IATROGENIC BILE DUCT INJURY. A SIGNIFICANT SURGICAL PROBLEM. ASSESSMENT OF TREATMENT OUTCOMES IN THE DEPARTMENT'S OWN MATERIAL

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Iatrogenic bile duct injuries (BDI) are still a challenging diagnostic and therapeutic problem. With the introduction of the laparoscopic technique for the treatment of cholecystolithiasis, the incidence of iatrogenic BDI increased.

The aim of the study was a retrospective analysis of 69 patients treated at the department due to iatrogenic BDI in the years 2004–2014.

Material and methods. In this paper, we presented the results of a retrospective analysis of 69 patients treated at the Department due to iatrogenic BDI in the years 2004–2014. The data were analyzed in terms of age, sex, type of biliary injury, clinical symptoms, the type of repair surgery, the time between the primary surgery and the BDI management, postoperative complications and duration of hospital stay.

Results. 82.6% of BDI occurred during laparoscopic cholecystectomy, 8.7% occurred during open cholecystectomy, whereas 6 cases of BDI resulted from surgeries conducted for other indications. In order to assess the degree of BDI, Bismuth and Neuhaus classifications were used (for open and laparoscopic cholecystectomy respectively). 84.1% of patients with confirmed BDI, were transferred to the Department from other hospitals. The average time between the primary surgery and reoperation was 6.2 days (SD 4). The most common clinical symptom was biliary fistula observed in 78.3% of patients. In 28 patients, unsuccessful attempts to manage BDI were made prior to the admission to the Department in other centres. The repair procedure was mainly conducted by laparotomy (82.6%) and by the endoscopic approach (15.9%). Hepaticojejunostomy was the most common type of reconstruction following BDI (34.7%).

Conclusions. The increase in the rate of iatrogenic bile duct injury remains a challenging surgical problem. The management of BDI should be multidisciplinary treatment. Referring patients with both suspected and confirmed iatrogenic BDI to tertiary centres allows more effective treatment to be implemented.

Key words: iatrogenic bile duct injuries, cholecystectomy, complications

Laparoscopic cholecystectomy (LC) is currently the gold standard in the management of cholecystolithiasis. It is also one of the most common surgical procedures. In the United States, approximately 700,000 cholecystectomies are performed annually, 70% of which are conducted laparoscopically (1, 2). When analysing iatrogenic BDI which occurred during open cholecystectomy (OC) and LC, it was observed that biliary complications occurred twice as frequently after laparoscopic procedures (2, 3). Due to the introduction of the laparoscopic technique to common use, the incidence rate ranges from 0.8-2.2% (1).

The first cholecystectomies performed by Mühe without the conventional open approach and, instead, with the use of specially prepared rectoscope were received with general criticism
However, the new surgical approach and technique aroused considerable interest which was reflected in the attempts to perfect this technique for its optimal application. In 1989, Dubois et al. proposed a new technique for removing the gall-bladder by making several independent insertions as a new surgical approach (5).

Apart from anatomic reasons (anomalies, male sex, inflammation, excessive fatty tissue in the area of the hepatoduodenal ligament), training of the medical staff and learning curve, which is longer in the laparoscopic method and requires different technical skills, are significant elements in the group of numerous factors that determine the occurrence of complications in the course of LC (6). Biliary injuries are associated with severe clinical implications and increased mortality risk due to general complications.

The spectrum of management of both endoscopic and open procedures depends on the advancement of bile duct injury, its level and type of trauma that has caused the injury.

The commonness of performing primary laparoscopic cholecystectomy is unfortunately not accompanied with the commonness of effective management of potential biliary injuries in most centres. Moreover, less than 30% of bile duct injuries are diagnosed during the primary surgery (7). Minimal invasiveness of medical procedures and miniaturisation of medical equipment result in the fact that more and more young surgeons are not sufficiently experienced in conventional procedures, which is associated with the inability to perform such procedures correctly if bile ducts become damaged and if immediate injury repair is necessary.

Referring patients to tertiary centres seems therefore justified and important. The experience of the medical staff is associated with higher effectiveness in managing biliary complications (8).

The aim of the study was a retrospective analysis of 69 patients treated at the department due to iatrogenic BDI in the years 2004-2014. MATERIAL AND METHODS

A retrospective analysis included 69 patients with confirmed bile duct injuries. They were treated in the Department of General, Endocrinological Surgery and Gastrointestinal Oncology in 2004–2014. The data were analysed in terms of age, sex, type of biliary injury, clinical symptoms, the type of repair surgery, the time between the primary surgery and the BDI management, postoperative complications and duration of hospital stay.

A considerable majority of patients were those referred from other centres due to suspected or confirmed iatrogenic BDI. A repair surgery was either attempted in the previous centres or not started at all.

BDI was confirmed in ERCP or in other imaging examinations (abdominal CT or US, MR cholangiography) while clinical signs, such as obstructive jaundice, bile in the drain left after the procedure in the abdominal cavity and septic shock, were also present.

In order to classify bile duct injury, the Bismuth and Neuhaus classifications were used (9, 10). The Neuhaus classification served for describing iatrogenic BDI in the course of LC. The Bismuth system, on the other hand, was used to classify iatrogenic BDI that occurred during OC and in the cases of bile duct injury that occurred in the course of surgeries conducted for other indications (and not for the removal of the gall-bladder).

In the cases of ineffective iatrogenic BDI repair performed in other centres prior to the admission to the Department, the grade was assigned to the initial bile duct injury.

RESULTS

The study included 69 patients treated in the department in 2004–2014 due to iatrogenic biliary injury. The group comprised 56.5% of females and 43.5% of males. The mean age of the patients was 50.5 (SD 16.2; range 20-82).

Cause of iatrogenic BDI

In the group of patients with bile duct injury, laparoscopic cholecystectomy was the most common primary procedure (57 patients, 82.6% vs 6 patients, 8.7% in whom open surgery was the primary treatment). The remaining 6 instances of bile duct injury developed due to procedures conducted for other indications, and not for the removal of the gall-blad-
The analysis of the BDI grade and the number of patients with a given grade of injury are presented in the tables separately for the Bismuth (tab. 1) and Neuhaus (tab. 2) classifications. In one case (injury to the accessory bile duct – duct of Luschka), the representation of biliary injury was not found in the Bismuth classification.

### Classification of iatrogenic BDI

The analysis of the BDI grade and the number of patients with a given grade of injury are presented in the tables separately for the Bismuth (tab. 1) and Neuhaus (tab. 2) classifications. In one case (injury to the accessory bile duct – duct of Luschka), the representation of biliary injury was not found in the Bismuth classification.

#### Onset of symptoms

The data of patients with iatrogenic BDI who underwent primary surgeries in other centres were not complete and therefore they were not included in the analysis. Of patients with confirmed iatrogenic BDI who were operated in the Department, the average time between the primary surgery and reoperation was 6.2 days (SD 4; range 1–13 days of the primary procedure). In 10 cases, BDI management was performed by means of laparotomy. In one case (bile leak from the duct of Luschka), a laparoscopic revision was conducted. None of the aforementioned cases were diagnosed intraoperatively.

#### Diagnosis of bile duct injury

The most common symptom that suggested BDI in the material analysed was biliary fistulas. In one case (injury to the accessory bile duct – duct of Luschka), the representation of biliary injury was not found in the Bismuth classification.
tula (78.3%). Bile leak from the drain left in the abdominal cavity in the postoperative period was confirmed with imaging examinations (US, CT and/or ERCP, MR cholangiography). The symptoms of jaundice confirmed in laboratory tests (total bilirubin level) were observed in 11 cases (15.9%). The presence of a biliary collection within the abdominal cavity occurred much more rarely (5.8%).

Management prior to admission to the Department

In the group of 58 patients with iatrogenic BDI acquired in other centres, the non-significant majority (30 patients) were referred to the Department when the symptoms had developed with no attempts to treat the injury. In 28 cases, attempts to revise and treat the injury were undertaken. The most common procedure was laparotomy with abdominal drainage (12 cases, including one percutaneous drainage). In 3 cases, ERCP with primary stenting of the injured biliary tract was conducted. In 7 patients, the bile duct repair was performed: Roux-en-Y anastomosis of the common bile duct with the small intestine – 1 and the common hepatic duct with the small intestine – 4 cases as well as the common bile duct with the duodenum – 2 cases. All these attempts were ineffective, which resulted in referring patients to the Department. Despite the availability of information about a repair attempt, it was not possible to specify the type of the repair procedure in the available documentation in 6 cases.

Type of repair procedure

Depending on the type and level of biliary injury, the patients underwent bile duct repair procedures. The majority of operations were open laparotomies (82.6%), and 11 patients underwent endoscopic procedures (ERCP) with simultaneous stent implantation at various levels of the injury (15.9%). In one case, revision and subsequent repair were conducted laparoscopically. More detailed information concerning the type of procedures to treat iatrogenic BDI in the patients analysed is presented in tab. 3.

Hospital stay

A complication in the form of iatrogenic BDI prolonged hospital stay in a considerable way. The average stay in the Department amounted to 22.8 days (SD 14.8; range 5-88 days).

When analysing the duration of hospital stay in the groups of patients with respect to the hospital in which the injury occurred (Department vs other centre), no statistically significant differences were observed. The duration of hospital stay amounted to: 22.4 (SD 10.4) vs 22.7 (SD 16.1) days respectively. It must be emphasised, however, that the patients, who were transferred from other centres for iatrogenic BDI treatment, were hospitalized in the primary centre prior to the admission to the department.

However, a difference in the duration of hospitalisation in the department was observed when the surgical procedures which

<table>
<thead>
<tr>
<th>Type of BDI repair procedure</th>
<th>No of patients</th>
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<tbody>
<tr>
<td>1 ligation of the stump of the cystic duct</td>
<td>3</td>
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<tr>
<td>2 ligation of the accessory duct (duct of Luschka)</td>
<td>6</td>
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<tr>
<td>3 suturing the transection/incision of a bile duct</td>
<td>3</td>
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<tr>
<td>4 bile duct drainage</td>
<td>4</td>
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<tr>
<td>5 hepaticojejunostomy</td>
<td>24</td>
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<tr>
<td>6 separate anastomosis of the left and right bile ducts with the jejunum</td>
<td>6</td>
</tr>
<tr>
<td>7 isolated anastomosis of the right bile duct with the jejunum</td>
<td>2</td>
</tr>
<tr>
<td>8 bile collection drainage</td>
<td>3</td>
</tr>
<tr>
<td>9 choledochoduodenostomy</td>
<td>3</td>
</tr>
<tr>
<td>10 choledochojejunostomy</td>
<td>4</td>
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<tr>
<td>12 endoscopic injury repair (ERCP + stenting)</td>
<td>11</td>
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</tbody>
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resulted in BDI were analysed. The mean duration of hospitalisation of the patients with iatrogenic BDI operated laparoscopically was 20.9 days (SD 10.4, range 5–51 days). As for the classical approach, the patients were hospitalised for 17.5 days (SD 11.9, range 7-39 days). The hospitalization was the longest in the patients who were treated due to BDI following surgeries conducted for other reasons than gall-bladder removal: 38.9 days (SD 26.7, range 10-88). The application of ERCP with stent implantation as a therapeutic procedure in iatrogenic BDI shortened hospital stay by 10.1 days (SD 5.7; range 5-19).

Two patients developed external biliary fistulae connected with wound dehiscence and septic complications. The repair procedures were ineffective and therefore it was decided to institute negative-pressure wound therapy. In both patients a complete recovery was observed.

Conclusion of treatment

53 patients were discharged when the treatment process had ended (76.8%). 12 patients were transferred to their primary centres for further conservative treatment (17.4%). Three patients died in the postoperative period due to septic shock (4.3%). One patient demanded discharge prior to the conclusion of treatment.

DISCUSSION

Bile duct injury acquired during cholecystectomy is associated with the risk of prolonged morbidity and mortality (11).

The nature of laparoscopic procedures requires a different manual and technical approach than surgeries conducted by the classical approach. Massarweh et al. noticed a significant correlation having analysed the training and practical aspects of LC among American surgeons (12). He proved that surgeons who reported at least one iatrogenic BDI in their surgical careers were characterised by older age and, paradoxically, longer surgical practice. Moreover, a group of surgeons working in academic centres showed a lower number of complications during LC which was statistically significant. The relatively novel laparoscopic techniques require a longer “learning curve” and a different technical approach.

Of numerous causes of iatrogenic BDI, the most common is incorrect identification of the biliary tract. Hugh and Olsen et al. demonstrated that as many as 70-80% of biliary complications were caused by such a misinterpretation (13, 14). Despite a certain evolution of the views concerning the “Calot’s triangle,” the assumptions remain unchanged (15). Proper dissection of the space between the cystic duct, common hepatic duct and the edge of the liver is a condition necessary for a good orientation and insight into the structures that require safe treatment.

Despite not being highly suggestive, the clinical signs such as increased body temperature, nausea and abdominal pain in the postoperative period should draw the surgeon’s attention. Bile leak through the drain (severing the bile outflow tract) and/or jaundice (occlusion of the main biliary tract) confirmed in imaging examinations and blood chemistry complete the clinical picture.

Bismuth was the first author to classify iatrogenic BDI in the course of OC (9). The development of the laparoscopic technique, however, made it necessary to systematise these types of injuries and their extensiveness. Therefore, several valuable classifications of iatrogenic BDI were prepared, among others: Strasberg and Stewart-Way classifications (16, 17). Of numerous available classifications that determine the grade of bile duct injury, the Neuhaus classification is, in the opinion of the authors, the most exact, the clearest and the simplest one (10).

The management of iatrogenic BDI is determined by numerous factors, and the final manner of treatment results from the work of numerous specialists, such as surgeons, endoscopists and radiologists.

A relatively large number of procedures to manage iatrogenic BDI conducted in tertiary centres and greater experience of the therapeutic team associated with it seem to be the most important reasons for conducting repair procedures in such centres. Having analysed patients treated due to iatrogenic BDI, Stewart et al. demonstrated that treating BDI in a tertiary centre is more effective than in the centre where the injury was sustained (94% vs 17%) (18). Similar conclusions were drawn by Lillemoe et al. who showed that the effective-
ness of procedures conducted in such centres amounted to 90% (8). Despite a common view concerning the difficulties resulting from the specificity of bile duct repair surgeries, Archer et al. demonstrated (based on a multicentre material) that it was attempted to manage confirmed BDI in primary centres in over 90% of cases. In the end, however, as many as 50% of patients were referred to tertiary centres due to an ineffective treatment attempt (19).

Of numerous surgical methods to manage bile duct injury, the following are distinguished: end-to-end ductal biliary anastomosis (EE), Roux-en-Y hepaticojejunostomy (HJ), choledochoduodenostomy (CHD) and, more rarely, Blumgart (Hepp) anastomosis or Smith procedure limited to injuries in the perihilar region. Irrespective of the technique, the principles associated with safe and effective anastomosis of the bile ducts with the gastrointestinal tract remain unaltered and do not differ between the methods considerably. Cleaning the ends of the connected surfaces carefully (fibrosis, inflammation, necrosis), absence of tension on the elements to be anastomosed and good perfusion of the connected structures determine a good late outcome (20). The ultimate selection of a technique to treat BDI should depend on many factors, such as the type of injury, its extensiveness, time of diagnosis or skills and experience of the surgeon as well as the availability of endoscopic equipment (1).

Hepaticojejunostomy (HJ) remains one of the most common repair surgeries characterised by the highest efficacy (8, 21-26). A narrow calibre of the common hepatic duct (which rarely exceeds 7 mm) and its thin walls contribute to technical difficulties of anastomosis. Single-layer anastomosis and usage of thin absorbable sutures were identified as significant factors that affected the late treatment outcome (18). However, two important aspects must be mentions when describing this method; namely, the risk of anastomotic stricture and non-physiological bile flow to the lumen of the gastrointestinal tract. The change of bile flow results in the loss of its neutralizing effect on gastric secretion, which causes an increase in the risk of peptic ulcer disease (6). The end-to-end anastomosis (EE) of the injured bile duct is associated with a high risk of stricture at the site of anastomosis (27).

Despite the fact that the conditions for a natural bile flow to the gastrointestinal tract are preserved, the procedure is associated with technical difficulties in the form of the necessity to mobilize the duodenum and the head of the pancreas (sometimes extensive) – Kocher manoeuvre. According to Jabłońska et al., anastomosis can be performed when the injury of the main biliary tract amounts to even 4 cm (6). The authors of this publication believe, however, that this technique may be indicated for smaller biliary injuries. Gazzaniga et al. recommend such a technique in the case of distal injury to the main biliary tract (below 2 cm from the hepatic duct confluence) (21). Choledochoduodenostomy (CHD) is performed rarely. This method is restricted to injuries in the distal part of the common bile duct (CBD). Moreover, it is also indicated that the risk of complications in the form of post-operative anastomotic stricture is higher than in the case of HJ. Although the bile flow remains more physiological (to the duodenum), CHD is associated with a higher rate of reflux from the gastrointestinal tract and recurrent bile duct inflammations associated with it (28). Moreover, it was observed that neoplasms within the biliary tract develop more frequently following CHD than HJ (29).

The presence of accessory bile duct of the right liver lobe (the duct of Luschka) is characterised by high individual variability, and it is estimated to occur in 1–50% of the population (30). Overlooking and failure to manage the duct of Luschka during cholecystectomy is usually caused by the variability of its localisation or too deep dissection within the gall-bladder bed (31). Routine usage of ERCP seems purposeful in the majority of patients with suspected iatrogenic BDI due to the possibility to assess the anatomy of the biliary tract with pinpointing the site and determining the extensiveness of damage. Moreover, simultaneous injury repair is also possible. Steward et al. proved that in as many as 96% of patients operated due to iatrogenic BDI without pre-operative ERCP, the repair procedure was associated with failure in its various aspects (18).

The application of the Amsterdam Classification, as a significant parameter that affects the selection of treatment, makes the qualification to a given repair procedure easier (32). The endoscopic repair of type A and C bile duct injury (according to the Amsterdam criteria) seems to be the method of choice in centres
with rich endoscopic experience, and the effectiveness of such a procedure is estimated at 89–100% (1). It must be emphasised that repair surgeries are ineffective in some patients. Moreover, possible subsequent repair surgeries are a considerable surgical challenge. The consequences may include biliary and intestinal fistulae connected with wound dehiscence, healing disorders and sometimes even septic state. The application of negative-pressure wound therapy seems fully justified in such cases. The therapy considerably improves the outcomes of open surgeries complicated with intestinal fistulae and treatment of biliary fistulae (33, 34).

Laparoscopic cholecystectomy has become the gold standard in treating cholecystolithiasis. The increased incidence of iatrogenic BDI following the introduction of LC is influenced by multiple factors. Longer learning curve and training of the surgical team that conduct LC are significant. The possibilities of iatrogenic BDI repair depend on anatomic aspects, type and degree of injury, technical possibilities and experience of the surgical team. Sometimes, multidisciplinary treatment is needed. The specificity of iatrogenic BDI management requires considerable experience and is burdened with a high risk of ineffectiveness. Therefore, it seems important to refer patients with confirmed and highly possible iatrogenic BDI to tertiary centres, and the surgeon who conducted the primary surgery should be present during the repair procedure.

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