the fact that the code for the procedure at the end of the surgery was mistakenly entered into the system rather than the initial operation, which was reported to TSSI, which our data were based on. Most of the injuries that occurred during laparoscopic cholecystectomy were caused by basic technical errors and incorrect intraoperative interpretation of the anatomy by the surgeon, rather than due to surgeon inexperience [3,4,8].

Mean total cost of the 39 patients operated on was 9199 TRY (4143 USD), which only included healthcare service provided by our faculty, excluding previous diagnostic and therapeutic costs. Laparoscopic and open cholecystectomy are regarded as an all-inclusive service by TSSI, which pays 1045 TRY (470 USD) and 792 TRY (356 USD) for each patient undergoing laparoscopic and open cholecystectomy, respectively. These prices include all the expenses of the patient.

Because it is the most severe form of injury, Bismuth type IV had a higher total treatment-related cost than those of Bismuth type II and type III groups, as would be logically expected.

The total cost continues to increase as long as the corrective surgical treatment becomes delayed, which we think can only be overcome by early diagnosis.

In 2015, Hofmeyr et al. performed a study with 44 patients presenting with bile duct injury, finding that repair by Roux-en-Y hepaticojejunostomy had a 6.4-fold higher cost compared with an uncomplicated laparoscopic cholecystectomy [11]. Our findings from 39 patients operated on due to major bile duct injury showed that the total cost of treatment of such a case was up to 8-fold the cost of an uncomplicated gallbladder surgery.

The annual number of TSSI-paid cholecystectomies is around 150 000 in Turkey, where we estimated the incidence of bile duct injury to be 1.5% to 2.4%, with a 0.3% rate of Bismuth type I–V. Considering the 8-fold cost of the major bile duct injury and 3.7-fold cost of the bile duct injury without need of reconstructive biliary surgery relative to an uncomplicated cholecystectomy, annual treatment-related cost of these patients was estimated to range approximately from 21 to 34 million TRY (9.5–15.3 million USD).

The mean length of hospital stay among the 39 patients operated on in our clinic was 37 days. The mean length of stay during the hospitalization due to corrective surgery was 20 days, where the postoperative length of stay was 11 days. The mean cost of hospitalization for corrective surgery was 4988 TRY (2247 USD). Most of our patients had difficulty resuming their normal daily lives due to being hospitalized and discharged multiple times for several different reasons, including intra-abdominal abscess, cholangitis, occlusion or displacement of percutaneous drains, infection or colonization with resistant microorganisms, and need for further preoperative tests due to cardiovascular comorbidities. On the other hand, patients could be discharged on the second day after an uncomplicated cholecystectomy, even returning to work within the same week.

In our study, we only calculated those costs of the healthcare service provided in our faculty, which should also take into account disease-related indirect costs arising from the workforce and production loss. In a Swedish study in 2008, Andersson et al. reported that losses due to production and workforce constituted 86% of total treatment-related costs of patients with bile duct injury, leaving only 14% of the cost due to the treatment itself [12,13].

The mean interval between the index injury and the corrective surgery in the 39 patients was 506 days. The minimum monthly wage in Turkey is 1404 TRY (632 USD), yielding a net daily wage of 46 TRY (21 USD). When we assume that these patients did not work from the day of injury to the day of surgery, the mean interval of 506 days in our study corresponds to a cost of 23 821 TRY (10 730 USD) for each patient. In a patient who developed bile duct injury, we estimated the mean total cost originated from the treatment and loss of workforce as 33 020 TRY (14 874 USD). Accordingly, treatment-related expenses constituted 27.8% of the total cost of a patient with bile duct injury in our study.

The interval between the index injury and the corrective surgery in fact ranged from 4 days to 4317 days in our study. We attributed this huge variation among patients to the differences in the clinical presentation of bile duct injuries and varying degrees of ease of access to the specialized centers.

When we examined costs of the 10 patients who were not operated on for several reasons, the mean total cost of these patients was found to be similar to that of patients who underwent corrective surgery. Considering this, it is obvious that operating on the patients with bile duct injury as clinically early as possible not only improves quality of life, but also reduces total treatment costs.

Some studies have reported medico-legal costs of cholecystectomy-induced bile duct injuries. In one of these, Roy et al.,

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in 2008, examined a series of 83 cases, each of which was a subject of a lawsuit for damages due to bile duct injury after laparoscopic cholecystectomy in the United Kingdom between 2000 and 2005. The authors reported that bile duct injury was discovered during the operation in 17 cases (20%), whereas 80% of the cases were diagnosed after the surgery. While half of the cases with injury repaired during the index operation had a successful outcome, this was achieved in 90% of the cases who had delayed diagnosis and underwent corrective surgery. Accordingly, when unsuccessful operations are excluded, the allowance for damage paid to the patients who underwent delayed corrective surgery was 1.8-fold that paid to patients whose injury was discovered during the index surgery [14,15].

Karakaya et al., in their 2014 study, examined 21 cases assessed by the Institution of Forensic Medicine due to bile duct injury after laparoscopic cholecystectomy from 2008 to 2012, finding that all cases of injury were due to surgical inadequacies in cholecystectomy. While the reason for the inadequacies was regarded as "late recognition of bile duct injury and delayed transfer of the patient" in 20 cases (95.3%), it was "failure to provide necessary professional care and attention" in the remaining 1 case (4.7%) [16].

Conclusions

Laparoscopic cholecystectomy is the treatment of choice for gallstone disease. All possible preventive measures should be taken to avoid major bile duct injury during cholecystectomy, upon which the operative strategy should be built. In all of the operations, a "critical view of safety" should be achieved before division of the cystic duct. The procedures performed during or after the injury not only escalate total treatment-related costs directly, but also have dramatic impacts on morbidity and mortality. Cholecystectomy-related iatrogenic bile duct injury is unfortunately a reality which the healthcare providers should also take into account, and it has a huge financial impact on the healthcare system.

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Conflicts of interest

None.

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