

Interventional endoscopic ultrasound: A new promising way for intrahepatic portosystemic shunt with portal pressure gradient

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ABSTRACT

Background and Objectives: Interventional endoscopic ultrasound (EUS) is a promising novel approach for intravascular interventions. The aim of this study was to assess the feasibility and safety of a EUS-guided intrahepatic portosystemic shunt (EGIPS) with portal pressure gradient measurement in a live porcine model. **Methods:** The left hepatic vein (LHV) or the inferior vena cava (IVC) was punctured with a needle that advanced into the portal vein (PV). A guidewire was then inserted into the PV, and a needle knife was used to create an intrahepatic fistula between LHV and PV. Portal pressure was recorded. The fistula was dilated with a balloon and a biliary metal stent was deployed between LHV and PV under sonographic and fluoroscopic observation. A portocavography validated the patency of the stent. Necropsies were realized after euthanasia. **Results:** Portosystemic stenting was achieved in 19/21 pigs. Final portocavography confirmed stent patency between PV and LHV or IVC in 17 pigs (efficacy of 81%): Four stents were dysfunctional as two were thrombosed and two were poor positioned. Portal pressure was documented before and after shunting in 20/21 pigs. Necropsies revealed that 19/21 procedures were transesophageal and two were transgastric. Hemoperitoneum and pneumothorax were found in one pig and hemothorax was found in two pigs. Morbidity was 14.2% (3/21 animals). **Conclusion:** EGIPS was feasible in 91% of cases, functional in 81%, with 14.2% per procedure morbidity. EGIPS still needs to be assessed in portal hypertension pig models with longer follow-up before being considered as an alternative when the transjugular intrahepatic portosystemic shunt fails.

Keywords: Interventional endoscopic ultrasound, portosystemic shunt, porcine model, portal pressure gradient, transjugular intrahepatic portosystemic shunt

INTRODUCTION

Transjugular intrahepatic portosystemic shunt (TIPS) is used as a rescue treatment for hemorrhage induced by portal hypertension and uncontrolled by medical

and endoscopic treatment and in refractory ascites.^[1-6] TIPS is also a first-line treatment in Child B patients

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with active bleeding or Child C patients^[7] and can also be performed in patients with portal vein (PV) thrombosis.^[8]

The technical success of TIPS is close to 90%.^[9] The main technical difficulty is the identification and catheterization of the intrahepatic portal branch as radiologists tend to use angiography more often than real-time ultrasound. The portal branch is located in an anterior-inferior position compared to the path of the right hepatic vein, and its intrahepatic length can vary from 20 to 60 mm depending on size of the liver. A portosystemic anastomosis becomes trickier to realize when the liver is small or refractory ascites are present. The ideal stent position is between a right portal branch, without occluding the lumen of the PV and the right hepatic vein near the caval ostium. Technical variations are possible, especially a median hepatic vein/right portal branch approach, but the alternative left hepatic vein (LHV)/left portal branch is rarely performed radiologically.

The combination of purely technical difficulties cumulated with difficulties tied to anatomic variations and liver dysmorphia results in a roughly 10% failure rate with the radiological approach^[9] increasing to 15 or even 30% in cases of portal thrombosis in cirrhotic patients, especially in patients presenting chronic thrombosis associated with cavernoma or a right or left intrahepatic portal thrombosis.^[7] If TIPS fails, the patient is often in a position of therapeutic impasse given the morbidity and mortality of surgical portosystemic shunts, which have thus been slowly abandoned.

The transgastric endoscopic ultrasound (EUS) approach emerges as a promising new way to access the PV.^[10,11] Approaching the PV by puncture followed by an EUS-guided catheterization allows performance of portal angiography and portal pressure measurements in healthy animals.^[12-14] This new method to access the portal system^[15] opens perspectives for the realization of portosystemic shunts and could be used in cases where TIPS fails.

Objective

The aim of this study was to evaluate the feasibility, efficacy, and morbidity of the creation of a EUS-guided left intrahepatic portosystemic shunt with pre- and post-shunt portal pressure measurement, in a healthy porcine model.

METHODS

Procedures were performed by an experienced endoscopist (LP) and a vascular radiologist (PC) in an experimental vascular catheterization room equipped with a digital vascular radiology table (digital vascular radiology table (Cath Lab, Siemens, Multistar T.O.P, Marburg, Germany), an automatic injector (MARK-V PLUS injector system, Medrad, Indianola PA), a pressure monitor (Hewlett Packard Cms 24 Omnicare Patient Monitor, USA), a linear echoendoscope (GF-UCT 140 Olympus Corp., Tokyo, Japan) coupled to an ultrasound platform (Aloka 5500-SSD Prosound, Aloka Co.,Ltd, Tokyo, Japan), and a monopolar electrosurgical generator (ICC 350, ERBE Elektromedizin GmbH, Tuebingen, Germany). Protocol, animal operating room, and staff were given approval by the French Ministry of Research (#B6311320, #B63177), and all experiments were performed according to the National Ethical Charter on Animal Welfare.

Animal preparation

The animals had been fasting for 12 h before the procedure. First, anesthetic premedication was administered by intramuscular injection of 3 mg ZoletilTM and 3 mg StressnilTM. Then, 1–2 h before the experiment, anesthesia was induced by injecting 5 mg of propofol. The animal was then intubated with a 5.5–6 mm probe connected to a respirator (Aéroporc, Clermont-Ferrand, France). The propofol was renewed regularly by 5 mg intravenous injections during the procedure.

Endoscopic procedure

The echoendoscope was positioned initially into the stomach. However, to get an ultrasound plane simultaneously including the left PV (LPV) and the LHV, the endoscope needed to be pulled back and positioned in the lower esophagus. When simultaneous visualization of the LHV and LPV was not achieved, the endoscope was a new positioned in the stomach and we obtained the LPV and the inferior vena cava (IVC) on the same plane. The LHV, or its confluence with the IVC, was punctured with a 19 gauge-needle (EUSN-19A; Cook Endoscopy, Winston-Salem, North Carolina, USA). The site of the LHV puncture was always chosen so that the needle would go through at least 5 mm of hepatic parenchyma before puncturing the targeted vessel. The needle was then advanced through the liver parenchyma into the lumen of the LPV under ultrasound guidance.

A rigid 0.035-inch straight tip guidewire (Dreamwire; Boston Scientific Corp., Marlborough, Massachusetts, USA) was introduced in the needle sheath and pushed into PV lumen until the superior mesenteric vein was reached (fluoroscopic visualization) [Figure 1]. The needle sheath was removed, then using a needle knife (Microknife XL Boston Scientific, diameter 5.5 F) with pure cutting current enabled to cross the digestive tract, liver capsule, venous walls, and liver parenchyma to create a fistula between the digestive lumen, LHV, or the IVC and the LPV. After intraportal positioning of the needle-knife catheter, it was connected to a pressure sensor to enable measurement of portal pressure after calibration (preshunt portal pressure) [Figure 1]. After blood aspiration through the catheter to avoid the risk of air embolism at the injection site, the catheter was connected to the autoinjector to perform the initial portography with an injection of 15 mL Visipaque 300 at 6 mL/s.

After repositioning of the guidewire into the superior mesenteric vein, the catheter was removed along it, until the tip was sonographically visible in the LHV or IVC lumen. A manual injection of 4 mL Visipaque 300 realized in digital subtraction angiography mode enabled a reference fluoroscopic image to allow fluoroscopic identification of the LHV and caval confluence [Figure 2].

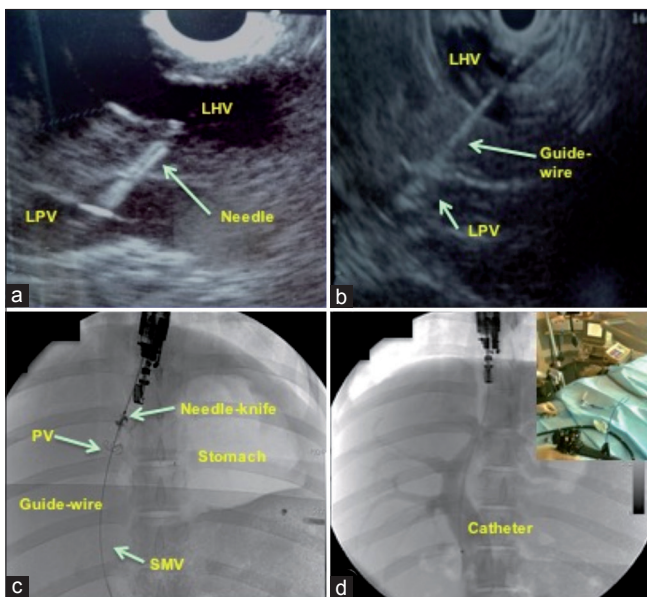


Figure 1. (a) The left hepatic vein (LHV) and left portal vein (LPV) are simultaneously punctured with the fine-needle aspiration needle under endoscopic ultrasound guidance. (b) Guidewire pushed into the portal vein (PV) under endoscopic ultrasound view. (c) Fluoroscopic view of the guidewire advanced up to the superior mesenteric vein (SMV). (d) Measurement of portal pressure

An 8 or 10 mm diameter biliary balloon dilator (Hurricane, Boston-Scientific) allowed the intraparenchymal fistula dilation under echographic and radiologic control [Figure 2].

A new reference image was taken when the balloon was insufflated (Encore™ 26 Inflator, Boston Scientific Corp) with its proximal pole in the lumen of the LHV without being in contact with the walls.

Then, a self-expanding metallic stent, partially covered (NITI-S TIPS stent Taewoong Medical) or uncovered (Cook Medical Zilver ZILBS), was then deployed between the LPV and the LHV or the IVC under radiologic and echographic control guided by the reference images [Figure 3]. The choice of covered *versus* noncovered stent use was based on convenience and stent availability. The patency of the portosystemic shunt created by stent deployment was assessed by color-Doppler EUS.

The catheter was repositioned into the PV while passing through the stent over the left in place guidewire enabling postshunt portal pressure measurement. This

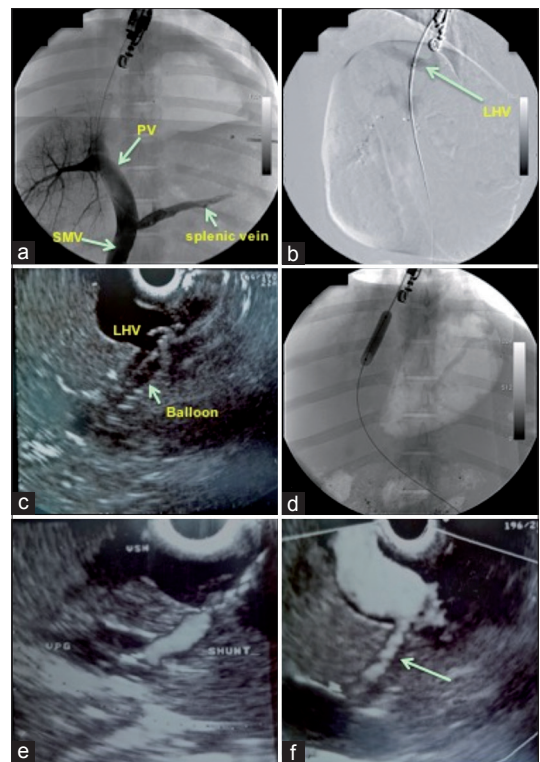


Figure 2. (a) Initial portography. (b) Fluoroscopic identification of the left hepatic vein (LHV) or caval confluence with a manual injection in digital subtraction angiography mode. (c and d) Dilation of the intraparenchymal fistula under dual endoscopic ultrasound-plus-radiologic control (reference image). (e) Portohepatic shunt. (f) Portocaval shunt

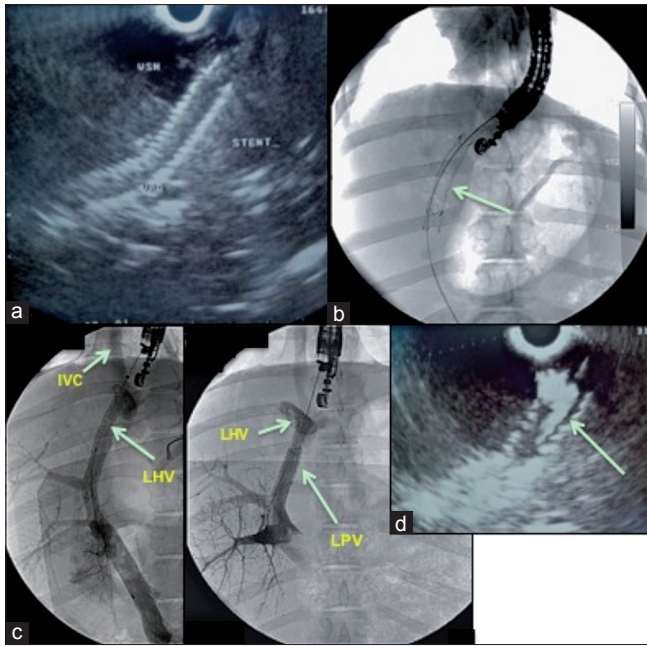


Figure 3. (a and b) Endoscopic ultrasound and radiologic view of the stent deployed from its distal end. (c and d) Final portocavography and color-Doppler study validating that the stent is functional

step also allowed the automatic injector to deliver a 20 mL injection of visipaque 300 at 6 mL/s in the front and left anterior oblique incidences. This final portocavography validated stent patency [Figure 3].

Morbidity evaluation

Animals were euthanized at the end of the procedure. The guidewire was left in place to facilitate perlaparotomy stent path tracking. A midline and bisubcostal laparotomy and a left median thoracotomy were performed to detect potential adverse events.

Statistical analysis

The population was described by effectives and percentages associated to qualitative and categorical variables and by mean \pm standard deviation associated and extended for quantitative variables. Qualitative data were crosscompared using Fisher's exact test. Quantitative data were crosscompared between independent groups using the Kruskal–Wallis test. Pressures before and after stent placement were compared using Student's paired *t*-test. Tests were two-sided (Type I error, $\alpha = 0.05$), using Stata 12 (StataCorp, College Station, Texas, USA).

RESULTS

Twenty-one procedures were performed in 21 healthy animals between January and July 2012 [Table 1]. Mean

pig weight was 37.1 kg (15–51) and the mean duration of the procedure was 112 min (40–300). Mean number of punctures performed to obtain a portosystemic path was 1.5 (range 1–3).

Simultaneous EUS-guided puncture of the LHV and LPV was possible in 19 cases (91%). In two other cases, simultaneous puncture of the IVC and LPV was performed (pig #3 and pig #17).

The introduction of an intrahepatic stent was possible in all cases, but with good positioning between the portal lumen and the lumen of the LHV or its confluence with the IVC in 17/21 cases. In two cases, the stents were too proximal (the proximal tip of the stent extended through the liver capsule in pig #5 and was located in the subcapsular hepatic parenchyma in pig #16); in two other cases (pig #9 and pig #10), the stents were too distal: The distal tip of the stent was deployed in the PV lumen and the proximal tip of the stent was deployed in the liver parenchyma between the LPV and LHV. This situation required a second stent to be fitted for full portosystemic stenting. Therefore, portosystemic shunting was achieved in 19/21 cases (feasibility of 91%) including PV-LHV shunting in 17/21 cases and PV-IVC shunting in 2/21 cases. The average sonographically measured distance between LPV and LHV or between LPV and IVC was 16.3 mm. Mean hepatic capsule-hepatic vein distance was 9.6 mm (range 5–14). The stents placed were 6 cm long in 11 cases and 8 cm long in 10 cases. The stents were partially covered in 10 cases and uncovered in 11 cases.

The final portocavography demonstrating the effectiveness of the shunt was achieved in 17/21 cases, so we obtained an efficacy of 81%. Four shunts were nonfunctional because two stents were thrombosed (pig #4 and pig #10) and two stents were poorly positioned as they were too proximal (pig #5 and pig #16). The color-Doppler signal was obtained in all cases where the shunt appeared functional on the portography. Portal pressure before and after shunting was measured in 20/21 cases and showed no significant differences (mean 11.1 ± 0.7 vs. 10.7 ± 0.6 mmHg before and after shunting, respectively, $P = 0.59$).

During laparotomies, it was found from the path of the left in place guidewire that the procedure was transesophageal and transdiaphragmatic in all cases where the LHV and LPV were punctured

Table 1. Experimental population and descriptive data on the procedures performed

Pig	Weight (kg)	Puncture tract	Preshunt portal pressure (mmHg)	Stent (diameter [mm]/length [cm]/type)	Doppler signal	Portocavography	Postshunt portal pressure (mmHg)	Necropsy: Procedure	Morbidity
1	15	LHV - LPV	11	10/6/covered	+	+	10	Transoesophageal	-
2	18	LHV - LPV	14	10/8/covered	+	+	14	Transoesophageal	-
3	32	IVC - LPV	8	10/6/covered	+	+	9	Transgastric	-
4	35	LHV - LPV	10	10/6/covered	- (thrombosis)	-	9	Transoesophageal	-
5	34	LHV - LPV	11	10/6/covered	-	-	9	Transoesophageal	Hemoperitoneum + pneumothorax
6	36	LHV - LPV	11	10/8/covered	+	+	11	Transoesophageal	Hemothorax
7	41	LHV - LPV	11	10/8/covered	+	+	10	Transoesophageal	-
8	34	LHV - LPV	13	10/6/covered	+	+	14	Transoesophageal	-
9	36	LHV - LPV	5	2x10/6/covered	+	+	15	Transoesophageal	-
10	37.5	LHV - LPV	6	10/8/covered + 10/4/noncovered	- (thrombosis)	-	8	Transoesophageal	-
11	38	LHV - LPV	8	10/8/covered	+	+	8	Transoesophageal	-
12	38	LHV - LPV	10	10/8/noncovered	+	+	10	Transoesophageal	-
13	32	LHV - LPV	9	10/6/noncovered	+	+	10	Transoesophageal	-
14	50	LHV - LPV	12	10/6/noncovered	+	+	12	Transoesophageal	-
15	51	LHV - LPV	11	10/6/noncovered	+	+	10	Transoesophageal	-
16	41	LHV - LPV	12	10/6/noncovered	-	-	12	Transoesophageal	-
17	46	IVC - LPV	12	10/8/noncovered	+	+	6	Transgastric	-
18	44	LHV - LPV	11	10/8/noncovered	+	+	10	Transoesophageal	-
19	39	LHV - LPV	12	10/8/noncovered	+	+	6	Transoesophageal	-
20	36	LHV - LPV	19	10/6/covered	+	+	16	Transoesophageal	Hemothorax
21	46	LHV - LPV	17	8/8/noncovered	+	+	14	Transoesophageal	-

LHV: Left hepatic vein, LPV: Left portal vein

simultaneously (19 cases) [Figure 4], but transgastric in all cases where the LPV and IVC were punctured simultaneously (2 cases).

Pig 5 presented with hemoperitoneum and pneumothorax, pig 6 presented with hemothorax, and pig 20 presented with hemothorax. Overall morbidity was 14.2% (3/21 animals).

We investigated whether number of initial punctures, type of shunt (portocaval *vs.* portohepatic), thickness of subcapsular parenchyma (length of the fistula track between the liver capsule and the LHV/IVC), or diameter of balloon dilation could be

prognostic factors of morbidity. None of these factors had a significant impact [Table 2].

DISCUSSION

The feasibility of EUS-guided puncture of the PV in an animal model with portography and pressure measurement was demonstrated for the first time in 2004.^[13] Then, two pilot series were reported on a porcine model dedicated to CO₂ portal angiography and EUS portal pressure.^[12,14] In 2009, a pilot study on 10 healthy pigs demonstrated the feasibility of an intrahepatic portosystemic shunt by EUS.^[16]

Here, we report a large experimental study on 21 healthy pigs that simultaneously coevaluated a portal pressure gradient and the establishment of an intrahepatic portosystemic stent by ultrasonography under radiological control. This is the first collaborative work between on portosystemic shunts' endoscopists and radiologists. Interestingly, the portography performed with the automatic injector connected to an endoscopic catheter was able to obtain unwashed shots equivalent to those achieved during TIPS procedures [Figure 2a]. These injectors are not currently used by gastroenterologists but can be expected soon to become routine equipment for vascular access by endoscopy. We showed that when an EUS-guided intrahepatic portosystemic shunt (EGIPS) is established, obtaining a portal pressure gradient makes it possible to assess the effectiveness of a portosystemic shunt. In this study, we did not get any significant difference between mean pre- and post-pressure shunt pressures. This result was expected in healthy nonportal hypertensive animals and it also validates

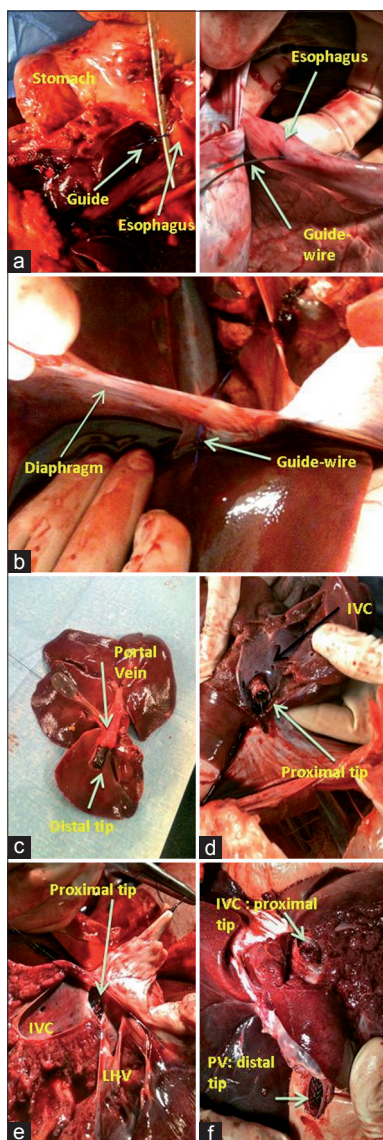


Figure 4. Necropsy with thoracotomy and laparotomy. (a and b) Transesophageal and transdiaphragmatic path of the guidewire. (c) Distal tip of the stent in the portal lumen. (d) Proximal tip of the stent in the caval lumen. (e) Proximal tip of the stent in the hepatocaval confluence. (f) Portocaval stent

Table 2. Impact on morbidity of shunt type, number of punctures, thickness of subcapsular parenchyma (length of the fistula track between the liver capsule and the left hepatic vein/inferior vena cava), and balloon diameter

Parameters	No morbidity (n=18)	Morbidity (n=3)	P
Type of shunt			
Portocaval	2 (11)	0	1
Portohepatic	16 (89)	3 (100)	0.49
Number of punctures	1.5±0.8	1.7±0.6	0.49
Thickness of subcapsular parenchyma	9.5±2.5	10.3±4	0.51
Balloon diameter (mm)			
8	11 (61)	3 (100)	0.52
10	7 (39)	0	

SD: Standard deviation

the consistency of the results. We intend to obtain a portal pressure gradient in further experiments using a portal hypertension porcine model. Furthermore, a comparative study between TIPS and EGIPS could be done experimentally to compare the efficacy and safety.

Otherwise, we report some technical differences. For transmural portosystemic shunt establishment, the crucial step is the creation of a fistulous track between the puncture site on the gastrointestinal wall and the portal lumen, to enable stent placement. Our experience is different from Buscaglia *et al.*^[16] who reported the establishment of transdigestive portohepatic stent directly after the implementation of a portal guidewire. We were unable to cross the digestive wall without using a needle knife because the passage of a 6F bougie across the bowel wall fails, after super stiff guidewire access. Furthermore, tract dilation with a balloon was also required before stenting.

Our technical success was 90.5%, on a par with radiological TIPS.^[17] The two failures correspond to two stents placed too proximally. The stent was too proximal if its proximal tip was deployed in-between the LHV and the hepatic capsule. The most challenging technical aspect is to open the proximal tip of the stent in the lumen of the LHV. Indeed, correct opening of the distal tip of the stent is easy in the portal lumen because the stent is in the longitudinal axis of the PV. Regardless of the length of the stent in the PV, the stent appears functional, nontraumatic, and can be repositioned if the intraportal length is not satisfactory as it is a distal release stent. In contrast, the stent is perpendicular to the axis of the LHV or IVC. If the proximal tip of the stent is dropped just before the lumen of the LHV (between LPV and LHV), the shunt is not functional, but the operator can fit a second stent into the first one. If the proximal tip of the stent is dropped above the lumen of the LHV or IVC (in the subcapsular parenchyma), fitting a second stent is not possible and presents a major risk of hemorrhage if the stent opens in the liver capsule or the peritoneum. A future perspective would be to manufacture a proximal release biliary stent, which is probably technically possible as there are already proximal release esophageal stents. A simple alternative would be to insert an echogenic marker on the delivery system at the proximal pole of the stent.

There were 3 cases of major complications in our study. Hemoperitoneum was due to a shunt from PV to peritoneum and the use of a proximal-release

biliary stent could avoid this type of complication. To prevent hemorrhage through the needle track/fistula in a EGIPS, the use of EUS-guided coil technique with a 19-gauge needle preloaded with stretched fin coil could be an alternative given promising results in EUS-choledochoduodenostomy^[18] and in gastric varices.^[19,20] Gelfoam in the transhepatic tract could be an alternative too,^[21] but its use with EUS needles appears less documented.

Two pigs that had undergone transesophageal procedures presented with a hemothorax whereas the stents were correctly deployed between hepatic and PV. During necropsies, we found no hemostasis clot at the esophageal wall and no platelet clot at the liver capsule in these pigs. This let us think that it was due to an esophageal wall or liver capsule bleeding rather than a shunt from PV or hepatic vein to the thorax. We thus suggest leaving the catheter in place longer, i.e., for 15 or 20 min instead of 5 min, before removal, which would promote the formation of thrombosis at the gastrointestinal and liver puncture point to reduce the risk of bleeding. Furthermore, we found some anatomical discrepancies compared to human anatomy resulting from our unintentional transesophageal approach. Indeed, we found that the intragastric position of the endoscope, even moving up along the lesser curvature, only allowed a simultaneous view of the IVC or its confluence with the LPV. In a porcine model, the liver has four lobes, the IVC takes a very particular setting compared to humans as it gets through full liver parenchyma.^[22] The posterior side of the left hepatic lobe contacts the diaphragmatic esophageal orifice. At this level, the left hepatic lobe has close interaction with the abdominal esophagus which always measured 4 or 5 cm.^[23] Indeed the puncture of the LHV requires a transoesophageal tract as confirmed by the path of the guidewire left in place, after thoracotomy and laparotomy [Figure 4 right and b]. Hemothorax and pneumothorax would not be reproducible in humans, where the LHV is well visualized from the stomach and a transgastric EUS-guided access to the LHV is expected.

Although this study presents the limitation that we have no survival data, this morbidity rate needs to be put in perspective. This technique should apply to cases of therapeutic impasse in a setting of TIPS failure. As the outcome for patients in this bleak situation is often death, the rate of morbidity of this technique appears relatively acceptable. However, longer period of

follow-up should be done in further studies to assess the short- and long-term morbidity and mortality.

If the technique is reproducible on live portal hypertension porcine models^[24,25] with acceptable morbidity, it would become a useful alternative if TIPS fails. Indeed, it is a minimally invasive technique with the same or less procedure duration (average of 112 min here *vs.* 120 min for TIPS) and does not require right heart or thoracic IVC catheterization. This technique could also be an alternative to TIPS in cases of Budd-Chiari syndrome^[26,27] or in cases of uncontrolled variceal bleeding in patients too unstable to withstand transport to radiology facilities that are often located outside the digestive surgery critical care unit. Finally, this option could be useful in cases of long TIPS delay in emergency settings and could also increase the availability of operators (endoscopists in addition to radiologists).

CONCLUSION

EGIPS with portal gradient measurement is technically feasible in 90.5% of cases and functional in 81% of cases, with a 14.2% morbidity in healthy animals. This procedure should be assessed and validated on a portal hypertension porcine model as it could offer an alternative option in emergency settings or if TIPS fails in portal hypertension patients facing therapeutic impasse.

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Conflicts of interest

There are no conflicts of interest.

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