Ex Vivo Evaluation of the ArtVentive EOS Occlusion Device for the Management of Biliary Leaks

Verschluss von Gallengangleckagen mit dem EOS Device von ArtVentive, eine Ex-vivo-Versuchsreihe

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ZUSAMMENFASSUNG

Ziel Die perkutane Behandlung von postoperativen Gallenleckagen ist eine zunehmend geforderte Intervention, die jedoch technisch anspruchsvoll und meist auf kleinere Leckagen beschränkt ist. Das Ziel dieser Ex-vivo-Studie war es, die okklusiven Eigenschaften des ArtVentive EOS für den Verschluss von Gallengangleckagen und Ductus-cysticus-Insuffizienzen zu untersuchen.

Materialen und Methoden Das verwendete Okklusions-Device – EOS – besteht aus einer ablösbaren, mit ePTFE überzogenen Nitinolspirale. Mittels EOS-Device wurden in insgesamt 5 explantierten Schweinelebern und 3 explantierten Rinderlebern künstlich geschaffene Gallenleckagen okkludiert. Nach Schaffung eines transhepatischen Gallengangzugangs in üblicher PTCD-Technik und Einwechslung einer 6F-Schleuse wurden über einen 6F-Führungskatheter die Gallenleckagen mit 5-mm- und 8-mm-EOS-Devices verschlossen. Mit dem 5-mm-Device wurden periphere (n = 3), zentrale (n = 1) und Ductus-cysticus-Leckagen (n = 1) verschlossen, während mit dem 8-mm-Device periphere (n = 1), zentrale (n = 1), Hauptgang- (n = 1) und Ductus-Leckagen (n = 2) verschlossen wurden. Ergebnisse: Selektives Freisetzen unmittelbar vor und sofortige Okklusion von zentralen Gallenleckagen (3/3) und Ductus-cysticus-Leckagen (3/3) war in allen Fällen mit dem EOS-Device erfolgreich. Periphere Gallenleckagen konnten in 3 von 4 Fällen nicht selektiv katheterisiert werden, sodass eine Platzierung des Device einige Millimeter proximal der Leckage notwendig war.

Schlussfolgerung Die selektive und sofortige Okklusion von Ductus-cysticus-, zentralen und größeren peripheren Gallenleckagen mit dem EOS ist ex vivo technisch in einer Sitzung machbar.

Kernaussagen

- Aufgrund des flüssigkeitsundurchlässigen ePTFE-Überzugs genügt ein EOS-Device zum Leckageverschluss.
- Mittels EOS-Device können zentrale und größere periphere Gallengangleckagen selektiv verschlossen werden.
- Ein selektiver Verschluss kleinerer Gallengangleckagen ist mit dem EOS-Device nicht möglich.

ABSTRACT

Purpose Percutaneous treatment of biliary leaks is frequently required, yet technically challenging and limited to smaller fistulas. This study sought to evaluate the off-the-shelf use of the ArtVentive EOS device for the occlusion of biliary or cystic stump leaks.

Materials and Methods ePTFE-covered ArtVentive EOS devices were used to perform biliary leak embolization in 5 explanted porcine livers and in 3 explanted bovine livers. After establishing standard percutaneous transhepatic biliary drainage access, artificially created biliary leaks were occluded using 5 & 8 mm EOS devices. Using the 5 mm device, peripheral (n = 3), central (n = 1) and cystic duct leaks (n = 1) were occluded. Using the 8 mm device, peripheral (n = 1), central (n = 1), main (n = 1) and cystic duct leaks (n = 2) were occluded. Total leak occlusion was controlled by cholangiography.

Results Selective deployment and occlusion of central biliary leaks (3/3) and cystic stump leaks (3/3) was successful in all cases. Peripheral leaks could not be selectively catheterized

in 3 out of 4 cases, making device deployment several millimeters proximal to the leaks necessary.

Conclusion Selective occlusion of the cystic stump, central biliary, and larger peripheral biliary leaks using the EOS device is technically feasible ex-vivo in a single setting.

Key points

- Due to the impermeable ePTFE membrane, one EOS suffices to completely occlude biliary leaks.
- The EOS enables selective occlusion of central and larger peripheral biliary leaks.
- Smaller biliary leaks cannot be treated selectively with the EOS.

Citation Format

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Background

Biliary leaks are common and potentially dangerous complications of open or laparoscopic hepatic surgeries including segmental resection or hemihepatectomy [1]. Cystic duct leaks are the most common complication following cholecystectomy [2]. Traditionally, intrahepatic biliary leaks required hepatic resection [3], bile duct reconstruction [4] or fistula enterostomy [5], while cystic duct leaks required re-laparotomy and oversewing. Nowadays, repeat surgery can be avoided in the majority of patients by the endoscopic placement of a biliary drainage catheter, unless biliodigestive anastomosis prohibits access. However, up to 10 % of biliary and cystic stump leaks are refractory to drainage therapy [6]. Although several techniques have been proposed for the treatment of biliary and cystic stump leaks, implementation of most techniques is challenging with a risk of over embolization and unintentional occlusion of adjacent biliary ducts. Furthermore, clinical experience with these techniques in the biliary system is either unavailable or limited to a few patients, and clinical success rates are often not satisfactory [7].

Recently the Endoluminal Occlusion System (EOS, ArtVentive Medical Groups Inc, Carlsbad, CA/USA) was approved for the endovascular embolization of medium to large vessels as an alternative to coils or vascular plugs [8]. Since then, vascular and non-vascular applications have been described, including the treatment of arteriovenous malformations, acute hemorrhages, pelvic congestion syndrome with venous insufficiency and ureteral leaks [9 – 12]. We hypothesized that the EOS occlusion device with its impermeable expanded polytetrafluoroethylene (ePTFE) membrane radially covering a strong self-expandable scaffold may be used as an uncomplicated and commercially available alternative for the occlusion of certain biliary and cystic stump leaks. The purpose of this study was therefore to evaluate the occlusive properties of the EOS occlusive device in the biliary system in an ex vivo experiment.

Methods

Experiments were performed by two radiologists (5 and 4 years of interventional experience) on a total of eight explanted livers (5 porcine and 3 bovine) with preserved biliary systems and gallbladders. Interventions were performed between 12 – 18 hours after explantation. After the creation of bile leaks (details below), their occlusion was attempted using the ArtVentive EOS occlusion device. The device is comprised of a nitinol spiral covered by an ePTFE membrane. The device is preloaded on a double-step detachment system with a double lever pull mechanism enabling precise positioning before final device release. Ten ArtVentive EOS devices with diameters of 5 and 8 mm (five each) were used. ▶ **Fig. 1** depicts device configuration and detachment.

Experimental setup

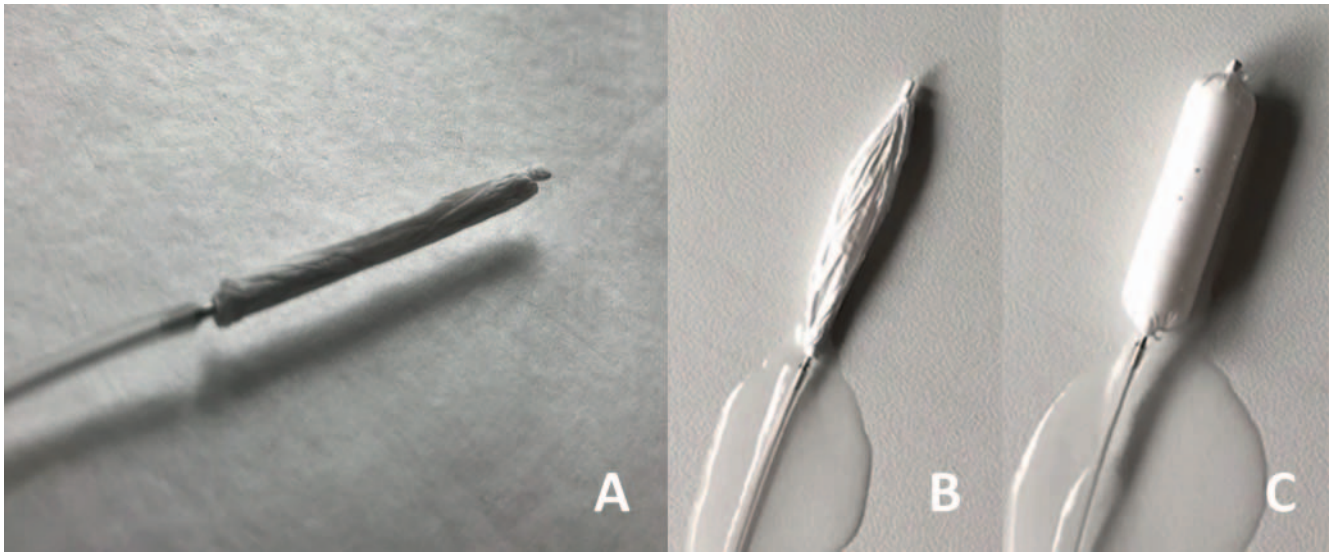
Examinations were performed and documented on a Philips Allura Xper FD30 X-ray system.

The common bile duct which had been severed during explantation in all livers was probed with the sheath of an 18G Arrow needle (Teleflex Incorporated, Wayne, PA/USA) over which a retrograde cholangiography was performed. A peripheral bile duct was then punctured using the common fluoroscopy-controlled technique for transhepatic biliary drainage access [13].

After sequential dilation of the puncture tract, a 6F sheath was advanced into the biliary system. The severed main bile duct was then oversewn in 7 out of 8 cases to prevent extravasation during further cholangiographies. Peripheral (n = 4; 3 in porcine liver, 1 in bovine liver) and central (n = 2; 1 in porcine liver, 1 in bovine liver) biliary leaks were artificially created by perforating a peripheral or central biliary duct with the stiff end of a Terumo J-Wire. Subsequent cholangiography was performed to document the location and extent of biliary leaks.

Cystic stump leaks (n = 3; 1 in porcine liver, 2 in bovine liver) were created by severing the cystic duct with a scalpel. One severed main biliary duct (bovine liver) was not oversewn and main biliary duct embolization was attempted.

Depending on the diameter of the biliary duct containing the leak a 6F guiding catheter was advanced via the peripherally introduced 6F sheath to a position immediately proximal to the biliary fistula/cystic stump leak (“selective position”) or to a position where further peripheral advancement of the catheter was not possible (“proximal position”). Repeat cholangiography was performed via the 6F guiding catheter to confirm the exact position and the extent of the biliary leak. The EOS was advanced out of the catheter and deployed according to the manufacturers’ instructions. This deployment is a two-stage process: First the proximal end of the implant is released with the proximal pull of the system. At this point repositioning is still possible. In the case of satisfactory positioning, the distal end of the implant was released with the distal pull, thereby unloading the entire device.



▶ **Fig. 1** EOS device deployment **A** Device with unfolded ePTFE membrane and crimped nitinol spiral. **B** Partially inflated ePTFE membrane, the nitinol spiral is still crimped. **C** Completely inflated ePTFE membrane, the spiral can now be released followed by detachment of the device.

▶ **Abb. 1** EOS-Freisetzung **A** EOS-System mit gefalteter ePTFE-Membran und gecrimpter Nitinolspirale. **B** Partiell inflatierte ePTFE-Membran, die Nitinolspirale ist weiterhin gecrimpt. **C** Vollständig entfaltete ePTFE-Membran, die Nitinolspirale kann jetzt freigesetzt werden.

If selective catheterization was possible in the bovine/porcine model, the ArtVentive EOS was advanced into a position where the tip of the occlusion device minimally protruded out of the insufficient bile duct. Doing so achieved selective embolization of biliary leaks while preventing device dislocation and ensuring the least possible over-embolization. After successful deployment, cessation of biliary leaks was evaluated by repeated cholangiography via the 6F catheter.

Results

Results are summarized in ▶ **Table 1**. Deployment of the ArtVentive EOS occlusion device was technically straightforward and successful in all cases. All peripheral leaks (n = 4), central leaks (n = 2), cystic stump leaks (n = 3) and the common bile duct leak (n = 1) were resolved after placement of the occlusive device.

Peripheral bile leak occlusion was attempted in one instance with the 8 mm device and in three instances with the 5 mm device. The device had to be deployed several millimeters proximal to the leak ("proximal position") in one instance using the 8 mm device (bovine liver) (▶ **Fig. 2**) and in two instances using the 5 mm device (porcine liver). In one instance (5 mm device), selective occlusion of peripheral biliary leaks could be performed (▶ **Fig. 1**). In all cases leaks were no longer evident following placement of the occlusive device.

Central bile leaks were immediately and completely occluded following selective placement of both a 5 mm and an 8 mm device. Cystic stump leak occlusion was successful in all three instances using one 5 mm device and two 8 mm devices (▶ **Fig. 3**). Common bile duct occlusion was successfully performed with an 8 mm device in one instance.

Discussion

Biliary leaks from central or peripheral bile ducts are serious and common (up to 12 %) complications following major hepatic surgery [1], while cystic stump leaks are a frequent complication following cholecystectomy [2], especially if the procedure is performed laparoscopically. Both types of leaks constitute a serious and difficult management problem.

Patients with biliary leaks typically present with postoperatively increasing, localized or diffuse abdominal pain, increasing fever and biliary secretion from wound drains. If biliary leaks remain untreated, they may result in peritonitis, abscess formation and/or sepsis. Patients with biliomas and signs of infection should receive immediate administration of broad-spectrum antibiotics followed by specific antibiotic therapy after microbiological testing. Apart from medical therapy, several invasive as well as minimally invasive therapeutic approaches are available for the treatment of biliary leaks.

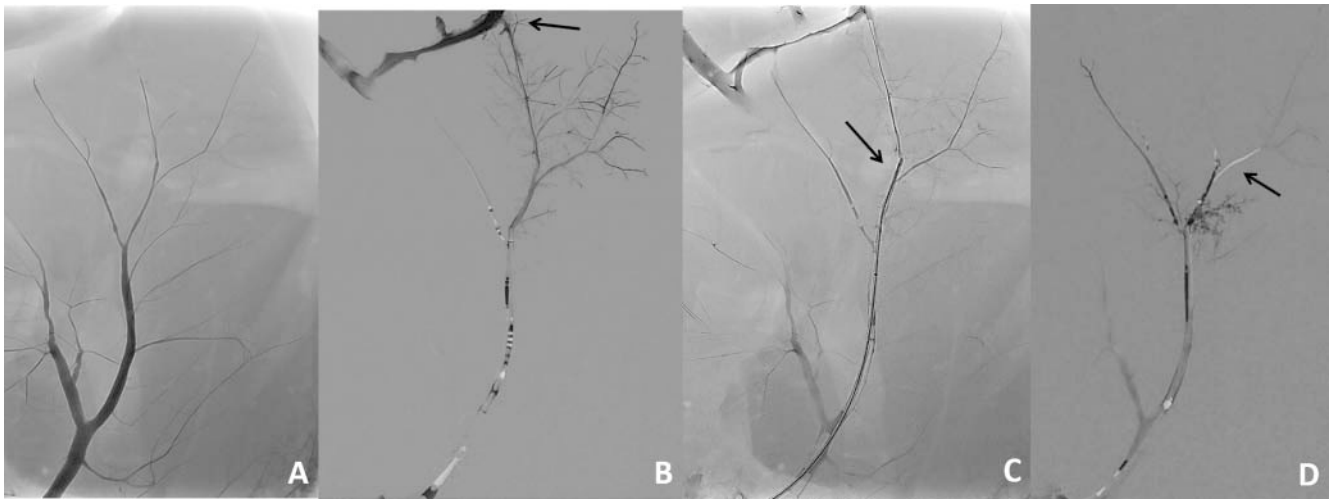
Multiple classifications have been developed to categorize biliary leaks [14, 15]. Although the location of bile duct injury/insufficiency is of central relevance for treatment, as recently highlighted by Schaible et al. [16], the currently available classifications are rather based on the extent of leak and the type of treatment mandated. In our opinion, the classification Nagano et al. [17] introduced is most suitable, as it allows for the differentiation of minor and major leaks, is easily applied and the indication for the treatment of biliary leaks can be based on it:

- Type A leaks: Minor biliary leaks from peripheral bile ducts on the surface of the liver.
- Type B leaks: Severe biliary leaks from major bile duct branches.
- Type C leaks: Biliary leaks following injury to the main duct.
- Type D leaks: Biliary leaks following partial segmentectomy with discontinuity of a biliary duct.

▶ **Table 1** Location of biliary leak, device used and position in which the device could be deployed. Selective position: selective catheterization of insufficient bile duct possible, deployment of the ArtVentive EOS device directly into the leak; proximal position: selective catheterization of insufficient bile duct not possible, deployment of the device several millimeters proximal to the leak.

▶ **Tab. 1** Lokalisation der Gallengangleckage, verwendetes System und Position, in der das System abgesetzt werden konnte. Selective position: Selektive Katheterisierung des insuffizienten Gallengangs möglich, genaue Platzierung des EOS-Systems in Leckageposition; Proximal position: Selektive Katheterisierung des insuffizienten Gallengangs nicht möglich, Platzierung des EOS-Systems mehrere Millimeter proximal der Leckage.

	5 mm EOS		8 mm EOS	
	selective position	**proximal position**	**selective position**	**proximal position**
peripheral	1	2		1
central	1		1	
cystic	1		2	
main duct			1	



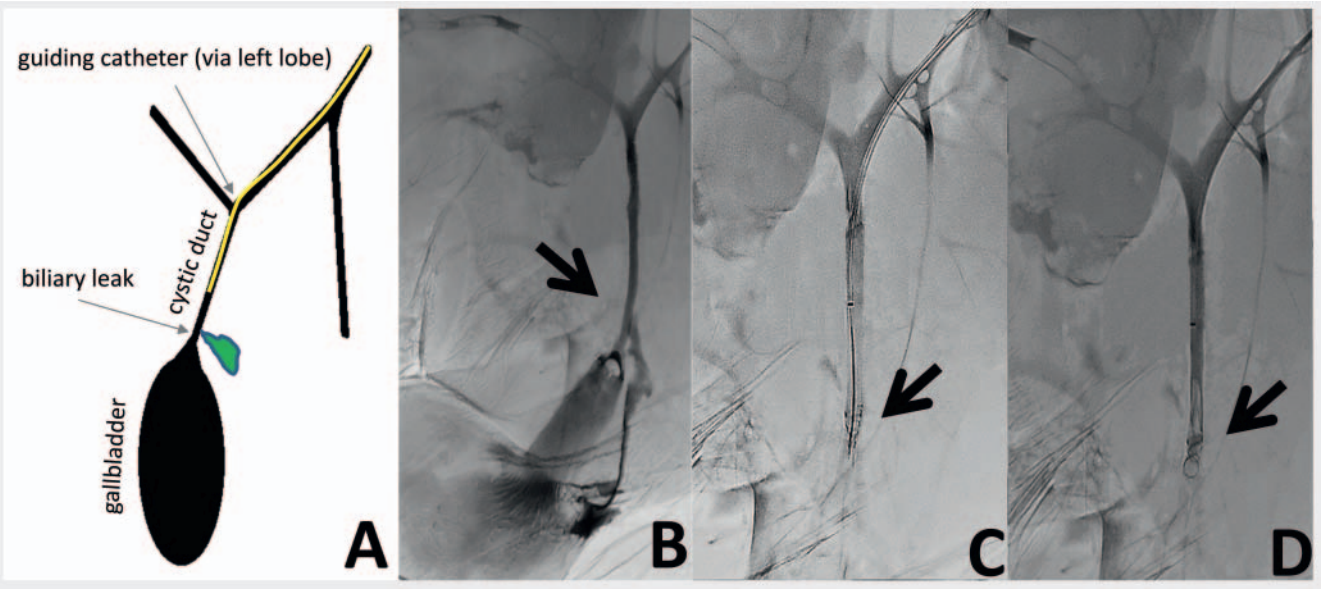
▶ **Fig. 2** Peripheral leak in a bovine model **A** Cholangiography of an intact biliary segment. **B** Cholangiography performed via a 6 F catheter after creating an artificial leak (arrow) in a small, peripheral biliary duct. Note that the 6F catheter cannot be manipulated more distally. **C** Deployment of an 8 mm ArtVentive EOS, the tip of the device is located in the proximal segment of the leaking biliary duct (arrow) [“proximal position”]. **D** Follow-up cholangiography following biliary occlusion, the leak is no longer evident. Note that the adjacent biliary duct was also occluded (arrow).

▶ **Abb. 2** Periphere Gallengangleckage – Rinderleber **A** Cholangiografie eines intakten Gallengangsegments. **B** Über einen 6F-Katheter durchgeführte Cholangiografie: künstliche Gallenleckage (Pfeil) in einem kleinen, peripheren Gallengang. Der 6F-Katheter kann nicht weit genug nach distal bis an die Leckage manipuliert werden. **C** Platzierung eines 8-mm-ArtVentive-EOS-Device: Die Spitze des Systems erfasst zwar den Gallengangast mit der Leckage, angrenzende Gallengangäste werden jedoch auch verlegt (Pfeil) [„proximale Position“]. **D** Cholangiografie nach Gallengangverschluss. Die Leckage ist nicht mehr abzugrenzen, angrenzende Gallengänge sind jedoch ebenfalls verschlossen (Pfeil).

Type A leaks are typically self-limiting. Associated biliomas can be managed with perioperatively or postoperatively placed wound drains [18].

Type B and C leaks usually respond to endoscopic or percutaneous placement of biliary drainage/plastic stents and sphincterotomy [19, 20]. However, up to 10 % of biliary leaks are refractory to drainage therapy [6], requiring additional surgical therapy or percutaneous embolotherapy.

Type D leaks typically require a combination of surgical therapy and percutaneous embolotherapy [17]. Several different interventional approaches have been proposed for the minimally invasive treatment of biliary leaks. The main materials that have been studied as potential sealants of the biliary ducts are fibrin [21], ethanol [22], glue [23], covered stents [24], vascular plugs [25] and coils [26]. Although most of the abovementioned techniques have several drawbacks [21, 27], they are still employed, as there is a lack of dedicated techniques/devices enabling technically simple and efficient occlusion, especially of larger biliary leaks [17]. Fibrin is difficult to apply over long distances and necessitates a double lumen application catheter to avoid unwanted early clotting. Furthermore, fibrin has been shown to be less effective in inflammatory situations [21, 27], rendering the therapy ineffective for superinfected biliomas. Ethanol has been used to successfully occlude biliary-cutaneous leaks. However, as ethanol may cause



▶ **Fig. 3** Cystic stump leak in a bovine model. **A** Schematic drawing of experiment set up. **B** Cholangiography performed via a 6 F catheter after partially severing the cystic duct (arrow). **C** Placement of an 8 mm ArtVentive EOS (arrow) in the cystic duct, proximal of the leak. **D** Follow-up cholangiography following cystic duct occlusion, the leak is no longer evident.

▶ **Abb. 3** Ductus-cysticus-Leckage – Rinderleber **A** Schematische Zeichnung des Untersuchungsaufbaus. **B** Über einen 6F-Katheter durchgeführte Cholangiografie nach partieller Durchtrennung des Ductus cysticus (Pfeil). **C** Platzierung eines 8-mm-ArtVentive-EOS-Device (Pfeil) im Ductus cysticus, proximal des Lecks. **D** Cholangiografie nach Okklusion des Ductus cysticus. Das Leck ist vollkommen verschlossen.

necrosis of the bile duct epithelium leading to irreversible damage and possible further biliary complications [28], intrabiliary ethanol application as well as application in biliomas directly communicating with the biliary system should be avoided [27]. Vascular plugs and coils can only achieve total biliary occlusion when combined with glue or fibrin, as the biliary system has no inherent clotting capabilities. Although hydrocoils have been successfully used to occlude biliary leaks [26], the risk of malconfiguration with consecutive over-embolization persists. Covered stents carry a risk of unintentional occlusion of adjacent biliary ducts and post-interventional cholangitis [29].

Although biliary duct embolization using glue (mostly n-Butyl-2-Cyanoacrylat (NBCA)) combined with vascular coils appears to be the most promising technique for biliary fistula occlusion, with good results concerning technical success [7], these techniques require advanced technical expertise. NBCA can spread distally or proximally to the intended application position leading to unintentional over-embolization [30] with consecutive segment atrophy or accidental intrabiliary fixation of the catheter.

The ArtVentive EOS device recently received FDA and European CE approval for the occlusion of blood vessels. In theory the EOS design which consists of an impermeable ePTFE-covered nitinol spiral allows for immediate vascular and non-vascular lumen occlusion independent of coagulation and polymerization times. This, in addition to the shortcomings of existing options for biliary occlusion, prompted us to perform this experimental study.

The main finding of this study is that the ArtVentive EOS allows precise and immediate occlusion of both larger biliary duct leaks and cystic stump leaks.

Type A leaks, as can be seen in ▶ **Fig. 2**, could not be treated selectively in all cases. Especially in the case of very peripheral leaks that were not reachable with the 6F guiding catheter, occlusive devices had to be placed several millimeters proximal to the biliary leak, while inevitably occluding adjacent peripheral biliary ducts and secluding the leaking segment. Although both the bovine anatomy and the porcine biliary duct anatomy differ from the human biliary duct anatomy, the same technical difficulties are to be expected in humans in the case of biliary leaks from smaller peripheral biliary ducts.

However, as most type A biliary leaks respond to wound drainage therapy or endoscopic therapy [17, 18], these leaks will only rarely require additional percutaneous treatment. Furthermore, it can be expected that in most cases treatment of small peripheral biliary leaks is also possible with “unselective” proximal biliary occlusion with the ArtVentive EOS, as the reduction of biliary inflow from adjacent segments should suffice for the cessation of a small peripheral leak. However, in the case of persistence of a peripheral biliary leak following proximal occlusion, the ePTFE-covered ArtVentive EOS itself would prevent alternative percutaneous embolization treatments. Therefore, in drainage-refractory small peripheral leaks that are not accessible with a 6F catheter, other embolic materials such as coil or glue should be considered.

Both the 5 mm and the 8 mm device are deployed via a 6F guiding catheter. Therefore, the limiting factor for placement is rather the catheter than the device itself. These limitations apply likewise for vascular applications (e. g., acute hemorrhages from small caliber vessels). Therefore, it remains to be seen whether smaller ArtVentive EOS devices will be developed, which allow for placement via a 5F or 4F catheter.

Previously percutaneous treatment was limited to smaller biliary leaks [17]. This was mostly due to the increased risk of peritoneal spilling during glue embolization as well as the increased risk of coil malconfiguration during treatment of leaks from larger biliary ducts.

Larger peripheral biliary duct leaks and central biliary leaks (type B) could be successfully treated with the ArtVentive EOS with the placement of a single device in all cases. The device design and the deployment technique allowed for precise placement in larger biliary leaks, meaning adjacent side branches could be spared from occlusion (▶ **Fig. 1**). Due to the two-lever deployment mechanism, which enables controlled repositioning and deployment, extrahepatic device dislocation was not observed in any of the cases and is unlikely to occur in vivo.

Furthermore, total occlusion of a severed main biliary duct (type C leak) was successfully performed using a single 8 mm ArtVentive EOS device. Although main biliary duct occlusion has no clinical applicability, it was performed in the bovine model where the diameter averaged 6 – 9 mm to further prove occlusion of large biliary leaks is feasible using the ArtVentive EOS.

Type D leaks are ideally treated with combination therapy using both percutaneous embolotherapy and surgical resection of the segregated segment [17]. Although this scenario was not tested ex vivo, we believe that larger type D leaks, analogous to type B and C leaks, may also be successfully treated with the ArtVentive EOS.

Cystic stump leaks, which are not covered by the Nagano classification, could be successfully treated with both the 5 mm and the 8 mm device without occlusion of adjacent biliary ducts.

Although complete occlusion of larger biliary duct and cystic stump leaks was achieved in all cases using both the 5 mm and the 8 mm EOS, size-dependent advantages of both devices should be considered. Both the 8 mm and the 5 mm devices are not expected to fully expand in peripheral biliary ducts. As the EOS device foreshortens during expansion, the less the device can expand the longer it remains. The 8 mm device, both "crimped" and expanded, is longer than the 5 mm device, so that the device covers a longer intrabiliary distance and therefore potentially more biliary side branches. Hence, the 5 mm device should be preferred for peripheral leaks. Although cystic stump occlusion was possible with both the 5 mm and the 8 mm devices in the bovine model, central biliary leaks in human livers (e. g. after hepatectomy) and cystic stump leakages may be larger than 5 mm, especially in patients with ectatic biliary systems. Therefore, the 8 mm system may be preferred.

The current study is limited by the experimental character. Although these preliminary results are encouraging, the optimal device size for human use cannot be concluded. Anatomical differences between human and porcine/bovine livers were not addressed in this feasibility study (e. g., the relatively steep angled ostium of the cystic duct in humans). In addition, examinations were performed in explanted livers at room temperature. As the EOS consists of a nitinol spiral, the temperature-dependent inherent memory effects did not reach full extent during in-vitro examinations. Procedures were performed under sterile conditions, further examinations are necessary to evaluate whether the ePTFE-covered EOS device may be used in an infective setting, or whether bacterial colonization of the ePTFE-covered membrane is to be expected. Additionally, as this was a feasibility study, long term data regarding device stability and durability are lacking. Further studies are warranted to assess the in vivo occlusive capabilities, including the ability to withstand respiration-associated liver motion without dislocation or device dysfunction.

Conclusion

The results from this experimental study indicate that occlusion of medium and larger diameter biliary leaks and cystic stump leaks using the ArtVentive EOS is feasible in a single session in an ex-vivo setup. If percutaneous embolotherapy is required for smaller, peripheral biliary leaks, which are not accessible with the 6F deployment catheter, other embolization techniques may be preferred.

Clinical Relevance

1. Biliary leaks can be difficult to manage clinically. Larger leaks frequently persist despite drainage therapy.
2. Especially larger leaks may be technically challenging to occlude with standard embolization materials (e. g., coils, glue) due to the risk of spilling and accidental over-embolization.
3. The EOS, a new embolization device, allows the immediate and precise occlusion of larger biliary leaks.
4. The EOS device may be an alternative to repeat surgery in patients with larger biliary leaks where drainage therapy fails.

Conflict of Interest

The authors declare that they have no conflict of interest.

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