Biliary leak after percutaneous biliary stenting: prevention with biopsy sealing device

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Aims and objectives

Over the past few decades, biliary interventions have improved notably. Current percutaneous biliary interventions include percutaneous transhepatic cholangiography (PTC) and percutaneous biliary drainage and stenting (PTBD), extremely useful both for benign and malignant lesions [1].

Among several complications following biliary stent placement (e.g. technical failure, stent migration, stent obstruction), abdominal pain related to biliary leak immediately after procedure seems to be one of the most frequent [2, 3].

Usually, the procedure requires placement of a 7 Fr sheath over a 0.35-inch guide-wire to facilitate the negotiation of the stricture [2,4].

Despite the lack of evidences at support, it is well known among interventional radiologists and surgeons that immediately after sheath removal, at the end of the procedure, a certain amount of bile goes throughout the proximal hole along the perihepatic area causing abdominal pain, nausea, and abdominal distention lasting for several days.

To lower the prevalence of periepatic biliary leak after percutaneous biliary stenting in order to reduce patients discomfort, we report our preliminary experience in using transhepatic compressed collagen foam plugs inserted into the sheath tract.
Methods and materials

This prospective, single-center, Health Insurance Portability and Accountability Act-compliant study was approved by our Institutional Review Board, and informed consent was obtained.

None of the Authors of this study is employ or consultant for industry or had control of inclusion of any data and information that could represent a conflict-of-interest. There was no industry support specifically for this study.

Population Study

Inclusion and Exclusion Criteria: 40 consecutive patients were prospectively enrolled to undergo biliary stenting at our academic medical centre. All patients, known to have primary pancreatic or biliary three cancer, were referred from the Gastroenterology, Hepatology and the Surgery Department based on results of prior imaging studies. Patients were randomly assigned, 1:1 ratio, in two groups: experimental, in which a compressed collagen foam plug was inserted into the sheath tract at the end of the procedure to reduce biliary leak; control group, in which the sheath was simply removed at the end of the procedure.

Subjects were considered not eligible if: (i) they were affected by benign biliary stricture, (ii) there were indication for endoscopic biliary stenting [1,5](iii) impaired coagulation (international normalized ratio #1.5 and platelet count #50,000/mm3 ) .

Biliary stenting procedure

The technique we currently routinely use involves the use of ultrasound guidance, a thin Chiba needle and a 0.014-inch guide-wire to gain access to the biliary system. A sheath is then placed over an 0.35-inch guide-wire and strictures are negotiated using standard 5-French angiographic catheters and hydrophylic guide-wires. For permanent stenting self-expandable metallic stents were used [4]. Transhepatic sheath tract occlusion with compressed collagen foam plug (Hunter, Vascular Solution) was performed in the 18 patients who were randomized into this group.

Prior to insertion of the plug, the sheath was pulled back under fluoroscopic guidance so that its tip extended no more than 2 cm into the intrahepatic biliary branch. The 3-cm-long plug was advanced into the sheath with a push rod stylet.

The outer sheath was then removed under fluoroscopic guidance, leaving the plug situated so that it extended through both the biliary branch and the liver parenchyma. Another plug was subsequently placed using the same approach, so that it extended
through both the liver parenchyma and the soft tissue of the thoracic wall (Figure 1). on page

All patients were positioned in supine position for at least 1h after the procedure and placed under nursing observation, which included regular vital sign checks for 2 hours. A short fluoroscopic examination was performed immediately after the sealing device placement in order to document any iodated biliary leak along the perihepatic area, and repeated after 10 minutes.

**Outcomes considered and Statistical Analysis**

The primary outcome was the prevalence of biliary leak documented immediately after procedure. Secondary outcomes included patient tolerance of the assigned procedure, prevalence of post procedural symptoms (nausea, abdominal pain) and major complications after treatment (sepsis, death).

Two days after the procedure, all patients were instructed to fill in a questionnaire to assess their acceptance. The questionnaire included a validated 100-mm (0 [best] to 10 [worst]) visual analogue scale (VAS) to gauge the intensity of discomfort after procedure, investigating nausea and abdominal pain (Figure 2).

Demographics and patient symptoms data were compared by Student's t-test for age after confirmation of a normal distribution, #² analysis for categorical variables, and Mann-Whitney U test for the visual analog scale

For all comparisons, statistical significance was assumed to be $P < 0.05$. All statistical analyses were performed by using a commercially-available statistical software package (MedCalc Statistical Software version 12.7, MedCalc Software bvba, Ostend, Belgium).
**Fig. 1:** The picture shows all the main steps of plug placement. In Figure a) is drawn the introducer sheath. In Figure b) it is possible to appreciate the advancement of the push rod stylet into the holding tube until the plug reaches the biliary branch. Figure c) shows the removal of the sheath and push rod stylet leaving the plug situated between the liver parenchyma and biliary branch.
**Fig. 2:** An example of VAS scale administered to patients after the procedure to assess the discomfort experienced.

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Fig. 3: Flowchart of study population enrollment.

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Fig. 4: Graphic representation of the prevalence of postprocedural biliary leak in the control group (83%, 15 of 18 patients) and in the plug group (5%, 1 of 18 patients).

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Fig. 5: Schematic representation of Hospital stay for the control group compared to plug group with a total amount of 8 days vs 5 days (30% increase in Hospital stay).

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Results

Figure 3 portrays the subjects' accrual flowchart. Four subjects were excluded from the study due to: (a) impossibility to get the intrahepatic biliary branch (n = 3) (b) suboptimal contrast material injection technique (n = 1). The final study cohort consisted of 36 patients (mean age, 60 ± 16 years; median age, 62 years; age range, 44-76 years), including 16 men (mean age, 62 ± 15 years; median age, 62 years; age range, 45-75 years) and 20 women (mean age, 58 ± 14 years; median age, 58 years; age range, 44-76 years). A total of 26 pancreatic adenocarcinomas were identified in 26 patients, and 10 extrahepatic cholangiocarcinoma in 10 patients. For all lesions the diagnosis was confirmed with biopsy (n=10) and/or was established on the basis of typical findings on MRI or CT examination.

The prevalence of postprocedural biliary leak was 83% (15 of 18 patients) in the control group and 5% (1 of 18 patients) in the plug group (Figure 4). That differences was statistically significative (P = 0.002). None of patients in both groups required abdominal drainage.

Hospital stay was longer for the control group compared to plug group with a total amount of 8 days vs 5 days (30% increase in Hospital stay, P = 0.03) (Figure 5).

Abdominal pain perceived after procedure were significantly higher for the control group (5 ± 2 vs 3 ± 2; P = 0.032). Concerning complication related to standard procedure (no Hunter group) has been noticed a single case of minimal bleeding (n = 1) and a single case of infection evolved in sepsis (n=1).

No complications related to plug placement were noted. No local morbidity, in the form of abscess formation, was observed at the site of the plugs in patients.
Conclusion

Our preliminary study has shown an important decrease of post-procedural biliary leakage (5% of the plug group compared to 83% of the control group).

Moreover has been underlined the related reduction of post-procedural discomfort, expressed through the lowest values reported in the VAS scale (3 ± 2 vs 5 ± 2;) and reduction of Hospital stay (30% decrease) both for the plug group. These results, as the only variable between the two groups was the affixing of the plug at the end of the procedure, are most probably to be ascribed to the reduction of the leakage of biliary fluid that could irritate the surrounding tissues causing pain or inflammation[7].

In conclusion, although the study has several important limitations such as the small sample of patients and the difficulty in distinguishing with absolute certainty the tenderness of patients due to the procedure by the perceived pain of their underlying disease, data from our preliminary clinical series of prospectively-enrolled patients render a proof-of-concept and foundation for the use of a sealing device with a compressed collagen foam plug in to prevent the development of complication related to biliary leak following biliary stenting.
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