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Initial experience with Double-vein Embolization in Hungary

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ABSTRACT

Introduction: In recent years several new techniques have emerged to induce hypertrophy of the future liver remnant prior to major hepatectomies. We aimed to summarize our initial experience with Double-vein Embolization as the first center in Hungary.

Methods: Between March 2023 and August 2024 a total of 16 Double-vein Embolization procedures were performed in Semmelweis University. Future liver remnant volume was calculated based on computed tomography scans obtained within 4 weeks prior and 2–3 weeks after the procedure. Tc-99m mebrofenin hepatobiliary scintigraphy results were available for 12/16 patients.

Results: Technical success rate was 100 %. No major complication was observed. Successful resection rate was 93.8 %. One patient died due to post-hepatectomy liver failure. Future liver remnant volume and ratio increased significantly after the procedure compared to baseline (433.1 ± 163.8 cm^3 vs. 603.5 ± 201.8 cm^3, $p < 0.0001$ and 27.2 ± 6.5 % vs. 37 ± 8.8 %, $p < 0.0001$, respectively). Future liver remnant clearance improved significantly 1 and 2 weeks after the procedure (1.68 ± 0.58 %/min/m^2 vs. 2.44 ± 0.64 %/min/m^2 and 2.39 ± 0.31 %/min/m^2, respectively). Mean function gain was 50.6 % after one week and 60.1% after two weeks, respectively.

Discussion: Volumetric and functional outcomes in the present study are comparable with results reported in the literature. Our findings provide further evidence that Double-vein Embolization is a safe procedure that offers sufficient volumetric and functional gain in most candidates for liver resection. However, further studies are needed to define the exact place of this new technique in clinical practice.

1. Introduction

Liver resection can improve survival of patients with primary or secondary liver malignancies [1,2]. Major hepatectomy is defined by the resection of at least 4 segments. After such procedures liver failure is a major cause of postoperative mortality [3]. The future liver remnant (FLR) volume, or according to recent data, more reliably its function is a strong, independent predictor of post-hepatectomy liver failure (PHLF) [4,5]. Portal vein embolization (PVE) is the standard procedure to induce hypertrophy and functional gain in the FLR. In recent years several new techniques emerged as an alternative to PVE such as liver venous deprivation (LVD), double-vein embolization (DVE), associating liver partition and portal vein ligation for staged hepatectomy (ALPPS) and radiation lobectomy. We aimed to review these techniques from an IR's perspective and present our initial experience as the first center to perform DVE in Hungary.

Abbreviations: FLR, Future liver remnant; DVE, Double-vein embolization; CT, Computed Tomography; PVE, Portal vein embolization; PHLF, Post-hepatectomy liver failure; ALPPS, Associating liver partition and portal vein ligation for staged hepatectomy; NBCA, N-butyl cyanoacrylate; PVA, Polyvinyl alcohol; LVD, Liver venous deprivation; HV, Hepatic vein; SOP, Standard of Practice; SIRT, Selective internal radiation therapy; US, Ultrasound; IVC, Inferior vena cava; CECT, Contrast enhanced computed tomography; AST, Aspartate aminotransferase; ALT, Alanine aminotransferase; ISGLS, International Study Group of Liver Surgery.

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1.1. PVE

The first PVE was performed in 1990 by Makuuchi et al. [6]. It became a standard procedure prior to major hepatectomy in patients being at increased risk of developing PHLF based on preoperative volumetry and functional tests. The portal system can be accessed via percutaneous transhepatic puncture either through the liver to be resected (ipsilateral approach) or through the FLR (contralateral approach). Advantages and disadvantages of both techniques are listed in Table 1. Alternative access routes (percutaneous transsplenic, transjugular, intraoperative transileocolic, via the round ligament) are rarely utilized [7,8]. A broad spectrum of embolizing agents can be used for PVE such as n-butyl cyanoacrylate (NBCA) mixed with iodized oil, spherical microspheres, polyvinyl alcohol (PVA), gelatin sponge, ethanol, polidocanol foam and combinations of these agents with coils or vascular plugs [9–12].

1.2. LVD and DVE

In 2009, Hwang et al. reported that the sequential embolization of the right hepatic vein following PVE has an incremental effect on FLR hypertrophy [13]. Initial results of right portal and right hepatic vein (HV) embolization in a single procedure called LVD were published by Guiu et al. [14]. Since then, several studies showed that LVD results in faster and greater FLR hypertrophy compared to standard PVE, with similar complication rates.

The right HV can be accessed via percutaneous transhepatic puncture (original technique) or via catheterization through the systemic veins (jugular/femoral venous access) [15]. Following the placement of a guidewire or a vascular sheath in the HV, PVE is performed. After PVE, an oversized (~ 40 %) vascular plug is deployed with its distal end positioned about 15 mm proximal to the vena cava junction. Distal venous branches and potential veno-venous collaterals can be occluded with NBCA. Treatment with plugs ± coils only is referred to as DVE in the recently published Standard of Practice (SOP) document by CIRSE [16].

1.3. ALPPS

ALPPS is a two-staged extended right hepatectomy procedure first published in 2012 by Schnitzbauer et al. [17]. During right portal vein ligation, the first stage of surgical exploration, in situ splitting and if necessary tumor resection in the FLR is performed. Hepatectomy is completed in the second stage. After promising initial results, concerns were raised due to high periprocedural morbidity and mortality rates [18]. Several studies revealed that fast initial growth in volume does not translate into an equivalent functional gain [19–21]. Therefore, functional evaluations were advised to assess whether it is safe to proceed with the second stage of the procedure.

1.4. Radiation lobectomy

Recent studies have shown that unilobar selective internal radiation therapy (SIRT) with ablative doses of yttrium-90 induces hypertrophy of the contralateral liver lobe [22,23]. In non-cirrhotic patients the degree of hypertrophy is lower and it takes more time compared to PVE. However, in liver cirrhosis portal blood flow is reduced while hepatic arterial blood flow is increased (hepatic arterial buffer response), therefore FLR hypertrophy rates after radiation lobectomy and PVE are comparable [24]. An important advantage of SIRT over other techniques is that it can also provide tumor control in the treated lobe.

Table 1
Advantages and disadvantages of ipsilateral and contralateral access during PVE.

	Ipsilateral	Contralateral
Advantages	does not jeopardize the FLR S4 branches are easily accessible	easier catheterization use of NBCA without the risk of catheter entrapment
Disadvantages	catheterization is more difficult risk of tumor seeding risk of catheter entrapment and embolic dislodgement using NBCA	risk of FLR injury

2. Methods

2.1. Patient characteristics

In Semmelweis University Department of Interventional Radiology a total of 16 patients underwent DVE procedures between March 2023 and August 2024. The mean age of the patients was 60.4 years (± 10.8 years), with a gender distribution of 9 males (56.25 %) and 7 females (43.75 %). In terms of underlying liver disease 1 patient (6.25 %) had metabolic dysfunction-associated fatty liver disease. The remaining 15 patients (93.75 %) had no underlying liver disease. Nine patients (56.25 %) received preoperative chemotherapy.

The indications for DVE included:

- Colorectal liver metastases: 6 patients (37.5 %).
- Cholangiocellular carcinoma: 7 patients (43.75 %).
- Other malignancies: 3 patients (18.75 %).

Patient characteristics are summarized in Table 2.

Preoperative assessments revealed a mean FLR volume of 433.1 cm^3 (± 163.8 cm^3) and a mean FLR ratio of 27.2 % (± 6.5 %). The follow-up period was 14 weeks after liver resection.

Patients' electronic medical records were reviewed to register complications. DVE procedure-related complications were classified according to the CIRSE classification system [25], while surgical complications were assessed using the Clavien–Dindo grading system [26]. DVE was considered technically successful, when the embolization of the portal and hepatic vein branches were carried out according to the procedure plan. Clinical success was defined as an adequate FLR increase after DVE that allowed the planned surgery to be performed. The targeted FLR ratio was 25 % in subjects with healthy livers, 30 % in patients who received preoperative chemotherapy and 40 % in patients with known parenchymal liver disease. Functional tests were also evaluated when available. The final decision to perform the planned hepatectomy was discussed individually at multidisciplinary team meetings.

2.2. Procedural details

Informed consent was obtained from all patients. Premedication consisted of IV Midazolam 5 mg, IV Metoclopramide 10 mg and IV

Table 2
Patient characteristics.

Age (years)		60.4 ± 10.8
Sex (male:female)		9:7
BMI (kg/m^2)		26.1 ± 5.6
Histology		
	Colorectal metastases	6 (37.5 %)
	Cholangiocellular carcinoma	7 (43.75 %)
	Hepatocellular carcinoma	1 (6.25 %)
	Gastrointestinal stromal tumor	1 (6.25 %)
	Neuroendocrine liver metastases	1 (6.25 %)
Planned surgery		
	Right hemihepatectomy	9 (56.25 %)
	Extended right hemihepatectomy	7 (43.75 %)
Preoperative chemotherapy		9 (56.25 %)
Liver fibrosis		1 (6.25 %)

Nalbuphine hydrochloride 20 mg. ECG, blood pressure and oxygen-saturation were monitored during the procedures.

Percutaneous transhepatic puncture of the right HV was performed under ultrasound (US) guidance using a 21 G chiba needle. The triaxial dilator of the puncture set was inserted using an 0.018 in. Cope wire, then it was exchanged to a 23 cm × 8 F brite tip sheath over a stiff guidewire (Amplatz superstiff). Plug deployment was performed after completion of PVE.

Peripheral portal vein branches were accessed from the ipsilateral approach in all cases. Following US guided puncture, needle position was confirmed with contrast injection under fluoroscopy. After wire placement, the triaxial dilator was exchanged for a 23 cm×4 F brite tip sheath. Portography (20 ml contrast, hand injection) was obtained in the anteroposterior and in the right anterior oblique view of 25° with a reverse curve catheter (4 F USL or SHK Cordis, Santa Clara, California, U.S.) placed in the portal venous confluence. Microcatheters were used only in complex cases. Portal vein branches were embolized either with spherical microparticles (5 cases) ± coils or with a 1:10 mixture of NBCA and iodized oil (11 cases). Right portal vein branches were embolized in all cases. An additional embolization of segment 4 branches were carried out in 3 cases (18.75 %). The parenchymal tract was embolized either with coils or with glue.

The right HV (in one case the accessory right inferior HV) was occluded with an Amplatzer Vascular Plug II (Abbott Laboratories, Chicago, Illinois, U.S.) oversized by 50–100 % (16–22 mm diameter) (Fig. 1). The distal end of the plug was positioned at least 15 mm proximal to the inferior vena cava (IVC) junction. Before releasing the delivery wire, the position was checked with US. The parenchymal tract was embolized with coils if deemed necessary by the operator.

2.3. Laboratory tests

The following lab tests were obtained preoperatively, as well as 1, 3 and 5 days after surgery: serum aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, prothrombin time and creatinine.

2.4. Liver volumetry

Baseline contrast enhanced computed tomography (CECT) was obtained within one month of the procedure. Follow-up CT scans were performed 2–3 weeks after the procedure. Liver volume was calculated by an independent radiologist using Philips IntelliSpace Portal CT Liver Analysis application (Philips Healthcare, Andover, MA, USA).

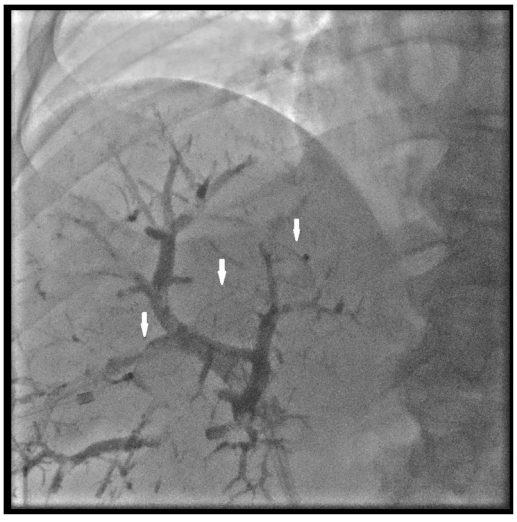

Fig. 1. Fluoroscopic image of plug deployment (white arrows) in the right hepatic vein. Glue cast can be observed in the right portal vein branches.

2.5. FLR function assessment

Tc-99m mebrofenin hepatobiliary scintigraphy was performed with MEDISO AnyScan TRIO SPECT/CT/PET hybrid scanner in 12/16 cases before and one week after DVE (Fig. 2). Two-week follow-up scintigraphy results were available for 8 patients.

2.6. Statistical analysis

Statistical significance was analyzed using GraphPad Prism software (GraphPad Software, San Diego, CA, USA). Normality was tested with the Kolmogorov-Smirnov test. Groups were compared using paired t-test and Tukey's multiple comparison test. P values < 0.05 were considered significant.

3. Results

3.1. Procedural outcomes

Technical success rate was 100 %. Sufficient FLR volume gain was reached within 2–3 weeks in 14 patients (87.5 %). In the remaining two cases subsequent volumetric and functional studies showed adequate results within 4–6 weeks.

Procedure-related complications were observed in three cases (18.75 %): two patients experienced minimal non-target embolization without portal vein thrombosis in the FLR (CIRSE-grade 1 and 3), and one patient exhibited an asymptomatic drop in hemoglobin levels after the procedure (CIRSE-grade 1). None of the complications delayed the planned hepatectomy. One of the patients with non-target embolization received anticoagulation prior to surgery. No additional treatment or imaging was required in the other two cases.

3.2. Surgical outcomes

The median time between DVE and surgery was 46 days (IQR 35.8). Successful resection rate was 93.8 %, extended right hemihepatectomy failed in one case due to vena cava infiltration. In a patient with hilar cholangiocarcinoma involving the right hepatic artery, bile duct resection was performed without the planned hemihepatectomy. After ligation of the right hepatic artery, intraoperative ultrasound showed arterial circulation in the right lobe of the liver from collaterals, therefore liver resection was unnecessary. The median length of postoperative in-hospital stay was 10 days (IQR 7). Overall surgical morbidity rate was 31.25 %. 90-day postoperative mortality rate was 6.25 %, one of our patients died 11 days after surgery due to PHLF. Complications are summarized in Table 3.

3.3. Laboratory tests

Lab test results are shown in Fig. 3.

3.4. Liver volumetry

FLR volume and FLR ratio increased significantly after DVE compared to baseline (433.1 ± 163.8 cm^3 vs. 603.5 ± 201.8 cm^3, $p < 0.0001$ and 27.2 ± 6.5 % vs. 37±8.8 %, $p < 0.0001$, respectively) (Fig. 4).

3.5. FLR function assessment

FLR clearance improved significantly 1 and 2 weeks after DVE compared to baseline (1.68 ± 0.58 %/min/m^2 vs. 2.44 ± 0.64 %/min/m^2 and 2.39 ± 0.31 %/min/m^2, respectively) (Fig. 5). Mean FLR function gain was 50.6 % after one week and 60.1 % after two weeks,

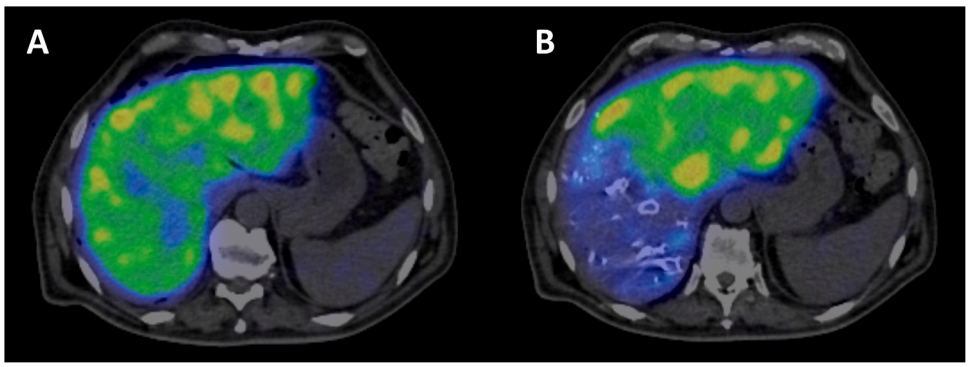

Fig. 2. Representative images of pre- (A) and post-DVE (B) Tc-99m mebrofenin SPECT-CT scans.

Table 3
Description and grading of postoperative complications.

Description	Clavien-Dindo classification
bile leak on surgical drain not requiring additional treatment	Grade I
postoperative abscess requiring percutaneous drainage	Grade IIIa
bile leak requiring ERCP and reoperation	Grade IIIa
biliary anastomosis insufficiency requiring reoperation	Grade IIIb
PHLF, death	Grade V

respectively.

4. Discussion

In line with previous findings, we concluded that DVE is a safe procedure with low complication rates. Based on CIRSE's SOP document, the complication threshold for PVE should be expected to be 2.5 % [16]. Until now, no such threshold was defined for DVE given the limited number of studies available in the literature. However, the possible complications of PVE can be applied for DVE as well, due to the significant overlap between the two techniques. These complications include subcapsular haematoma, haemoperitoneum, pneumothorax, haemobilia, arteriovenous shunts, pseudoaneurysm, cholangitis, sepsis, post-embolization syndrome, non-target embolization, portal vein thrombosis and transient liver failure [27]. During hepatic venous embolization plug migration is a potential risk which can be avoided by the use of appropriately oversized devices. To the best of our knowledge, no such complication was reported in the literature. Non-target glue spillage due to reduced flow in the right portal vein was reported by Najafi et al. in a case where hepatic venous embolization was carried out prior to PVE [28]. Therefore, it is recommended to perform PVE first to allow better glue penetration into portal vein branches and to reduce the risk of non-target embolization [16,28]. Studies comparing PVE alone to either DVE or LVD have shown no increase in complication rates or

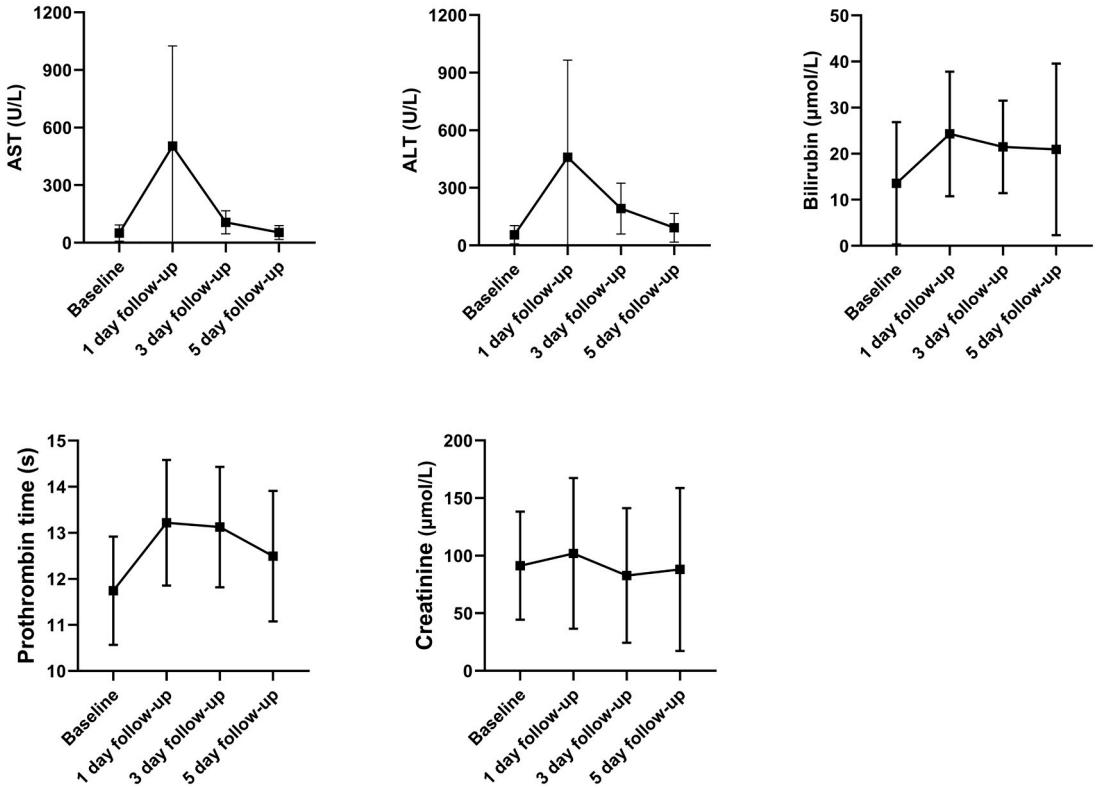

Fig. 3. Results of laboratory tests obtained preoperatively, as well as 1, 3 and 5 days after surgery.

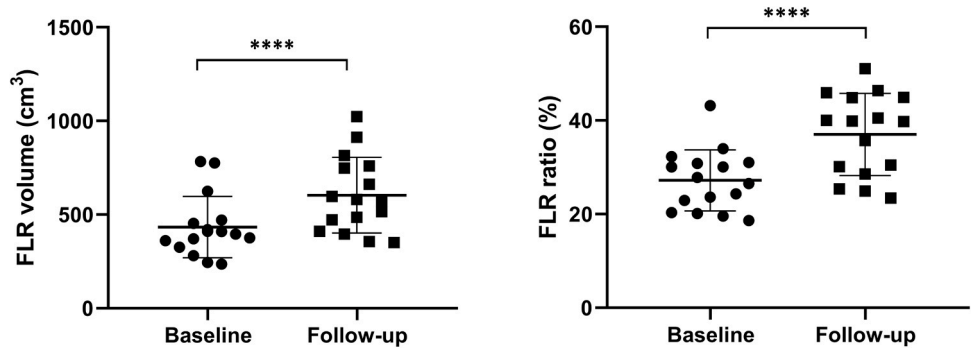

Fig. 4. FLR ratio increased significantly after DVE compared to Baseline (paired t-test, ****p < 0.0001).

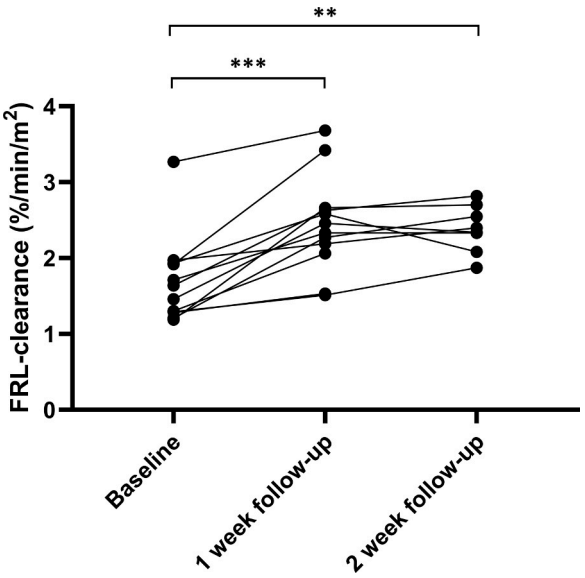

Fig. 5. FLR clearance improved significantly 1 and 2 weeks after DVE compared to Baseline (Tukey's multiple comparison test, ***p < 0.001 and **p < 0.01, respectively.

postoperative morbidity [29]. According to a systematic review, major complications after PVE led to unresectability of the patients in 0.4 %. Regarding DVE, we did not find any relevant data on this subject. Mortality after PVE has been scarcely reported, the expected rate should be a maximum of 0.1 % [9]. We found one report of mortality after DVE: a patient died 40 days after the procedure due to liver failure caused by infected tumor necrosis [28].

The two most important technical considerations during PVE are the preferred access route and the choice of embolic agent. In our study the ipsilateral access was utilized in all cases in accordance with current trends. Unlike the contralateral approach, this type of access does not jeopardize the FLR [16]. Comparing different types of embolics, the most effective agent in terms of FLR hypertrophy is NBCA according to several studies [30–32]. Our cohort is heterogeneous in that regard: 5/16 patients were embolized with spherical microspheres in combination with coils or gelfoam, while NBCA was used in 11/16 cases. Due to low patient numbers we did not analyze the two groups separately. Another technical consideration in DVE and LVD is the type of hepatic venous access. The HV can be reached either by performing transhepatic puncture or via catheterization through the systemic veins [15]. In the present study transhepatic access was utilized exclusively. Plug positioning can be more challenging using systemic venous access. However, there is no evidence in the literature that either technique is superior compared to the other. Following PVE (especially glue embolization) some patients experience discomfort despite the use of analgesics. Therefore, most operators prefer to begin with venous access in order to shorten the time of venous embolization at the end of the procedure [16, 33]. This results in better compliance that can be useful during plug positioning.

In the present study successful resection rate was 93.8 %, which is higher than most results reported in the literature. Resection rate after PVE is around 85 % according to a metaanalysis [9]. The main reasons for non-resection are insufficient FLR growth and tumor progression. It was found by several studies that tumor growth rate is accelerated after PVE [34,35]. The upregulation of growth factors and cytokines that induce liver regeneration can stimulate tumor growth particularly in the non-embolized part of the liver. For that reason, the rate of FLR growth and the timing of liver resection can influence patient survival. According to literature, sufficient FLR hypertrophy after PVE requires about 4–6 weeks [36]. ALPPS overcomes this limitation of PVE at the cost of significantly higher complication rates. As previously discussed, functional gain may be overestimated based on post-stage 1 vol growth [19–21]. Therefore, functional assessment of FLR before hepatectomy may help reduce postoperative morbidity and mortality in ALPPS [16]. The aim of simultaneous hepatic venous embolization in DVE and LVD is to achieve faster and greater liver regeneration compared to PVE, without higher risk for complications. The effects of hepatic venous embolization on liver regeneration are related to changes in arterial circulation. Hepatic arterial buffer response is a compensatory mechanism, which results in increased arterial inflow following PVE. By blocking the hepatic venous outflow arterial inflow decreases. This results in increased damage to the embolized part of the liver, thus increased FLR hypertrophy. Several studies confirmed the superiority of the new techniques over PVE in terms of volume gain [37–41]. Moreover, Cassese et al. found similar FLR growth rates and survival outcomes in patients undergoing LVD or ALPPS for colorectal liver metastases [42]. In our study FLR volume and FLR ratio increased significantly after the procedure. Mean hypertrophy rate was 43.3 %, which is comparable with literature data. An international multicenter study including 7 centers reported preliminary results of 44 % standardized FLR ratio increase and 74 % resection rate in a total of 191 patients who underwent LVD [43].

In recent years functional tests before major hepatectomies have become part of the clinical routine. Several authors showed that volumetric results are unreliable in patients with impaired liver function [44, 45]. Using hepatobiliary scintigraphy de Graaf et al. found good correlation between the estimated FLR function and the actual function following liver surgery [46]. They proposed an FLR clearance cutoff of 2.69 %/min/m^2 before major hepatectomy, based on postoperative outcomes of 55 high-risk patients of which the majority (55 %) had parenchymal liver disease. None of their patients underwent PVE or other procedures inducing FLR hypertrophy. In our series baseline FLR clearance was way below the desired cutoff, although there was only one patient with known parenchymal liver disease. Our patients' FLR clearance improved significantly one and two weeks after DVE. Function

gain was 50.6 % after one week and 60.1 % after two weeks which is very similar to results reported by Guiu et al. [37].

Despite advancements in preoperative analysis of FLR and preventive interventions such as PVE and its alternatives, PHLF remains a predominant cause of hepatectomy-related mortality. The reported incidence of PHLF varies between 1.2 % and 32 % depending on the studied patient population, the performed procedure and the definition of PHLF [47]. In patients who underwent DVE or LVD before major hepatectomy, the incidence of PHLF ranges from 0 % to 23.1 % [16]. In our series PHLF occurred in one case (6.25 %), which led to the death of the patient. The severity of PHLF can be graded according to the International Study Group of Liver Surgery (ISGLS), where grade B and C has a mortality rate of 13 % and 54 %, respectively [47]. Several studies have shown that PHLF is associated with more postoperative complications, longer hospital stay, and has a negative impact on long-term survival [48–50]. Apart from PHLF, possible complications of major hepatectomies include bile leakage, acute renal failure, ascites, surgical site infections, coagulation disorders, pneumonia and other respiratory disorders [43]. Overall surgical complication rate in patients with prior DVE or LVD is 10–15 %. The long-term survival of patients after major hepatectomy is influenced by numerous factors. According to a systematic review and meta-analysis, PVE has no negative effect on tumor recurrence or overall survival [51]. Further studies are needed to evaluate the effects of DVE on long-term outcomes.

Our study has several limitations. Patient number is relatively low. The lack of a control group only allowed us to compare our results with literature data. Hepatobiliary scintigraphy was not performed in all cases due to the retrospective nature of the study. Finally, the technique was heterogeneous in terms of embolizing agents.

5. Conclusion

This retrospective study provides further evidence that DVE can induce robust FLR volume and function gain in patients awaiting major hepatectomy with low complication rates. Further studies are needed to define the exact place of DVE among the other techniques.

CRediT authorship contribution statement

Pal Akos Deak: Supervision, Conceptualization. **David Adam Korda:** Writing – review & editing. **Andras Bibok:** Investigation. **Attila Doros:** Investigation. **Nadasdy-Horvath Domonkos:** Investigation. **Anna Zsofia Meltzer:** Investigation. **Attila Szijarto:** Supervision, Conceptualization. **Denes Horvathy:** Investigation. **Oszkar Hahn:** Investigation, Conceptualization. **Balint Kokas:** Investigation. **Damjan Pekli:** Investigation.

Ethical statement

All procedures performed in studies involving human participants were approved by the Institutional Review Board and were in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

Funding Statement

This study was not supported by any funding.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

Acknowledgments

Compliance with Ethical Standards: All procedures performed in studies involving human participants were approved by the Institutional Review Board and were in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

The authors declare that they have no conflict of interest.

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