

## Minimally Invasive Management of Post Hepatectomy Localized Bile Leak

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### Abstract

**Background:** Bilomas (localized bile leak) are localized post-operative collections of bile. Bile leakage is a common complication after hepatectomy with an occurrence rate of 2.9%-17%. Bile leak is always correlated to increased morbidity and mortality due to risk of serious biliary infection. Previously, biloma usually required reoperation. Yet surgical solution for bile leakage usually increases the incidence of patient morbidity and mortality especially in early post-operative period.

**Aim of Study:** The purpose of this study is evaluate non-surgical minimal invasive strategies as an effective choice in management of biloma (localized bile leak) and these include different strategies as minimally invasive US or CT guided percutaneous drainage with or without ERCP.

**Patients and Methods:** 20 patients were enrolled in our descriptive study (13 males, 7 females; mean age 49.40 ±9.30 years; range, 30 to 62 years) with biliary collections after open hepatectomy non of them had biliary reconstruction were treated using non-surgical methods between October 2017 and March 2019 at Al-Demerdash Hospital and Ain Shams University Specialized Hospitals and they were followed-up for at least 3 month. Percutaneous drainage using a 10Fr drainage catheter using US or CT guidance with/without (ERCP) were performed for management of those collections.

**Results:** Minimally invasive intervention could be successfully applied in all 20 cases. In all the cases, a pigtail was inserted for drainage, 17 cases (85%) were successfully drained and 3 cases (15%) weren't drained adequately due to extensive septations and they needed surgical intervention for drainage.

**Conclusion:** Non surgical (minimal invasive) management is an effective way in treating biloma (localized bile leak).

**Key Words:** Biloma – Pigtail – Post hepatectomy complication.

### Introduction

**BILOMAS** are defined as localised collections of bile, which occur in the post-operative period or as a result of some other invasive procedures

(intervention radiology, ERCP, liver biopsy, ...), in cases with the original injury in the bile duct bile usually accumulates in specific anatomical location which is in most cases identified by US and/or CT [1]. Biliary leak is a common complication after hepatectomy with an incidence rate of 2.9%-17% [2,3]. Post hepatectomy bile leak usually arise from the following sites; the cut surface of the transected liver and from suture line after biliary tract closure in formal hepatectomies or from the anastomosis if there is biliary reconstruction. Bile leakage may be life threatening due to risk of serious biliary infection, which may cause sepsis and septic shock that may impair quality of life, in addition to the financial burden on patients and society [4]. Previous literature reports cases of bile leak with major bile injury of large bilious volume in drains that required reoperation.

Furthermore, surgical therapy for bile leakage in the initial post-operative period is always risky and carries high morbidity and mortality incidence [5]. Recently excellent results of minimal invasive non surgical management of bile leak have made fundamental changes in treatment strategies [6]. Thus, currently, non-surgical treatment strategies is considered first line in the treatment plan of post-operative bile leakage in most of cases, and these include minimally invasive procedures such as percutaneous drainage with or without ERCP, biliary fistula ablation, Endoscopic Naso-Biliary Drainage (ENBD), or Percutaneous Transhepatic Biliary Drainage (PTBD). Sakamoto et al., had achieved promising outcome of non-surgical treatment for biliary collections after hepatectomy cases, which was categorized into two groups as with and without communication with the biliary system, the outcome in the communicating group showed better response to non-surgical management [2].

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**Aim of work:**

The aim of this study is evaluate non-surgical minimal invasive strategies as an effective choice in management of biloma (localized bile leak) and these include modalities such as Ultrasound (US) or CT guided percutaneous drainage with or without ERCP.

**Patients and Methods****Patients:**

20 consecutive patients were enrolled in our descriptive study. Patient characteristics are mentioned in (Table 1). All of them with Child-Pugh A score (13 males, 7 females; mean age  $49.40 \pm 9.30$  years; range, 30 to 62 years). All patients have biliary leak after open hepatectomy without biliary reconstruction and were managed using non-surgical methods between October 2017 and March 2019 at Al-Demerdash Hospital and Ain Shams University Specialized Hospitals and they were followed-up for at least 3 month. Of the 20 patients, 9 (45%) had Hepatocellular Carcinoma (HCC), 4 (20%) had colorectal liver metastases, 5 (25%) intrahepatic cholangiocarcinoma and 2 cases (10%) of hemangioma Fig. (1). 7 cases (35%) underwent segmentectomy (segments 2, 3, 4, 7, or 8), left hepatectomy was performed in 7 cases (35%) and right hepatectomy in 6 cases (30%) Fig. (2).

**Inclusion criteria:**

Patients underwent formal hepatectomy or segmentectomy with post-operative localized biliary collection.

**Exclusion criteria:**

- Hepatectomy with bilioenteric anastomosis.
- Patients that refused pigtail insertion or ERCP.

**Ethical consideration:** Informed consent was obtained from the patients, and this study was approved by Al-Demerdash Hospital Ethics Committee.

**Procedure:** Abdominal drains were removed a few days post procedure, when the drain fluid was clear and had decreased or disappeared. If bile leakage was suspected based on symptoms such as fever or jaundice, an ultrasound and Computed Tomography (CT) scan were performed to find any abdominal fluid collection. If bile leakage was indeed detected, percutaneous drainage using a 10Fr drainage catheter using US or CT guidance (Dawson-Mueller Multipurpose Drainage Catheter, Cook Medical) with/without Endoscopic Retrograde Cholangiopancreatography (ERCP) was performed. Bilirubin level from the drained fluid

is measured, if more than 3 fold serum level, this confirm it is bile. When the amount of bilious fluid in the drainage catheter was greater than 100mL per day and persisted for several days (3 or 4 days) after the initial procedure, ERCP was done to decompress the biliary tree.

If bile leakage had decreased significantly, or if it had nearly disappeared when evaluated by ultrasound, the percutaneous drain was removed. ERCP stent was removed after 3 month after confirming there is no leak. Antibiotic therapy was chosen based on bacterial cultures of the drainage fluid. Reoperation was considered only if these modalities failed. To summarize; our strategy for non-surgical management of bile leakage is to drain the biloma by percutaneous drainage and if the output is more than 100 per day for more than 3 days ERCP is done with stenting but if the pigtail output is persistently greater than 100cc or the biloma is not adequately drained from the beginning, due to extensive septations for example, then the patient undergo surgery.

**Statistical analysis:**

Data were coded and entered using the statistical package SPSS (Statistical Package for the Social Sciences) Version 23. Data were summarized using mean, standard deviation, median, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Comparisons between quantitative variables were done using Chi2 and paired *t*-test.

**Chi-square test:**

*p*-value >0.05 Non significant.

*p*-value <0.05 Significant.

*p*-value <0.01 Highly significant.

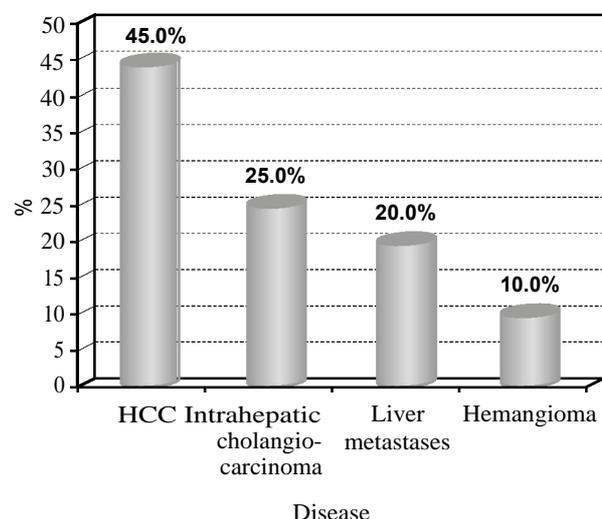


Fig. (1): Indications of hepatectomy.

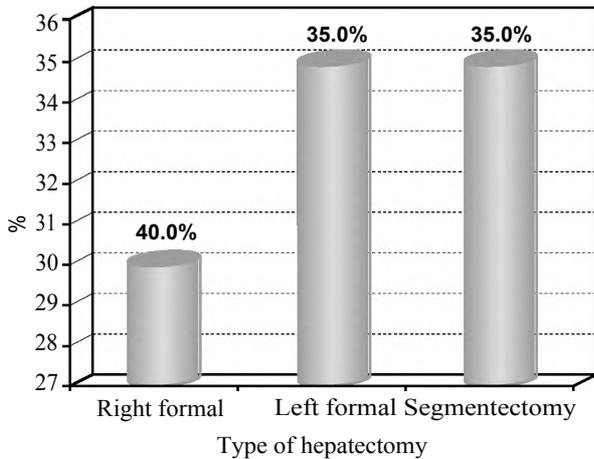


Fig. (2): Type of hepatectomy.

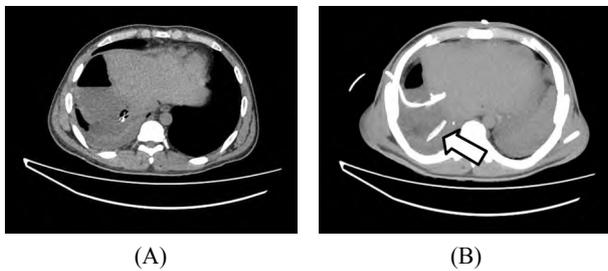


Fig. (3): Male patient 30 years with right lobe hemangioma underwent formal right hepatectomy (A) Shows cut surface biloma (B) Pig tail is inserted in the biloma CT guided narrow arrow and malpositioned surgical drain broad arrow.

Table (1): Patient characteristics.

	No.	%
<b>Disease:</b>		
• <b>HCC:</b>		
No	11	55.0
Yes	9	45.0
• <b>Intrahepatic cholangiocarcinoma:</b>		
No	15	75.0
Yes	5	25.0
• <b>Liver metastases:</b>		
No	16	80.0
Yes	4	20.0
• <b>Hemangioma:</b>		
No	18	90.0
Yes	2	10.0
<b>Type of hepatectomy</b>		
• <b>Right formal:</b>		
No	14	70.0
Yes	6	30.0
• <b>Left formal:</b>		
No	13	65.0
Yes	7	35.0
• <b>Segmentectomy:</b>		
No	13	65.0
Yes	7	35.0

**Results**

The outcomes after minimally invasive therapy for bile leakage are illustrated in (Table 2) and Fig. (4). Bile leakage was from the following sites; the cut surface of the liver in 6 cases (30%) and from the bile duct stump in 3 cases (15%), the site could be detected by the ERCP or during surgery but it was not identified in 11 cases (55%). The size of biloma was 234.5 134.3 8cc (100-600cc). Primary biliary intervention could be successfully applied in all 20 cases. For all cases combined, the mean interval from operation to primary biliary intervention (pigtail insertion) was 12.35±4.67 days (3-20 days), in 3 cases of which the biloma was formed on the 3rd, 4th and 6th days, although there were still drains in these cases but mostly they were malpositioned. In all the cases, a pigtail was inserted for drainage, 17 cases (85%) were successfully drained and 3 cases (15%) weren't drained adequately due to extensive septations and they needed surgical intervention for drainage.

Table (2): Outcomes after minimally invasive therapy for bile leakage.

	No.=20
<b>Site of leak:</b>	
Not identified	11 (55.0%)
Stump	3 (15.0%)
Cut surface	6 (30.0%)
<b>Size of biloma (cc):</b>	
Mean ± SD	234.50± 134.38
Range	100-600
<b>Interval from operation to primary biliary intervention (days):</b>	
Mean ± SD	12.35±4.67
Range	3-20
<b>Need for ERCP:</b>	
No	4 (20.0%)
Yes	16 (80.0%)
<b>Duration of drainage therapy (days):</b>	
Mean ± SD	8.95±4.58
Range	3-20
<b>Successful drainage of the pigtail:</b>	
No	3 (15.0%)
Yes	17 (85.0%)
<b>Need for surgery:</b>	
No	17 (85.0%)
Yes	3 (15.0%)

Of the 17 patients successfully drained by pigtail, 16 cases needed ERCP due to prolonged output in the drain (>100cc for more than 3 days), which represent 80% from the whole group. And in 4 cases (20%) the leakage did not need ERCP, 3 of them are the cases that underwent surgery.

Therefore, at the end of the study, only 3 patients (15%) needed surgical intervention and they didn't need ERCP.

No mortality or further morbidity occurred in the study group.

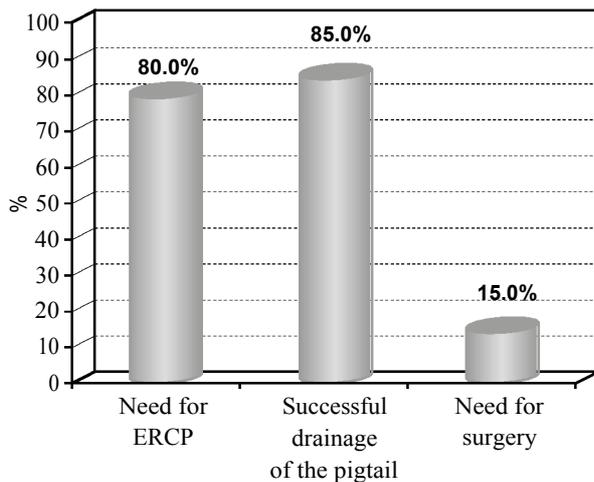


Fig. (4): Outcomes after minimally invasive therapy for bile leakage.

### Discussion

As mentioned before, bile leakage after hepatectomy is a common complication with high impact on patients and health institutes [2] and currently non-surgical treatment is being considered as first choice in the treatment of post-operative bile leakage.

In our study, the main concept of management is drainage by pigtail  $\pm$  ERCP for cessation of bile leakage, this strategy was successful in 17 cases out of 20 cases, the mean duration of drainage therapy was  $8.95 \pm 4.58$  days (range 3-20 days). In another study by T. Kimura et al., in 2018 about non-surgical management of post-hepatectomy biloma [7], they divided the type of biliary leak into two categories; with (central-type) and without communication (peripheral type) with the biliary system. Central-type leakage was mainly and effectively treated by PBLD and ENBD, which decrease internal pressure in the bile duct and reduce leakage volume, in case the ENBD failed the rendezvous technique was successfully used to decrease duct pressure in three of five central-type cases. All central-type leakage cases were treated within a median period of 316.8 days (range 145-531 days). On the other hand, for peripheral type leakage, PBLD was their first choice of treatment. Some unresolved cases of peripheral-type leakage required newer non-surgical interventional therapies, including biliary ablation with absolute ethanol.

Importantly, surgical intervention should be always considered if the different non-surgical techniques failed, surgical intervention should not be delayed when ever needed. In our study 15% of cases needed surgery due to inadequate drainage by the pigtail, the surgery was mainly for drainage and lavage and trial of cessation of bile leak, in one the cases the leakage was from the stump and could be secured by ligature, the other 2 cases the leakage was from the cut surface and stopped spontaneously.

In the previously mentioned study for T. Kimura et al., no cases needed surgical intervention, they owed that to using the appropriate technique according to type of leakage [7]. Sakamoto et al., (2016) had mentioned some cases that underwent reoperation as the non-surgical treatments failed [2]. In our study, 30% of the patients had right hepatectomy and 70% had underwent left hepatectomy and segmentectomy evenly distributed (35% each). Sakamoto et al., (2016) have stated that patients who underwent atypical resections (segmentectomy or central hepatectomy) were found to be at high risk for bile leakage [2]. Nagano et al., (2003) have demonstrated that hepatectomies, in which there is much exposure of the major Glisson's sheath or includes the hepatic hilum, are independent risk factors for bile leakage [8]. However, the relation between the post-operative bile leakage and type of hepatectomy has not yet been clearly defined, so prospective studies on this issue are necessary. Also the underlying disease is for further investigations for any relation to bile leak, in our study, 45% had HCC, 25% had cholangiocarcinoma, 20% liver metastases and 10% had hemangioma.

In our study, successful non-surgical management of bile leakage was achieved in 17 patients (85%), 16 of them required ERCP. Previous studies have announced cure rates ranging from 82%-90%, including endoscopic management [9-12]. The cure rate of drainage therapy achieved by our strategy is comparable to that mentioned in previous studies.

When considered in its entirety, our results indicate that non-surgical therapy for bile leakage after hepatectomy is adequately practical, efficient and safe.

*Limitations of the study:* A limitation of this study is that it's of relative small sample size. larger prospective studies are needed to determine the optimal strategy.

Another limitation is that our study is a single-center study.

**Conclusion:**

Minimal invasive non-surgical strategies are effective management for treating post-operative bile leakage.

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## تقنيات طفيفة التوغل في علاج تسرب السائل المرارى بعد إستئصال الكبد

مقدمة: إن تجمع السائل المرارى داخل تجويف البطن من المضاعفات المتكررة بعد عمليات الإستئصال الجزئى للكبد ونسبة حدوثها تتراوح بين ٢.٩ إلى ١٧٪. وقد يحدث هذا التجمع نتيجة تسريب من سطح الكبد المقسوم أو من مكان الغرز فى حالة غلق القناة المرارية فى حالة قطعها فى حالات إستئصال فص كامل من الكبد أو فى حالة توصيل القناة المرارية بالأمعاء.

إن التسريب المرارى له مضاعفات خطيرة قد تؤدى للوفاة مثل التسمم الذى يؤدى إلى صدمة تسممية بالإضافة إلى الأعباء المادية على الأفراد والمؤسسات المجتمعية.

والتدخل الجراحى فى هذه الحالات يحمل الكثير من المخاطر لهذا فإن التداخلات غير الجراحية لاقت قبولاً واسعاً مؤخراً لأن مخاطرها أقل مما أحدث طفرة نوعية فى علاج تلك المشكلة وهذا يشمل تركيب قسطرة تحت توجيه أجهزة الأشعة وكذلك يشمل منظار القنوات المرارية وحقن مادة لغلاق مكان التسريب وكذلك تركيب أنبوبة مرارية عن طريق الأنف والقسطرة الكبدية.

هدف العمل: هو دراسة جدوى التدخل غير الجراحى لعلاج تسريب وتجمع السائل المرارى بعد عمليات الكبد.

طريقة الدراسة: مجموع المرضى الذين خضعوا للدراسة ٢٠ مريض يعانون من تجمع سائل مرارى بعد عمليات إستئصال جزء من الكبد دون توصيل القناة المرارية بالأمعاء فى الفترة من شهرى أكتوبر ٢٠١٧ إلى مارس ٢٠١٩ فى مستشفى الدمرداش وعين شمس التخصصى وتمت متابعتهم لمدة ٣ شهور على الأقل. منهم ٧ حالات إستئصال جزئى للكبد وإستئصال الفص الأيسر فى ٧ حالات وإستئصال الفص الأيمن فى ٦ حالات.

معايير الإشتمال: المرضى الذين خضعوا لعمليات إستئصال جزئى أو نصفى للكبد ويعانون من تجمع مرارى بعدها.

معايير الإستبعاد: المرضى الذين خضعوا لتوصيل القناة المرارية بالأمعاء والذين يرفضون عمل منظار قنوات مرارية أو تركيب قسطرة فى التجمع.

الإعتبارات الأخلاقية: تم أخذ إقرار من جميع المرضى بموافقتهم على تلك الإجراءات بعد موافقة لجنة أخلاقيات مستشفى الدمرداش.

الخطوات: عند التحقق والتأكد من وجود تجمع سائل مرارى عن طريق السونار والأشعة المقطعية يتم تركيب قسطرة فيها ثم إذا إستمرت الكمية من تلك القسطرة أكثر من ١٠٠ سم لمدة أكثر من ٣ أيام يتم عمل منظار قنوات مرارية وتركيب دعامة ويتم إزالة تلك القسطرة بعد أن يتوقف السائل المرارى تماماً ويتم إزالة دعامة القناة المرارية بعد ٣ شهور.

النتائج: حجم التجمعات المرارية كان فى المتوسط (100-600cc)  $234.5 \pm 134.38$  cc. وتم عمل تلك القسطرة فى جميع الحالات. وكان متوسط المدة بين العملية الرئيسية تركيب القسطرة (3-20days)  $12.35 \pm 4.67$  days وقد تحسنت حالة ١٧ حالة منهم بعد تركيب القسطرة ٣ حالات فقط إحتاجوا إلى تدخل جراحى. وقد تم عمل منظار قنوات مرارية ل ١٦ حالة من ال ١٧. ولم تحدث أى مضاعفات أخرى نتيجة القسطرة أو المنظار ولم تحدث وفيات.

المناقشة: إن تلك الطريقة غير الجراحية أثبتت نجاحاً فى ١٧ حالة من ال ٢٠ بمتوسط مدة العلاج (Range 3-20 days)  $8.95 \pm 4.58$  days وفى دراسة مشابهة ل T. Kimura et al. فى عام ٢٠١٨ وجد أنه يمكن تقسيم التسريب المرارى إلى نوعين: تسريب مركزى متصل وتسريب طرفى غير متصل وإن التسريب المركزى أفضل إستجابة للتدخل بالمنظار المرارى وتركيب القسطرة فى التجمع.

ولكن يجب دائماً وضع التدخل الجراحى فى الإعتبار فى حالة فشل التداخلات الأخرى فى حل المشكلة جذرياً. فى دراستنا هذه ١٥٪ من الحالات إحتاجت تدخل جراحى لتفريغ التجمع ومحاولة إيقاف التسريب. ولكن فى الدراسة السابق ذكرها لم يحتاجوا إلى التدخل الجراحى فى أى من الحالات.

كذلك نوع إستئصال الكبد قد يكون له دور، ففي بحث Sakamoto et al. ٢٠١٦ وجد أن المرضى اللذين يخضعون لإستئصال جزئى غير تشريحي يعانون من التسريب المرارى أكثر من المرضى اللذين يخضعون لإستئصال التشريحي أى إستئصال نصف الكبد. الأيمن أو الأيسر وفى دراستنا وجد أن إستئصال الفص الأيمن يعانى بنسبة أقل من باقى الأنواع ولكن ذلك غير مؤثر إحصائياً.

الخلاصة: عند النظر فى مجملها، تشير نتائجنا إلى أن العلاج غير الجراحى لتسرب الصفراء بعد إستئصال الكبد هو فعال وآمن بشكل كاف.