ORIGINAL ARTICLE

Procedure Time, Efficacy, and Safety of Portal Vein Embolisation Using a Sheathless Needle-Only Technique Compared with Traditional Technique

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ABSTRACT

Introduction: Portal vein embolisation is traditionally performed through an access sheath for selective catheterisation and embolisation of portal vein branches. This study aimed to compare the procedure time, efficacy, and safety of a previously reported sheathless technique versus the traditional technique.

Methods: Two retrospective cohorts of portal vein embolisation from two different institutions were reviewed, one for each technique. Baseline characteristics included patient demographics, liver and renal function tests, international normalised ratio test, tumour type, and planned resection extent. The primary outcome was procedure time. Secondary outcomes were technical success, procedural sedation, resection rate, complications, and 30-day mortality. For cases with available computed tomographic volumetry, future liver remnant volume (FLRV), %FLRV, and increase in FLRV and %FLRV were recorded. The two cohorts were then compared statistically.

Results: Fifty portal vein embolisation procedures on forty-nine patients were included in each cohort. There were no statistically significant differences in baseline characteristics including age, sex, Model for End-stage Liver Disease, and albumin-bilirubin scores between the cohorts. The sheathless cohort had significantly lower albumin, bilirubin, and international normalised ratio levels (though all within normal limits), a significantly lower proportion of hepatocellular carcinomas and a significantly higher proportion of cholangiocarcinomas and planned trisectionectomies. The sheathless cohort had significantly shorter procedure times and less use of procedural sedation, with no significant differences in technical success, absolute increases in FLRV and %FLRV, resection rate, complications, or 30-day mortality.

Conclusion: The sheathless technique was associated with shorter procedure time and reduced use of procedural sedation compared with the traditional technique, with comparable efficacy and safety.

Key Words: Carcinoma, hepatocellular; Cholangiocarcinoma; Embolization, therapeutic; Endovascular procedures; Liver neoplasms; Liver regeneration; Portal vein; Radiology, interventional

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Submitted: 16 Nov 2020; Accepted: 2 Dec 2020.

Contributors: All authors designed the study. KCHY and SSMW acquired data. KCHY, SSMW and SCHY analysed the data. KCHY drafted the manuscript. All authors critically revised the manuscript for important intellectual content.

Conflicts of Interest: The authors have no conflicts of interest to declare that are relevant to the content of this article.

Funding/Support: This study received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Data Availability: All data generated or analysed during the present study are included in this published article (and its supplementary information files).

Ethics Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required. Ethical approval was waived and approved (NTWC/REC/19133) respectively for the two retrospective cohorts in this study.

Acknowledgement: This research was submitted to and accepted for oral presentation at the 28th Annual Scientific Meeting of the Hong Kong College of Radiologists, 14-15 November 2020.

中文摘要

無鞘單針技術與傳統方法的門靜脈栓塞術:比較手術時間、療效和安全性 余俊鴻、王先民、王耀忠、陳崇文、蕭志偉、劉顯宇、陳積聖、蔡紹俊、余俊豪

引言:門靜脈栓塞術(PVE)傳統上通過通路鞘進行,用於選擇性導管插入和栓塞門靜脈分支。本 研究旨在比較先前報導的無鞘技術與傳統技術的手術時間、療效和安全性。

方法:分析來自兩個不同機構的兩個PVE回顧性隊列,每個機構一種技術。基線特徵包括患者基本 特點、肝功能檢測、國際標準化比值測試、腫瘤類型和計劃切除範圍。主要結果是手術時間。次要 結果包括技術成功率、手術鎮靜、切除率、併發症和30天死亡率。對於具有可用計算機斷層掃描計 算體積的病例,記錄術後肝殘餘體積(FLRV)、%FLRV百份比,以及FLRV和FLRV百份比的增加。 這兩個隊列進行統計學比較。

結果:每個隊列包括49名患者的50次PVE手術。兩組之間的基線特徵包括年齡、性別、終末期肝病 模型(MELD)或白蛋白膽紅素(ALBI)評分無統計學顯著差異。無鞘隊列患者的白蛋白、膽紅素 和國際標準化比值水平顯著較低(儘管都在正常範圍內),肝細胞癌比例顯著較低,膽管癌和計劃 三段切除的比例顯著較高。無鞘隊列的手術時間顯著縮短,並且較少使用程序性鎮靜,在技術成功 率、FLRV和FLRV百份比的增加、切除率、併發症或30天死亡率方面無顯著差異。

結論:與傳統技術相比,無鞘技術的手術時間更短,鎮靜劑用量減少,療效和安全性相若。

INTRODUCTION

Portal vein embolisation (PVE) is an interventional radiology procedure first reported in 1986 as an alternative to open PV ligation.¹ It is performed prior to hepatic resection for primary or secondary malignancy to increase the size of future liver remnant (FLR), in patients initially contraindicated for upfront hepatectomy due to borderline liver function or inadequate FLR volume. This is achieved by selective embolisation of PV branches supplying the tumour-bearing hepatic lobe, resulting in increased blood flow to the FLR to induce hypertrophy with a high success rate,²⁻⁴ along with reduction in postoperative hepatic dysfunction, complications, and an increase in the ability to subsequently perform hepatic resections with curative intent.5,6 PVE traditionally involves transhepatic puncture of a segmental or sectoral PV branch, insertion of an access sheath, portography for anatomical delineation and planning, and selective embolisation of PV branches.7 Various embolic agents including liquid, spherical, particulate agents, and coils have been utilised.8

Performing PVE with a simplified sheathless needleonly technique, in which direct portography and glue embolisation are performed via the puncture needle, has been reported to have a high technical success rate and satisfactory FLR hypertrophy.⁹ This study aimed to compare the procedure time, efficacy, and safety of PVE with the sheathless technique versus the traditional technique.

METHODS

Two retrospective patient cohorts were retrieved from two tertiary institutions, one comprised of patients that had undergone the sheathless technique and the other comprised of patients that had undergone the traditional technique (Figure 1). The decision to perform PVE had been made by a multidisciplinary consensus with hepatobiliary surgeons and interventional radiologists in accordance with local guidelines.¹⁰⁻¹² Ethical approval was waived for the sheathless technique cohort and approved for the traditional technique cohort (NTWC/REC/19133) by their respective institutional review boards. Patient consent was waived due to the retrospective nature of the study.

Data Collection

Data collection and reporting was done with reference to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist.¹³ Patient data



Figure 1. Patient cohort recruitment.

Abbreviations: HCC = hepatocellular carcinoma; PVE = portal vein embolisation.

were retrieved via the electronic patient record system. These included age, sex, baseline blood test results (sodium, creatinine, alanine transferase, albumin, total bilirubin, international normalised ratio [INR]), tumour type (hepatocellular carcinoma, cholangiocarcinoma, or metastasis), technical success, use of procedural sedation, planned hepatectomy extent (right hepatectomy or trisectionectomy), eventual hepatectomy, and complications. Model for End-stage Liver Disease (MELD) and albumin-bilirubin (ALBI) scores were used as markers of chronic hepatic derangement, and were calculated with their original formulas.^{14,15}

Traditional Technique Cohort

Forty-nine consecutive cases of PVE in 2008 to 2019 were analysed. Traditional PVEs were performed by interventional radiology specialists with 5 to >20 years of experience, in one of two dedicated interventional angiography suites (Allura Clarity, Philips Healthcare, Best, the Netherlands; Artis Q with PURE[®], Siemens Healthcare, Erlangen, Germany).

Under local anaesthesia (1% lidocaine) and using sonographic guidance, a segmental PV branch was located and punctured with a 20-22 G needle (Chiba; Cook Incorporated, Bloomington [IN], US; Inrad, Inc., Kentwood [MI], US). Procedural sedation with fentanyl or midazolam was administered if necessary. The puncture was ipsilateral to the tumour-bearing lobe. Typically, right lobe anterior sectoral branches, which have been shown to be safer and would not violate the FLR, were chosen.¹⁶ Contralateral (left-sided) puncture was performed in cases of markedly distorted anatomy or difficult access of the right PV system. Position was confirmed by free aspiration of venous blood and direct portography (Omnipaque 300; GE Healthcare, Shanghai, China). An access sheath was then inserted via an introducer set (Skater 6 Fr × 18 cm; Argon Medical Devices Inc., Athens [TX], US) or a 4 to 5 Fr vascular sheath (Cook Incorporated, Bloomington [IN], US; Radifocus Introducer II, Terumo Corporation, Tokyo, Japan). Using a 0.035-inch guidewire (0.035-inch Terumo guidewire; Radifocus, Angled Terumo Corporation, Tokyo) and angiographic catheters (4-5 Fr C1; SHK, Rim, MPA etc., Cordis Corporation, Miami Lakes [FL], US), portography was performed to delineate the anatomy (Figure 2). Branches of the right PV were then selectively catheterised and embolised with microcatheters (2.4 Fr Merit Maestro; Merit Medical Systems Inc., South Jordan [UT], US and 2.8 Fr Renegade Hi-Flo; Boston Scientific, Marlborough [MA], US) and a microguidewire (0.014-inch Traxcess; MicroVention Terumo, Tustin [CA], US). The embolic agent of choice was n-butyl-2-cyanoacrylate (Histoacryl; B Braun Surgical S.A., Rubi, Spain) diluted to 10% to 25% in iodised oil (Lipiodol® Ultra Fluid; Guerbet LLC, Princeton [NJ], US). In a few selected cases, 100- to 300-µm polyvinyl alcohol particles (Contour; Boston Scientific) were employed. The angiographic endpoint was satisfactory occlusion of the selected right PV branches by glue cast or polyvinyl alcohol particles.

Sheathless Technique Cohort

The same 45 consecutive cases of PVE from 2009 to 2017 from our previous study⁹ plus five additional cases from 2017 to 2019 were analysed. Full technical details and considerations are as previously described.⁹ In brief, a right PV branch, typically segment V/VI, was punctured with a Cook 15 cm 18 G Diamond needle under sonographic guidance, followed by direct portography with iodinated contrast for anatomical delineation, and finally injection of 16% N-butyl cyanoacrylate glue diluted in Lipiodol[®] Ultra Fluid all from the same

PVE Using a Sheathless Needle-Only Technique



Figure 2. Traditional technique. (a) Portography via a 5-Fr sheath and a pigtail catheter delineating the portal venous system. Sequential catheterisation of the posterior (b) and anterior (c) sector branches, followed by glue embolisation. (d) Postembolisation fluoroscopic image showing a glue cast in the right portal venous system.

needle under careful manual control of injection rate and fluoroscopy to avoid nontarget embolisation to the FLR (Figure 3). Additional puncture(s) was / were needed in cases with short right PVs (<2 cm), main PV trifurcating into right / left / segment IV branches, or the segment IV branch arising from the right PV. These were performed by a single interventional radiology fellow with >20 years of experience. Intravenous (IV) procedural sedation (single-dose 50 µg IV fentanyl) and cone beam computed tomography (CT) were both used at the operator's discretion.

Volumetric Analysis

In cases where DICOM data of both pre- and post-PVE CTs were available (Figure 4), volumetric analysis was performed using commercial imaging software (IntelliSpace Portal v5.0.2.30010; Philips Healthcare or OsiriX v7.0.3, Pixmeo, Bernex, Switzerland) on 5 mm sections by two radiology fellows with 5 and

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9 years of experience in liver volumetry, respectively. The latest pre-PVE CT and post-PVE CT, typically 4 weeks before and 4 to 6 weeks after PVE, were used for volumetric analysis. Hepatic segments were defined according to the Couinaud classification. Since segment I is usually partially or completely resected during hepatectomy, FLR refers to segments II-IV for right hepatectomy candidates, and to segments II/III for right trisectionectomy candidates. The percentage of FLR volume (%FLRV) is defined as [*FLRV* × 100%/(*total liver volume - tumour volume*)]. Tumour volume was included except for infiltrative or ill-defined tumours.

Outcome Measures

Primary outcome was procedure time, defined as time elapsed from the first to the final angiographic runs, plus time taken for sonographic evaluation, universally assumed to be 10 minutes. Secondary outcomes included technical success, use of procedural sedation, degree of



Figure 3. Sheathless needleonly technique (a) fluoroscopic image showing trocar needle in situ with direct portography performed via the needle. (b) Post-embolisation fluoroscopic image of another case, showing satisfactory glue cast in the right portal venous system.



Figure 4. (a) Area and (b) volume of each hepatic segment as calculated by volumetric analysis as performed with Philips ISP software in one of the cases in the traditional technique cohort.

FLR hypertrophy, resection rate, and complications. Technical success was defined as satisfactory occlusion of right PV branches by glue cast.

Use of procedural sedation was defined as any use of any IV sedation agents, regardless of dose.

The degree of FLR hypertrophy was assessed by the absolute increase in FLRV, absolute increase in %FLRV, and percentage increase of %FLRV after PVE. The resection rate was the proportion of patients eventually undergoing hepatectomy. Staged hepatectomy was performed in patients with satisfactory FLR hypertrophy or improvement in liver function tests, and delayed or cancelled in patients with inadequate FLR hypertrophy, inadequate liver function, tumour progression, or

new contraindications to surgery. Complications were classified according to Society of Interventional Radiology guidelines.¹⁷

Data and Statistical Analysis

Sample size was calculated with the formula for difference in two independent sample means for our primary outcome (procedure time). The ratio of controls to cases was 1:1. Two-sided significance level (α) and statistical power (1- β) were taken as 0.05 and 80%, respectively. From the previously published series,⁹ the mean procedure time and standard deviation (SD) for the sheathless technique was 19.4 ± 15.3 minutes. The most recent 10 cases of PVE with traditional technique performed in 2018 to 2019 were reviewed as a pilot series, with mean procedure time of 84.3 ± 38.1 minutes.

The expected difference in means was 64.9 minutes. However, we consider a 50% decrease in procedure time with the sheathless technique (42 min) to be clinically meaningful. The required sample size for each cohort was therefore 13.

The normality of data was tested by a Shapiro-Wilk test, with p > 0.05 indicating normal distribution. Categorical variables were listed as number and percentage to total and compared using Fisher's exact test (two-tailed). Continuous parametric variables were expressed as mean \pm SD and compared using an independent-samples t test. Continuous nonparametric variables were expressed as median and interquartile range (Q1-Q3) and compared using the Mann-Whitney U test. A p value of <0.05 (two-tailed) was defined as statistically significant. Data collection was performed using commercial software (Office Excel version 16.29.1, Microsoft, Redmond [WA], US). Statistical analyses and graph plots were also performed on commercial software (SPSS Windows version 24.0; IBM Corp, Armonk [NY], US).

RESULTS

Forty-nine patients undergoing 50 PVE procedures were included in each cohort. Baseline characteristics are summarised in Table 1. There was no statistical difference in age, sex, MELD, or ALBI scores. The sheathless technique cohort showed significantly lower serum albumin, bilirubin, and INR levels (all p < 0.05), although all levels were within normal limits. There was a significantly lower proportion of hepatocellular carcinoma, higher proportion of cholangiocarcinoma and higher proportion of planned trisectionectomy (all p < 0.05). For the sheathless group, 38 patients (76%) required only a single puncture while the others (n = 12, 24%) required two punctures. None of the patients required three or more punctures.

Outcome measures are shown in Table 2. The sheathless technique cohort showed significantly shorter procedure time (24 min vs 85.5 min; p < 0.001) and a lower proportion of patients required procedural sedation (16% vs 78%; p < 0.001). There was no significant difference in technical success rate (p > 0.05). There was a comparable number of CT volumetry data sets available in the two cohorts, with no significant difference in absolute FLRV increase, absolute %FLRV increase, or percentage increase in %FLRV (p > 0.05) [Table 3 and Figure 5]. There was no significant difference in resection rate, minor complications, major complications, or 30-day mortality (p > 0.05).

In the sheathless technique cohort, there were

Table 1. Baseline characteristics.*

	Sheathless needle-only technique (n = 50)	Traditional technique (n = 50)	p Value
Patient demographics			
Age, y	60 (56-64)	64 (56-71)	0.100
Male	43 (86%)	39 (78%)	0.436
MELD score	7 (6-8)	7 (6-8)	0.610
ALBI score	-2.73 (-3.01 to -2.33)	-2.83 (-3.01 to -2.61)	0.205
Baseline blood tests			
Sodium, mmol/L	140 (137.0-141.0)	140 (138-141.3)	0.622
Creatinine, µmol/L	79 (66-89)	76.5 (68.5-85.3)	0.964
ALT, IU/L	35.5 (25-56.3)	41 (26-64.75)	0.430
Albumin, g/L	37.9 ± 4.9	40.3 ± 3.5	0.008
Total bilirubin, µmol/L	9.5 (5.8-16.3)	12.5 (9-16)	0.024
INR	1.0 (1.0-1.1)	1.1 (1.0-1.1)	0.029
Tumour type			
Hepatocellular carcinoma	27 (54%)	42 (84%)	<0.001
Cholangiocarcinoma	16 (32%)	2 (4%)	
Metastases	7 (14%)	6 (12%)	
Planned liver resection			
Right hepatectomy	23 (46%)	43 (86%)	< 0.001
Extended right hepatectomy or right trisectionectomy	27 (54%)	7 (14%)	

Abbreviations: ALBI = albumin-bilirubin; ALT = alanine aminotransferase; INR = international normalised ratio; MELD = Model for End-stage Liver Disease.

* Data are shown as No. (%), median (range), or mean \pm standard deviation.

three major complications (6%). One patient with cholangiocarcinoma developed an infected right subphrenic collection after PVE, which resolved 4 days after percutaneous drainage, but was further complicated with cholangitic abscesses that were successfully managed conservatively with IV antibiotics. Resection was cancelled due to disease progression. In another patient with hepatocellular carcinoma, there was glue reflux into the common hepatic artery leading to infarction of the right posterior segment, which was resected during right hepatectomy. In one patient with cholangiocarcinoma, a glue cast migrated into the hepatic vein and right atrium, which was successfully captured and removed by inferior vena cava filter insertion, retrieval, and aspiration thrombectomy. This patient subsequently underwent right trisectionectomy

Table 2. Outcome measurements.

	Sheathless needle-only technique (n = 50)	Traditional technique (n = 50)	p Value
Procedure time, min	24 (21-29.5)	85.5 (61.75-121)	<0.001
Technical success	50 (100%)	48 (96%)	0.495
Procedural sedation	8 (16%)	39 (78%)	<0.001
Liver resection rate	38 (76%)	36 (72%)	0.488
Minor complications	3 (6%)	2 (4%)	0.665
Major complications	3 (6%)	1 (2%)	0.342
30-day mortality	1 (2%)	0	0.474

* Data are shown as No. (%) or median (range), unless otherwise specified.

Table 3. Computed tomography analysis.*

uneventfully. There were three minor complications, all of which involved asymptomatic nonocclusive emboli in FLR detected on post-embolisation CT. Two of these patients underwent resection uneventfully, and the third did not undergo resection as a result of disease progression.

In the traditional technique cohort, there was one major complication (2%). A patient with cholangiocarcinoma developed a liver abscess and cholangitis a week after PVE, requiring intensive care unit admission and repeated percutaneous drainages. The patient later underwent hepatectomy uneventfully. There were two minor complications. In a patient with hepatocellular carcinoma, there was nontarget embolisation to a segmental pulmonary artery detected on cone beam CT upon completion of PVE and confirmed on CT pulmonary angiography. The patient remained asymptomatic, not requiring additional treatment, and was discharged on day 4, which only qualified as a minor complication according to Society of Interventional Radiology guidelines. Another patient with hepatocellular carcinoma was readmitted on day 2 for right upper quadrant pain, which was successfully managed conservatively.

There was only one case of 30-day mortality, specifically in the sheathless technique cohort, without statistically significant difference between the two cohorts. This patient had hepatocellular carcinoma on a background of multiple medical comorbidities including motor neuron

	Sheathless needle-only technique (n = 50)	Traditional technique (n = 50)	p Value
Cases with volumetric analysis	26 (52%)	31 (62%)	0.419
Pre-PVE CT			
Total liver volume, cm ³	1336.5 (1216-1565)	1392.0 (1151-1549)	0.798
Tumour volume, cm ³	28.8 (10.5-154.5)	121.4 (37.3-280.7)	0.015
FLRV, cm ³	378.5 (278.0-506.5)	399.9 (292.4-586.1)	0.491
%FLRV	30.3 ± 10.2	35.4 ± 7.8	0.042
Post-PVE CT			
Total liver volume, cm ³	1352.5 (1266-1557)	1417.7 (1220-1720)	0.974
Tumour volume, cm ³	39.6 (8.2-120.0)	77.1 (38.6-306.1)	0.030
FLRV, cm ³	604.2 (382.3-788.0)	557.8 (441.1-737.9)	0.936
%FLRV	41.8 ± 13.0	46.9 ± 9.6	0.103
Serial change			
Absolute increase in FLRV, cm ³	139.5 (87.0-241.0)	141.0 (86.0-204.0)	0.810
Absolute increase in %FLRV	10.6 (5.0-15.5)	11.3 (7.1-14.4)	0.597
Percentage increase in %FLRV	47.2 ± 32.9	39.4 ± 26.6	0.337

Abbreviations: CT = computed tomography; FLRV = future liver remnant volume; PVE = portal vein embolisation.

* Data are shown as No. (%), median (range), or mean \pm standard deviation.



Figure 5. Future liver remnant hypertrophy in the traditional and sheathless technique cohorts. Absolute increase in future liver remnant volume (FLRV) (a), absolute increase in %FLRV (b) and % increase in %FLRV (c).

disease, with an initially uneventful post-PVE recovery, but later presented on day 27 with a fall and head injury, with sudden asystole while still in the emergency department. No significant abnormality was found on CT of the brain or plain radiograph of the chest, including intracranial haemorrhage, airspace opacification, or inadvertent glue migration. Liver function tests were also normal. The patient succumbed on the same day after joint consensus of comfort care was made. The cause of mortality was presumed to be more likely related to the underlying motor neuron disease rather than as a consequence of PVE.

DISCUSSION

The sheathless technique was found to be a feasible alternative to the traditional technique in a previous study.9 This study further confirmed its advantages in terms of shorter procedure time and a reduced need for sedation while maintaining similar efficacy and safety profiles. The traditional technique of PVE has a few obvious disadvantages. It requires placement of an access sheath, which is painful, and frequently requires sedation. Selective segmental catheterisation for portography and embolisation can also be tedious with significantly longer procedure times, up to 214 minutes in our series. This is likely also associated with higher radiation dose to the patient. Last but not least, tract embolisation also has to be performed. Complications of the traditional technique reported in the literature include bleeding, vascular or bile duct injury, pneumothorax, inadvertent embolisation of the FLR, and migration of embolic agents, among others.^{16,18} There were instances of nontarget embolisation in both of our series, without statistically significant differences. Specifically, this involved the hepatic vein and hepatic artery in the sheathless group, and probable hepatic vein followed by segmental pulmonary artery in the traditional group. This was likely due to either vascular shunts, which are common in hepatic malignancies, or inadvertent double puncture of the involved hepatic artery or hepatic vein, which is in theory equally likely in both techniques. The cases of minor asymptomatic FLR emboli in the sheathless group may be attributable to the more technically demanding nature of the sheathless technique, requiring a painstakingly careful steady injection and backflow of glue to the right PV in order to reach all the targeted right PV branches. Importantly, none of these complications was significant enough to preclude subsequent hepatectomy.

As shown in our results, the sheathless technique negates

a few major drawbacks of the traditional technique in selected patients, while maintaining comparable outcomes and safety profile.

There are a few important technical issues. First, the pre-PVE CT should be carefully analysed for PV anatomy. This is especially important for the sheathless technique because the image quality of direct portography via the 18 G needle is not as good as via the access sheath or catheter in the traditional technique. Second, test runs using iodinated contrast should be performed before embolisation to estimate the optimal flow rate and volume, to avoid nontarget embolisation as well as premature polymerisation of the glue cast before it reaches all target PV branches. Third, in cases where PV anatomy is grossly distorted by tumour or with complex variant anatomy, the traditional technique probably remains the safer and more conservative approach.

The major limitation of this study is the separate patient cohorts for the two different techniques. There were statistically significant differences in the baseline serum albumin, bilirubin, and INR levels. Given that these parameters were within normal range, such a small difference might not be clinically significant. The sheathless technique cohort also contained significantly higher proportion of cholangiocarcinoma and planned trisectionectomy, as well as smaller tumour volume and %FLRV. These were likely due to different degree of utilisation of PVE in cholangiocarcinoma in different institutions. Although this may imply different prevalence of chronic hepatitis in the two cohorts, the degrees of liver derangement were comparable, as there was no significant difference in their MELD and ALBI scores. As such, the difference in tumour type in the two cohorts should not influence the outcome. The MELD^{14,19} and ALBI15 scores were adopted in this study instead of Child-Pugh score, as the latter incorporates subjective factors such as presence of ascites and encephalopathy.

Another limitation is the limited generalisability of the results of the sheathless technique series, which was performed by one experienced operator in a tertiary academic institution. We do not have reference outcome measures of the traditional technique in this institution by this operator to compare with our control group, which was performed by multiple operators with varying levels of experience in another tertiary institution, and this may be a confounding factor. Undeniably, operator experience has significant bearings on both procedure time and utilisation of procedural sedation, while institutional differences likely also account for baseline differences such as tumour type, planned hepatectomy extent, procedural sedation protocol, etc. to name just a few. Due to this study's retrospective nature, we were unable to standardise or control for these factors. CT volumetry data was also incomplete, as some patients received their CT in outside facilities.

In conclusion, the sheathless technique for PVE results in a shorter procedure time and reduced need for sedation compared with the traditional technique, with a comparable degree of FLR hypertrophy and complication rate.

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