La radiologia medica (2020) 125:609–617
https://doi.org/10.1007/s11547-020-01155-5

ABDOMINAL RADIOLOGY

Radiation exposure during transjugular intrahepatic portosystemic shunt creation in patients with complete portal vein thrombosis or portal cavernoma

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Received: 8 October 2019 / Accepted: 6 February 2020 / Published online: 18 February 2020

Abstract

Background This study aims to evaluate radiation exposure in patients with complete portal vein thrombosis (CPVT) or portal cavernoma (PC) undergoing transjugular intrahepatic portosystemic shunt (TIPS) creation using real-time ultrasound guidance for portal vein targeting.

Materials and methods This is a single institution retrospective analysis. Between August 2009 and September 2018, TIPS was attempted in 49 patients with CPVT or PC. Radiation exposure (dose area product [DAP], air KERMA (AK) and fluoroscopy time [FT]), technical success, clinical success, complications and survival were analyzed.

Results In total, 29 patients had CPVT and 20 patients had PC. 41/49 patients had cirrhosis. TIPS indications were refractory ascites ($n = 25$), variceal bleeding ($n = 16$) and other ($n = 8$). TIPS was successfully placed in 94% (46/49) of patients via a transjugular approach alone ($n = 40$), a transjugular/transhepatic approach ($n = 5$) and a transjugular/transsplenic approach ($n = 1$). Median DAP was 261 Gy * cm^2 (range 29–950), median AK was 0.2 Gy (range 0.05–0.5), and median FT was 28.2 min (range 7.7–93.7). Mean portosystemic pressure gradient decreased from 16.8 ± 5.1 mmHg to 7.5 ± 3.3 mmHg ($P < 0.01$). There were no major procedural complications. Overall clinical success was achieved in 77% of patients (mean follow-up of 21.1 months). Encephalopathy was observed in 16 patients (34%), grade II–III encephalopathy in 7 patients (15%). TIPS revision was performed in 15 patients (32%). Overall survival rate was 75%.

Conclusion In our experience, the use of real-time ultrasound guidance allowed the majority of the TIPS to be performed via a transjugular approach alone with a reasonably low radiation exposure considering the high technical difficulties of the selected cohort of patients with CVPT or PC.

Keywords Ascites · Bleeding · Liver · Cirrhosis

Introduction

Transjugular intrahepatic portosystemic shunt (TIPS) is a well-established procedure for the treatment of cirrhotic and non-cirrhotic patients with complications of portal hypertension such as variceal bleeding and refractory ascites [1] and is considered to be one of the most complex and radiation intensive procedures in abdominal interventional radiology [2]. The presence of complete portal vein thrombosis (CPVT) or portal cavernoma (PC), previously considered as relative or absolute contraindications to TIPS creation, increases technical difficulties of TIPS creation. As familiarity with this procedure grows, an increasing number of these patients have undergone successful shunt placement, with technical success reported between 75% and 98%

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of cases in centers with high experience [3–7]. The data available regarding patient radiation exposure during TIPS creation are sparse, and a few series with a large number of procedures are available [2, 8–10]. Data reported in those series are based, however, on all TIPS creation, including a majority of patients with a patent portal system, and are not focused on patients with CPVT and/or PC. Our aim was to quantify TIPS-related patient radiation exposure in our center in patients with CPVT or PC using real-time ultrasound guidance for portal vein targeting; technical success, clinical success and complication rates were also evaluated.

Materials and methods

This single center retrospective study was reviewed and approved by the institutional research review board, and informed consent form was waived. Informed written consent to the TIPS procedure was obtained from all patients. No financial support has been provided for this study.

From July 1999 to September 2018, 787 TIPS creations were performed in the radiology unit of a single transplant center. All TIPS was performed by 3 faculty interventional radiologists with 28, 18 and 14 years of experience in TIPS creation at the time of writing. Procedures performed before August 2009 were excluded since fluroscopic guided portal vein targeting with the use of bony landmarks was used as the routine method for portal venous puncture. After August 2009, real-time ultrasound guidance was introduced in our center as the standard technique for portal vein targeting. Between August 2009 and September 2018, at our institution a total of 459 patients underwent TIPS creation and insertion of an e-PTFE-covered endoprosthesis (Viatorr®; W.L.GORE & Associates, Inc., Flagstaff, AZ, USA) for complications of portal hypertension using real-time ultrasound guidance for portal vein targeting. Totally, 49 out of 459 patients (10%) had a diagnosis of CPVT or PC prior to TIPS creation and were included in this study (Fig. 1). CPVT was defined as complete occlusion of the main portal vein, with or without involvement of intrahepatic portal branches on contrast-enhanced computed tomography and/or magnetic resonance imaging performed within 1 month before TIPS creation; PC was defined as the presence of tortuous hepatopetal collateral veins that bypassed the occluded portal vein for the patent intrahepatic segmental vessels with the replacement of the original main portal vein with a fibrotic cord on contrast-enhanced computed tomography and/or magnetic resonance imaging performed within 1 month before TIPS creation. Patient characteristics are reported in Table 1. Liver cirrhosis was diagnosed by liver biopsy or by unequivocal clinical, laboratory and imaging findings. The exclusion criteria for TIPS placement were hepatic encephalopathy (HE) within

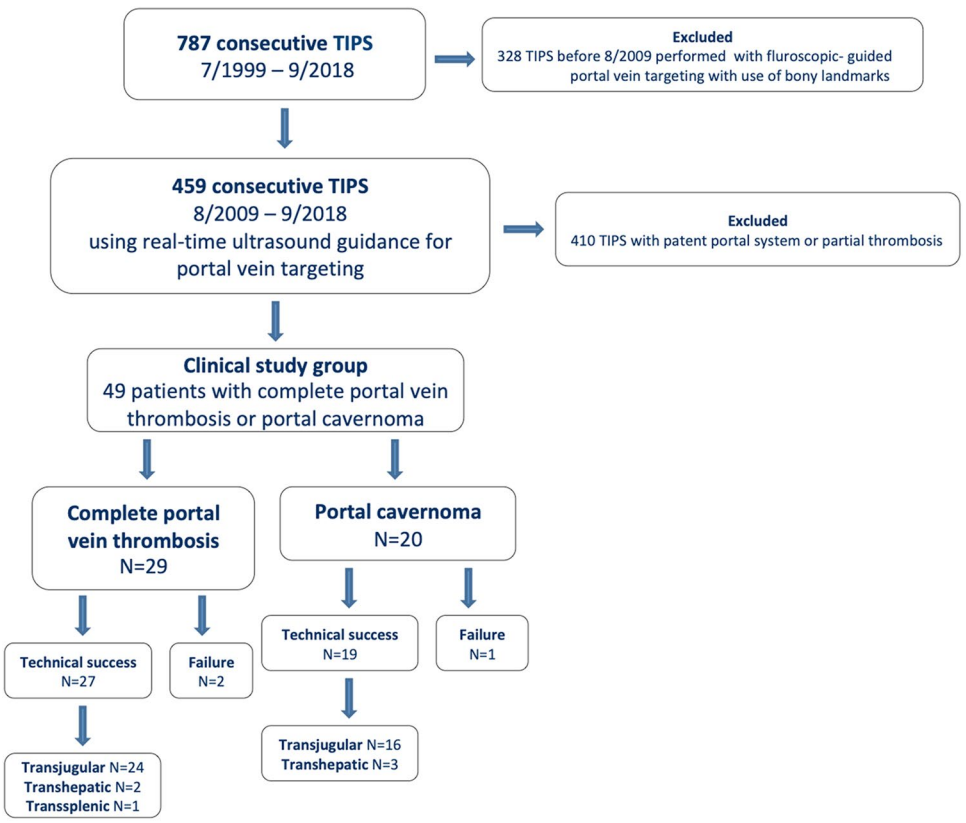

Fig. 1 Flowchart of the study

Table 1 Baseline characteristic of 49 patients with CPVT or PC underwent TIPS creation

Variable	
Mean age (years)[a]	55.1 (± 11.6)
Gender (M/F)	32/17
Cirrhosis (yes/no)	41/49
Mean follow-up (mo)[a]	21.1 (± 26.6, range 1–105.6)
Complete portal vein thrombosis	29
Portal cavernoma	20
Indication for TIPS	
Refractory ascites	25
Gastrointestinal bleeding	16
Other	8

Unless otherwise indicated, data are number of patients

[a]Data are mean ± SD

3 months prior to evaluation for TIPS creation or previous severe encephalopathy (grade III–IV), multinodular HCC, tumoral PVT, cardiopulmonary comorbidity, active infection, presence of pulmonary hypertension, MELD > 20, total obstruction of the portal system, including the entire superior mesenteric vein and splenic vein and cavernous transformation with no detectable portal remnant or without a possible "landing zone" for the stent such as patent spleno-mesenteric confluence or at least a deep, large collateral vessel.

TIPS procedure

Non-ionic iodinated contrast material was used during the procedures (Visipaque, GE Healthcare, Princeton, NJ, USA). All TIPS was performed under general anesthesia, with a right or left internal jugular vein approach. Access to the intrahepatic portal vein branch was achieved with real-time ultrasound guidance using a Colapinto needle (Ring Transjugular Intrahepatic Access Set, CooK, Bloomington, USA or GORE TIPS Set W.L.GORE & Associates, Inc., Flagstaff, AZ, USA) as previously described [9, 11, 12]. In cases of failure of portal system catheterization using real-time ultrasound guidance, a combined ultrasound-guided transhepatic–transjugular [13–15] or transsplenic–transjugular [16, 17] approach was used as previously described. Following portal system catheterization, direct portography was performed, followed by portosystemic pressure gradient (PSG) measurement, defined as the difference between the portal pressure and inferior vena caval pressure [18]. Dilatation of the intrahepatic tract and portal vein was performed with a 10-mm non-compliant balloon catheter (Mustang; Boston Scientific, Galway, Ireland); subsequently, a Viatorr Endoprosthesis (Viatorr®; W.L.GORE & Associates, Inc., Flagstaff, AZ, USA) was deployed, followed by 10-mm-diameter balloon dilatation. Dilatation was always performed using an inflation device (Encore 26; Boston Scientific, Galway, Ireland). Direct portography was then performed again, followed by the measurement of the post-TIPS PSG. After TIPS creation, all patients received prophylactic therapy for HE with lactulose 30 ml, 3 times per day, and rifaximin 400 ml, 3 times per day. Both the transhepatic and transsplenic tracts were embolized with coils after TIPS. All patients were followed up in the outpatient clinic with clinical, biochemical and Doppler ultrasound evaluation, initially at 1 month after TIPS, then at 3 months, and every 6 months thereafter. TIPS was revised in case of recurrent variceal bleeding, continued need for paracentesis without the evidence of HE for more than 3 months post-TIPS creation, and in cases of Doppler findings of TIPS dysfunction. Doppler US criteria for TIPS dysfunction included portal flow velocity lower than 30 cm/s, change in the direction of flow in the intrahepatic portal branches from hepatofugal to hepatopetal, intra-stent flow velocity lower than 60 or higher than 190 cm/s or intra-stent flow velocity gradient greater than 50% [19].

Dosimetric data for every TIPS procedure were systematically archived into our Radiology Information System (RIS) and Picture Archiving and Communication System (PACS) (Centricity RIS 4.2i, General Electric Medical Systems, USA). For every procedure, the dose area product (DAP) given in Gy * cm^2, air KERMA (AK) given in Gy and fluoroscopy time (FT) given in minutes were retrospectively documented. DAP (or Kerma area product) was considered as a surrogate measurement of the entire amount of energy delivered to the patient by the radiation beam during the procedure and is the quantity recommended by the International Commission on Radiation Units to measure patient doses in interventional radiology [20]. AK is an additional diagnostic reference level to be monitored in interventional procedures as recommended by the International Atomic Energy Agency (IAEA) [21]. It is measured at the interventional reference point (IRP) defined as a point that is 15 cm closer to the focal spot than the system isocenter around which the gantry rotates. FT was considered as a surrogate marker of procedural complexity. The Society of Interventional Radiology–Cardiovascular and Interventional Radiology Society of Europe (SIR–CIRSE) international guideline on patient radiation management states that fluoroscopy time should not be used to monitor patient irradiation during interventional procedures; however, fluoroscopy time might provide an indication of procedure complexity, even though it does not always correlate with other dose metrics [22, 23].

Procedures were performed in an angiographic suite with an image intensifier-based digital system (Advantax, General Electric Medical Systems, USA) during the period before July 2010. Procedures performed after July

2010 were performed in a flat-panel-based detector angiographic suite (Innova 4100, General Electric Medical Systems, USA). The majority of the procedures included in the study, 45 out of 49, were performed in the flat-panel based angiographic suite. This equipment allows operators to choose from five different trajectories, each one using a different nominal dose (100, 90, 70, 50 and 35%, respectively), three different frame rates (30, 15 and 7.5 frame/s) and two different image detail levels (normal and low). Each one of these factors independently influences image characteristic and patient dose. All procedures were performed using the trajectory using 50% of the nominal dose, optimized to produce high-contrast images. The trajectory was never changed. Most TIPS procedures were performed with the detector in the posteroanterior projection with no cranio-caudal or oblique tilting; however, these maneuvers were at times required in a few of the more complex procedures. During TIPS creation, two angiographic runs were performed as part of the standard procedure: the first after portal system catheterization and the second after stent deployment. A low-dose acquisition angiographic protocol was used; this protocol minimizes the dose by reducing the maximum kV output of the X-ray tube. This, coupled with the enhanced detective quantum efficiency of the detector, lowers the receptor entrance dose levels and produces enhanced image contrast at the expense of increased noise. It has been previously reported that this technique results in a mean reduction of 75% in DAP per image when compared to a default reference standard dose acquisition protocol used during TIPS creation [24]. In both angiographic systems, DAP, AK and FT were measured with a dual-channel DIAMENTOR M4-KDK DAP/dose meter transmission ion chamber (PTW, Freiburg, Germany) fixed to the collimator with a valid calibration and quality control certificate revalidated every 6 months. DAP, AK and FT values were archived into our RIS/PACS system at the end of every procedure. Standard dose reduction measures were routinely employed. These included tight collimation limited only to the region of interest, and a low object-to-detector and source-to-image distance. Low-frame rate pulsed fluoroscopy (7.5 frames/s) without magnification was routinely employed in procedures performed using both systems. High frame rates (up to 15–30 frames/s) and/or magnification was only used when absolutely necessary in technically challenging steps of the procedure. Fluoroscopy protocols were optimized in each system. The automatic exposure control system, designed to automatically determine the optimal technique parameters such as kV, mAs, focal spot size and spectral filtration, was used in both systems. The "last image hold feature," which displays the last active fluoroscopic image, was always used since this enables image capture without additional fluoroscopic exposure.

Results

Our study cohort consisted of 49 patients. Based on Yerdel's classification, 40 patients had grade-2 portal system thrombosis, while 9 patients had grade-3 portal system thrombosis. Forty-one out of 49 patients were cirrhotic.

Twenty-nine patients (60%) had radiological evidence of CPVT; of these patients, 5 had concomitant complete intrahepatic portal vein thrombosis, 18 had concomitant partial intrahepatic portal vein thrombosis, and 6 had patent intrahepatic portal branches.

Twenty patients (40%) had PC; of these patients, 10 had concomitant intrahepatic cavernoma.

Primary indications for TIPS insertion were prevention of recurrent episodes of gastroesophageal variceal bleeding in patients who had failed endoscopic and/or medical therapy ($n = 14$), uncontrollable variceal bleeding ($n = 2$) and refractory ascites or refractory hydrothorax ($n = 25$). Eight patients underwent TIPS on the basis of portal system thrombosis alone, unresponsive to anticoagulant therapy, in order to recanalize the portal vein and maintain transplant waiting list status. Five patients had previous liver transplantation, 3 of whom received whole liver transplantation, while the remaining 2 patients underwent partial liver transplant (right lobe graft).

TIPS was successfully created in 46 out of 49 patients (94%) with a transjugular approach alone ($n = 40$), a transjugular/transhepatic approach ($n = 5$) and a transjugular/transsplenic approach ($n = 1$). In 2 patients, the percutaneous transhepatic ultrasound-guided "gun sight" approach was used [15], while in 3 patients, the percutaneous transhepatic balloon-assisted approach [14] was used.

As expected, there was a wide variation in radiation exposure, air KERMA and fluoroscopy time, and the collected data exhibited asymmetric and typically non-Gaussian distributions (Fig. 2). Median procedural DAP was 261 Gy * cm^2 (mean 314, range 29–1050, 75th percentile 413), median AK was 0.3 Gy (mean 0.2, range 0.05–0.5, 75th percentile 0.4), and median FT was 28.2 min (mean 38.1, range 7.7–93.7, 75th percentile 56.5). Dosimetric results are reported in Table 2. No deterministic or stochastic radiation-related complications were observed in our study group.

In 3 patients, we were not able to successfully create a TIPS: 2 patients had CPVT and 1 patient had PC. A single stent was deployed in 29 out of 46 patients (63%), and two coaxial stents were deployed in the remaining 17 patients (37%). Mean PSG decreased from 16.8 ± 5.1 mmHg to 7.5 ± 3.3 mmHg ($P < 0.01$). No patients had major procedural complications. At a mean follow-up of 21.1 months (± 26.6, range 0.02–105.6), overall clinical success was 77% (66% in refractory ascites, 100% variceal bleeding,

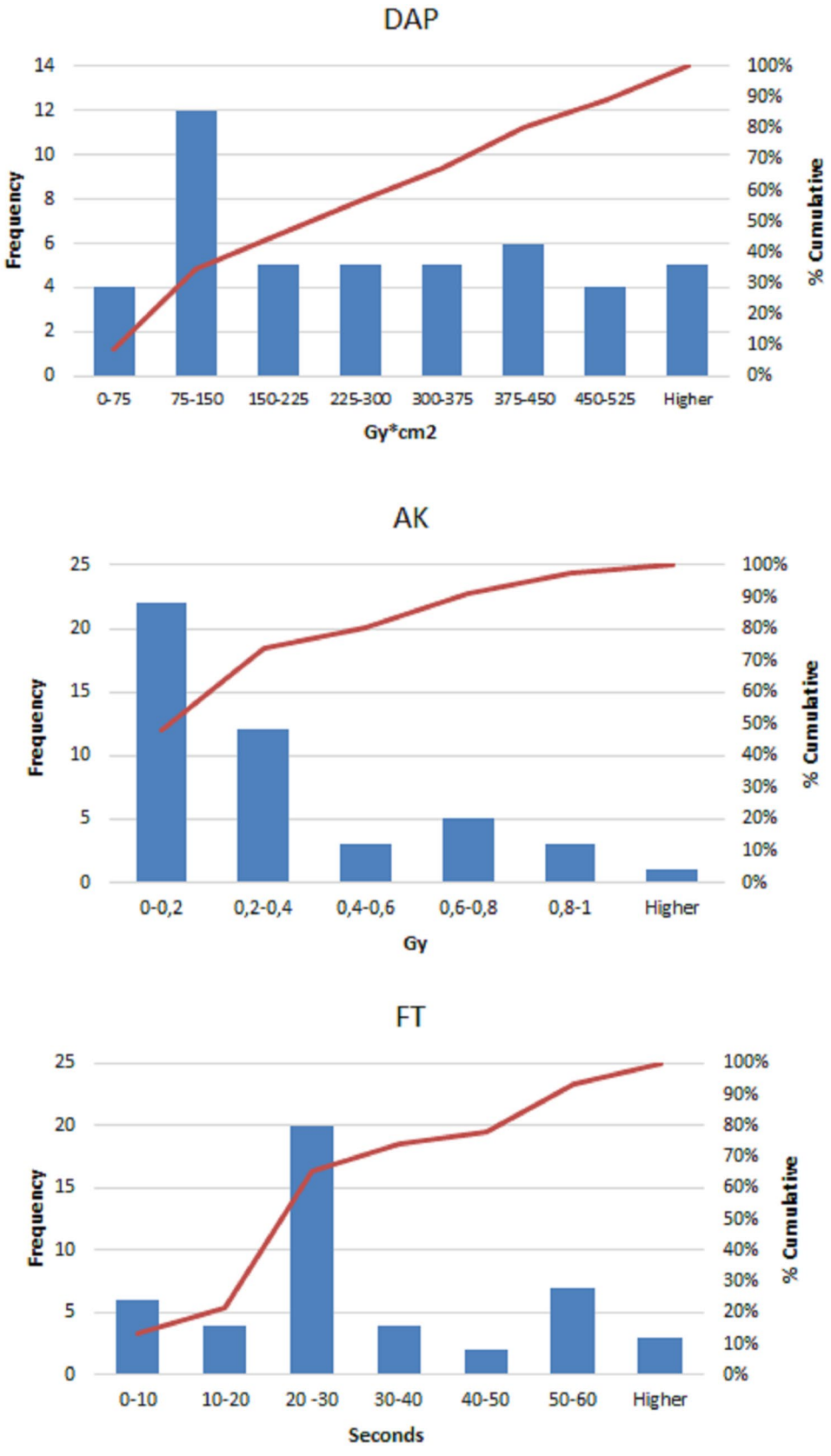

Fig. 2 DAP, AK and FT distribution in 46 patients with CPVT or PC who underwent successful TIPS creation

Table 2 Dosimetric results of 46 patients with CPVT or PC who underwent successful TIPS creation

	DAP (Gy * cm^2)	AK (Gy)	FT (min)
Median	261	0.3	28.2
Mean	314	0.2	38.1
75%	413	0.4	56.5
SD	262	0.3	22.3
Range	29–1050	0.05–0.5	7.7–93.7

Table 3 Clinical results of 46 patients with CPVT or PC who underwent successful TIPS creation

Variable	
Technical success (yes/no)	46/49 (94%)
PSG before TIPS (mmHg)[a]	16.8 (±5.1)
PSG after TIPS (mmHg)[a]	7.5 (±3.3)
Overall HE post-TIPS	16 (34%)
HE grade II–III post-TIPS	7 (15%)
Clinical success	
Refractory ascites	16/24 (66%)
Gastrointestinal bleeding	16/16 (100%)
Other	4/6 (66%)
TIPS revision	15/46 (32%)
Death	11/46 (23%)

Unless otherwise indicated, data are number of patients

PSG portosystemic pressure gradient, *HE* hepatic encephalopathy

[a]Data are mean ± SD

66% other). Overall encephalopathy was observed in 16 patients (34%). Grade II–III encephalopathy was observed in 7 patients (15%). TIPS revision was performed in 15 patients (32%). Overall survival rate was 77%. Six patients underwent liver transplant with end-to-end PV anastomosis between 3 and 47 months after TIPS. Clinical results are summarized in Table 3.

Discussion

As expected, radiation exposure in our cohort of patients varied according to the complexity of the procedure, with a wide range in DAP, AK and FT. The data available regarding patient radiation exposure during TIPS are sparse, and only a few series with a large number of procedures are available. Miller et al. [2, 8] reported in 134 TIPS a 75th percentile DAP of 525 Gy * cm^2 and a 75th percentile FT of 60 min; Miraglia et al. [9] reported 211 TIPS performed using real-time ultrasound guidance for portal vein targeting a 75th percentile DAP of 150 Gy * cm^2 and a 75th percentile FT of 25.7 min; more recently, Bundy et al. [10] reported in 120 TIPS a 75th percentile DAP of 609 Gy * cm^2 and a 75th percentile FT of 63.7 min. Data reported in those series are based, however, on all TIPS creation, including a majority of patients with a patent portal system, and are not focused on patients with CPVT and/or PC. To the best of our knowledge, our study is the first single-center survey reporting data on patient radiation exposure during TIPS creation in patients with CPVT and/or PC. Overall, our DAP in complicated procedures with CPVT and/or PC is below the results reported by Miller et al. [2, 8] and Bundy et al. [10] in their general population of patients undergoing TIPS creation; this result could be due to the systematic use of real-time ultrasound guidance used for portal vein targeting. In our experience, this technique showed advantages such as allowing the puncture of intrahepatic portal branches filled by thrombus in cases of thrombosis extending into the intrahepatic portal branches (Fig. 3), or the selective puncture of the intrahepatic portal branch in communication with the portal vein remnant in patients with PC (Fig. 4). Of note, in this case series of TIPS creation in patients with CPVT or PC, a transjugular approach, with real-time ultrasound guidance for portal vein targeting, was used in the majority of cases, reserving the more complex transhepatic or transsplenic approaches for only a few cases, thus further decreasing patient radiation dose.

The AK median and 75th percentile levels recorded in this study are relatively low when given the complexity of the procedures being performed. The IAEA uses the AK cutoff level of 2 Gy as the dose below which cutaneous reactions are unlikely to occur. In the AK dose range of 2–5 Gy, it states that "not so serious effects may be observed" [25]. While the AK range in this study is rather wide (0.05–0.5 Gy), the upper value is still much lower than the 2 Gy threshold described by the IAEA. In fact, none of the patients suffered any deterministic or stochastic radiation-related complications during the follow-up period.

These data are particularly relevant since TIPS is being increasingly performed in patients with CPVT and/or PC. Complete and extensive thrombosis may exclude patients from transplantation or require complex surgical techniques associated with a high risk of morbidity and mortality [26, 27]; for this reason, recently, TIPS creation has been recommended in liver transplant candidates who have progressive portal vein thrombosis refractory to anticoagulation therapy [6]. Overall our technical success is similar to the results recently reported by Thornburg et al. [13] in a similar cohort of patients; of note, Thornburg et al. report a systematic use of the transsplenic approach with 5 cases of hemoperitoneum (8%), 3 of which were secondary to the splenic access, and one case (2%) of radiation skin burn. Notably, the clinical results obtained in our cohort showed TIPS creation to be effective not only in patients with previous bleeding but also in patients with refractory ascites with results similar

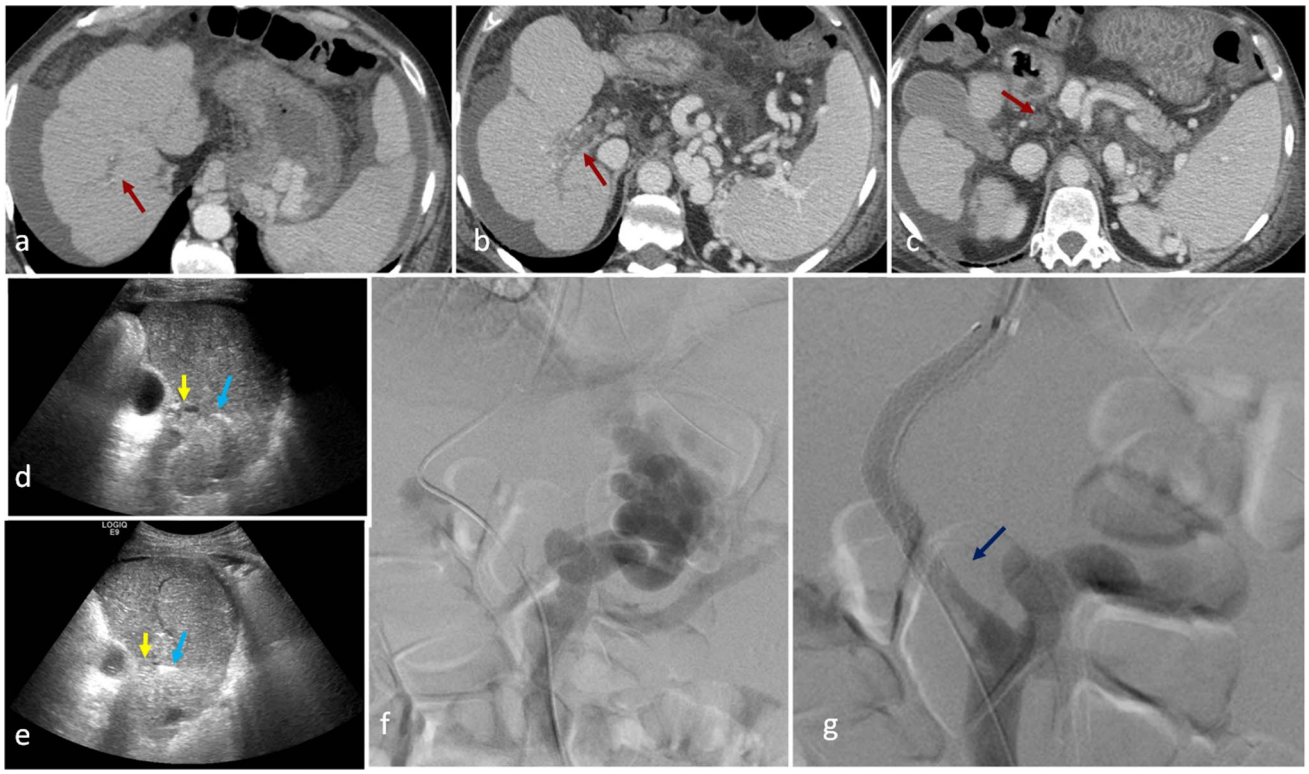

Fig. 3 65-year-old man with primary biliary cirrhosis and recurrent variceal hemorrhages despite endoscopic therapy. **a–c** MDCT, portal venous phase, showing mild ascites, splenomegaly, large gastroesophageal varices, complete thrombosis of intrahepatic portal branches (↑) and main portal vein up till the spleno-mesenteric confluence (not shown). **d**, **e** Using real-time sonographic guidance, the needle (blue ↑) is advanced in the occluded lumen of right portal vein (yellow ↑). **f** Portography performed after portal system catheterization shows complete thrombosis of the intrahepatic portal branches and main portal vein. Of note, there is reverse flow in the splenic vein and a large patent coronary vein filling gastroesophageal varices. Portosystemic gradient 13 mmHg. **g** Portography after 10-mm-diameter e-PTFE-covered stent placement shows good flow in the stent, reduced filling of the coronary vein, no reverse flow in the splenic vein and mild residual filling defect in the main portal vein in keeping with partial residual thrombosis (↑). Portosystemic gradient reduced to 8 mmHg. No bleeding recurrence in 7 years of follow-up. DAP 85 Gy * cm^2; AK 0.25 Gy; FT 16.1 min

to other studies with large cohorts of patients with refractory ascites but without CPVT or PC [28, 29]. Real-time sonographic guidance during TIPS creation was described in 1992 by Longo et al. [11]. To date, this technique has not gained global acceptance despite it being relatively simple. This can be easily demonstrated by reviewing the methodology described in recent TIPS-related publications, with many centers still advocating the use of other techniques [30–38].

The limitations of our study include the lack of accurate risk estimation for stochastic effects, since these should be quantified using the patient-specific Monte Carlo simulation. This was not feasible in our retrospective study, since inaccurate values would be derived. (Field size and possible field size variations during the procedure were not recorded.) Prospective studies are therefore needed to explore this issue with more accuracy. Another limitation is that the number of procedures analyzed is relatively low; however, the majority of the TIPS-related dosimetric studies available were performed with different cohorts of patients with a patent portal system. All procedures were performed by 3 faculty level radiologists with several years of experience in TIPS creation, with a potential impact on fluoroscopy time.

Conclusion

TIPS creation in patients with CPVT and/or PC is technically challenging and radiation intensive; however, high technical and clinical success can be achieved in procedures performed by experienced operators. Real-time sonographic guidance to target the portal venous system can be helpful to obtain technical success via a transjugular approach alone in majority of cases with a reasonably low radiation exposure considering the high technical difficulties of the selected cohort of patients, reserving the more complex transhepatic or transsplenic approaches only for few cases.

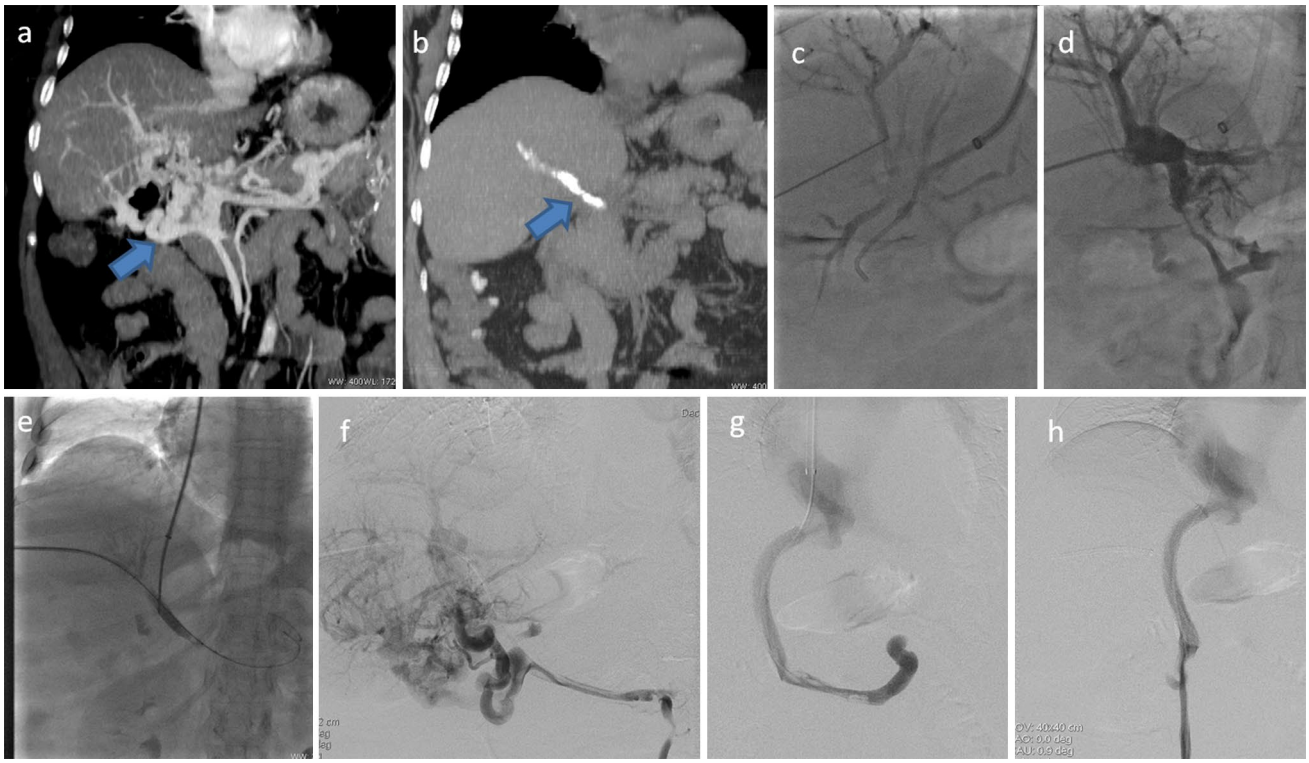

Fig. 4 62-year-old female with severe bleeding from ectopic duodenal varices (↑). CT diagnosis of cavernous transformation of the portal vein and a completely calcified portal vein remnant (↑) (**a**, **b**). A combined percutaneous transhepatic/transjugular approach was performed to recanalize the portal vein remnant (**c**–**f**) and successfully deploy an e-PTFE-covered stent (**g**, **h**). Portosystemic pressure gradient reduced from 20 to 8 mmHg. No recurrence of variceal hemorrhage in 1 year of follow-up. DAP 520 Gy*cm^2; AK 0.9 Gy; FT 56.1 min

Funding This study was not supported by any funding.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standards This article does not contain any studies with human participants or animals performed by any of the authors.

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