

PERCUTANEOUS RADIO-FREQUENCY ASSISTED LIVER PARTITION WITH PORTAL VEIN EMBOLIZATION IN STAGED LIVER RESECTION (PRALPPS) IN PATIENTS WITH PERIHILAR AND INTRAHEPATIC CHOLANGIOCARCINOMA: EVALUATION OF SHORT-TERM RESULTS

Olga V. Melekhina, Mikhail G. Efanov*, Ruslan B. Alikhanov, Victor V. Tsvirkun, Yuliya V. Kulezneva, Ivan V. Kazakov, Pavel P. Kim, Andrey N. Vankovich

The Loginov Moscow Clinical Scientific Centre of Moscow Healthcare Department, Russia, Moscow

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OBJECTIVE. To estimate the short-term results of modified variant of ALPPS (PRALPPS) in patients with perihilar and intrahepatic cholangiocarcinoma. **MATERIAL AND METHODS.** Procedure was indicated for future liver remnant <40%. **RESULTS.** PRALPPS was applied in 13 patients and completed in 10 patients. Degree of hypertrophy and kinetic growth rate were 48 and 4.3%/day, respectively. Major morbidity (>II) after the stage 1 and 2 was presented in 3 (only IIIa) and 7 patients, respectively. **CONCLUSION.** PRALPPS may be considered as an effective and safe procedure in patients with perihilar and intrahepatic cholangiocarcinoma.

Keywords: PRALPPS, ALPPS, perihilar cholangiocarcinoma, intrahepatic cholangiocarcinoma

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Corresponding author: Mikhail G. Efanov, The Loginov Moscow Clinical Scientific Centre of Moscow Healthcare Department, 86 shosse Entuziastov, Moscow, Russia, 11123. E-mail: m.efanov@mknc.ru.

Чрескожное разделение печени радиочастотной термоабляцией с эмболизацией воротной вены при этапной резекции печени (PRALPPS) у пациентов с околоротной и внутripеченочной холангиокарциномой: оценка ближайших результатов

О. В. Мелехина, М. Г. Ефанов*, Р. Б. Алиханов, В. В. Цвиркун, Ю. В. Кулезнева, И. В. Казаков, П. П. Ким, А. Н. Ванькович

Государственное научное учреждение здравоохранения «Московский клинический научный центр имени А. С. Логинова» Департамента здравоохранения Москвы, Москва, Россия

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ЦЕЛЬ. Оценить ближайшие результаты модифицированного варианта ALPPS (PRALPPS) у пациентов с перихилярной и внутripеченочной холангиокарциномой. **МАТЕРИАЛ И МЕТОДЫ.** Операцию выполняли при объеме будущего остатка печени <40 %. **РЕЗУЛЬТАТЫ.** PRALPPS был применен у 13 пациентов и завершен у 10 пациентов. Степень гипертрофии и кинетическая скорость роста sFLR составили 48 и 4,3 %/день соответственно. Серьезные осложнения (>II) после 1-го и 2-го этапов выявлены у 3 (только IIIa) и 7 пациентов, соответственно. **ЗАКЛЮЧЕНИЕ.** PRALPPS может рассматриваться как эффективная и безопасная операция при перихилярной и внутripеченочной холангиокарциномах.

Ключевые слова: PRALPPS, ALPPS, перихилярная холангиокарцинома, внутripеченочная холангиокарцинома

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Автор для связи: Михаил Германович Ефанов, ГБУЗ «Московский клинический научный центр имени А. С. Логинова» ДЗ Москвы, 11123, Россия, Москва, шоссе Энтузиастов, д. 86. E-mail: m.efanov@mknc.ru.

Introduction. The routine tool to stimulate hypertrophy of the future liver remnant (FLR) is portal vein embolization (PVE). Nevertheless, the rate of FLR hypertrophy does not exceed 30–40 % in patients with cholangiocarcinoma after PVE [1]. One of the most effective tools to stimulate FLR hypertrophy is recently elaborated Associated

Liver Partition and Portal vein ligation for Staged hepatectomy (ALPPS) [2]. Extremely poor immediate outcomes of ALPPS in patients with different types of cholangiocarcinoma were critically reviewed in several papers, including analysis of the data of international ALPPS register [3–5]. As a result, ALPPS was not recommended

to be applied in patients with cholangiocarcinoma. The feasibility of applying ALPPS for treatment of biliary cancer remains inconclusive.

Several variants of ALPPS with reduced surgical trauma were proposed to decrease the risk of severe morbidity irrespectively to the type of the tumor needed to be removed by extended liver resection, nevertheless, there are still no data justifying implementation of modified ALPPS for FLR hypertrophy stimulation by estimation of outcomes in series of cholangiocarcinoma patients [6–10]. In this study we aimed to evaluate the short-term outcomes of Percutaneous Radio-frequency Assisted Liver Partition with Portal vein embolization in Staged liver resection (PRALPPS) in patients with perihilar (PHCC) and intrahepatic (IHCC) cholangiocarcinoma.

Material and Methods. *Study Design* – retrospective observational study. Data were collected prospectively over the period of September 2014 – March 2018. The indication for PRALPPS was the volume of FLR < 40 %. Patients with PHCC, type II–IV, T1-3N0-1M0 and IHCC, T1-3N0-1M0 were included in the study. Exclusion criteria were stage IVA, B for PHCC, stage IVB and T4N0-1M0 for IHCC patients.

The volume of FLR was estimated initially by multispiral CT. The hypertrophy of FLR was evaluated by calculation of the rate of FLR hypertrophy, degree of hypertrophy (DH) and kinetic growth rate (KGR). The rate of hypertrophy was calculated using the standard formula:

$$[(\text{Post-PVE FLR} - \text{Pre-PVE FLR}) / (\text{Pre-PVE FLR})]100. [11, 12].$$

Calculation of standard FLR (sFLR), DH and KGR was performed according to formulas proposed by authors from MD Anderson Cancer Center [13, 14]. Hepatic failure after liver resection was defined according to ISGLS criteria (International Study Group of Liver Surgery) [15]. Morbidity was estimated according to Clavien – Dindo scale, including 90-day mortality estimation [16].

Surgical technique. The stage 1 of PRALPPS included minimally invasive procedures performed by only percutaneous approach: portal vein embolization combined with radio-frequency ablation (RFA) of liver parenchyma along one of the portal planes depending of the type of major liver resection. The depth of liver parenchyma destruction by RFA was not exceed 50 % of future liver resection plain. Detailed description of surgical technique was presented in our previous papers [17]. FLR volume was estimated 7–9 days after the first stage. If the volume of FLR did not reached 40 %, the second stage was postponed for the next 7–11 days with repeated CT volumetry. Major liver resection was performed on a second stage, which also included regional lymphadenectomy, extrahepatic bile duct resection, and biliary reconstruction with Roux-en-Y hepaticojejunostomy through the laparotomy or minimally invasive approach (laparoscopic or robotic).

Outcomes. The primary end point of the study was to evaluate the safety of PRALPPS by taking into account the frequency and nature of morbidity, as well as mortality after stage 1 and 2 of PRALPPS. The secondary end points were rate of FLR hypertrophy intraoperative blood loss. Short-term oncological outcomes were estimated by the comparison of R0 rate resection.

Statistical Analysis. Continuous data are presented as median values. SPSS version 23.0 (IBM SPSS, Inc., Chicago, IL) software package was applied for data analysis.

Table 1

Demographic data and perioperative outcomes in stage 1

Parameter	Value
Age, year	58 (42–73)
Gender (female, male), n	4/9
ASA PS*	3 (3–4)
Diagnosis (PHCC/IHCC), n	11/2
Total bilirubin before drainage, μmol/L	187 (21–313)
Cholangitis before procedure, n	9
Duration of jaundice, week	4 (0–8)
Chemo before procedure, n	1
Volume of FLR initially, %	32 (20–41)
Volume of FLR after stage 1, %	45 (35–58)
Volume of sFLR initially, %	38 (18–88)
Volume of sFLR after stage 1, %	54 (30–116)
Rate of FLR hypertrophy, %	44 (15–93)
Duration of FLR hypertrophy, day	15 (6–29)
Degree of hypertrophy, %	48 (17–117)
Kinetic growth rate, %/day	4.3 (0.6–11.0)
Severe morbidity (>II) after stage 1, n	3

* – American Society of Anesthesiologists

Table 2

Perioperative outcomes in stage 2

Parameters for stage 2 (n=11)	Value
Blood loss during stage 2, ml	580 (50–2200)
Residual tumor (R1,2), n	0
Severe morbidity (>II) after stage 2, n	7
Liver failure B (ISGLS) after stage 2, n	1

Results. A total of 110 patients with PHCC and IHCC were treated with curative intent during the period of October, 2013 – March, 2018, including 84 patients with PHCC and 26 patients with IHCC. PRALPPS was performed in 13 patients.

All jaundiced patients with the bile duct tumor obstruction underwent percutaneous biliary drainage (PTBD). PTBD was effective in all patients and led to decrease of total bilirubin less than 50 $\mu\text{mol/l}$.

Demographic data, tumor characteristics, laboratory data before surgery and outcomes of stage 1 are presented in *table 1*.

The second stage of PRALPPS was completed in 10 patients. Despite the high rate (75 %) and long duration (23 days) of FLR hypertrophy after the first stage of PRALPPS, major liver resection was refused in one patient with PHCC due to insufficient final volume of FLR (35 %). Parenchymal-sparing resection was performed with R0 bile duct resection. The second stage was cancelled in two patients because of peritoneal canceromatosis revealed after laparotomy. In one patient, the reason to decline the second stage was the relapse of cholangitis and tumor progression during the time that was required for treatment of cholangitis.

Data on stage 2 of surgery are presented in *table 2*.

Distribution of complications according to their severity according to Clavien – Dindo classification is presented in *table 3*. In most of the patients with postoperative morbidity complications of grade II and IIIa were observed.

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served. Morbidity according to stage of surgery is presented in *table 4*.

The severe morbidity in 3 patients after the first stage of PRALPPS included only grade IIIa complications which were presented by abscesses in ablated liver parenchyma resolved after percutaneous drainage. Severe complications after the second stage of resection are presented in *table 3*. Most of complications after the stage 2 were estimated as grade IIIa. The only death after the stage 2 in patient with IHCC was not directly related to the liver resection. The reason for lethal outcome was multiple relapsed small intestinal wall perforation due to division of severe adhesions caused by canceromatosis, which was revealed only on histological examination.

Discussion. Analysis of ALPPS short-term outcomes based on the data from International ALPPS Registry, revealed the most frustrating morbidity and mortality after the both stage of procedure in patients with different types of cholangiocarcinoma. The severe complications rate after ALPPS in patients with PHCC reached 64 %. The rate of 90-day mortality and liver failure was 36 and 57 %, respectively, in patients with PHCC [3, 4]. The high risk of ALPPS in treatment of patients with PHCC was confirmed by recent multicenter study Olthov et al (2017), where authors revealed mortality rate reached 48 % in 90-days in unmatched patients [5]. One of the ways to overcome the negative impact of ALPPS on immediate results of surgical treatment is reduced surgical trauma on the first stage of procedure [18]. Several modified less traumatic

Table 3

Severity of morbidity according to Clavien – Dindo classification

Grade of complications	After stage 1 (n=13)	After stage 2 (n=10)
Grade 1	NA	NA
Grade 2	3	1
Grade 3a	3	5
Grade 3b	0	1
Grade 4a	0	0
Grade 4b	0	0
Grade 5	0	1
Total	6	8

NA – non available.

Table 4

Morbidity after the stage 1 and 2 of PRALPPS

Complications	After stage 1 (n=13)	After stage 2 (n=10)
Fever (post RFA)	3	–
Liver abscesses	3	–
Bile leakage	–	3
Cholangitis	–	1
Pleural effusion	–	1
Ascites	–	1
Anastomotic stricture	–	1
Peritonitis	–	1
Total	6	8

variants of ALPPS were described over the past few years [8, 19]. Nevertheless, rare case reports presented implementation of this technique in patients with PHCC and IHCC [8–10, 20].

One of the advantages of PRALPPS is the only percutaneous approach for the first stage. Combined percutaneous PVE and microwave ablation were proposed by Hong de F and coauthors in 2016 [6]. The same technique as we used was described by Giménez et al. in experimental study on four pigs (PRALPPS) in 2017 [21]. Nevertheless, there is no English language publication on clinical implementation of PRALPPS, including treatment of patients with biliary cancer. Open RFA assisted liver partition combined with portal vein ligation was applied in patients with colorectal metastases and HCC (so called, RALPP and RALPPS techniques, respectively) [7, 22]. We have been using PRALPPS technique in our clinical practice since 2014. Initially we define the procedure as RALPPS (Radio-frequency Assisted Liver Partition with Portal vein embolization in Staged liver resection). The first analysis of short-term results in heterogeneous group included patients with different liver tumors was published in 2016 in Russian language paper [17].

Conventional PVE provides only 33.6 % rate of FLR hypertrophy before major resection for PHCC according to data of Higuchi and Yamamoto (2014), analyzed PVE outcomes in 836 patients [1]. Low liver capacity for hypertrophy is partly attributable to deterioration of liver parenchyma due to jaundice and acute cholangitis. Therefore, there is a need for more effective tool than conventional PVE to stimulate liver hypertrophy in order reach 40 % or even more volume of FLR, which was the main reason to apply PRALPPS in cholangiocarcinoma patients before major resection.

The main obstacle in implementation of ALPPS for bile duct cancer is enormous rate of liver failure and 90-day mortality. Therefore, the evaluation of nature and rate of morbidity of PRLAPPS was the first end point for investigation in our study. We obtained lower rate and severity of complications after the stage 1

in comparison with other authors presented outcomes of classical ALPPS in cholangiocarcinoma patients [5]. All of three patients with severe adverse events after stage 1 had only grade IIIa complications (infected fluid collection in liver parenchyma along RFA plane), that were resolved after percutaneous treatment. Severe complications after stage II of PRALPPS in our series developed in 8 out of 11 patients; nevertheless, the majority of them were not life-threatening and were estimated as grade IIIa according to Clavien-Dindo classification. Mortality rate after PRALPPS (1/11) was the same as it was published after PVE for biliary cancer (8.8 %) in specialized high volume centers [23]. No mortality was obtained after the stage I. A single lethal outcome after stage II was not related to liver resection.

The mean rate of FLR hypertrophy after the first stage was 43 %, which appears more effective than mean rate after PVE (33.6 %) presented in review paper of Higuchi and Yamamoto [1]. The hypertrophy was evaluated using volume of sFLR and DH proposed by MD Anderson Cancer Center [13]. Critical volume of sFLR after portal vein occlusion was estimated as 30 % for posthepatectomy liver failure prognosis in several papers. It was the same for patients with colorectal liver metastases and hilar cholangiocarcinoma [5, 13]. In our study mean volume of sFLR after the stage I was 54 (30–116) %. KGR estimation with controversial outcomes was performed previously only for patients with colorectal liver metastases. The critical rate of KGR for liver failure prediction changed from 2 %/week to 6 %/day [14, 24]. In our study mean KGR was 4.3 (0.6–11.0) %/day.

Short-term oncological results (R0 resection) were acceptable. The estimation of survival was not aimed in this study.

The limitations of our study are small number of cases and retrospective analysis. Further accumulation of experience is needed, nevertheless, the evaluation of the first results is important to understand that the modified variants of ALPPS demonstrate enough safety to continue their evaluation in cholangiocarcinoma patients.

Conclusion. According to preliminary evaluation, PRALPPS may be considered as the safe and effective procedure of stimulating FLR hypertrophy in cholangiocarcinoma patients. The first stage of PRALPPS is potentially reversible procedure unlike the conventional ALPPS. Comparative estimation of PRALPPS with conventional PVE is needed to clarify the advantages of former over the latter technology in terms of safety and efficacy.

Conflict of interest / Конфликт интересов

The authors declare no conflict of interest. / Авторы заявили об отсутствии конфликта интересов.

Compliance with ethical principles / Соответствие нормам этики

The authors confirm that they respect the rights of the people participated in the study, including obtaining informed consent when it is necessary, and the rules of treatment of animals when they are used in the study. Author Guidelines contains the detailed information. / Авторы подтверждают, что соблюдены права людей, принимавших участие в исследовании, включая получение информированного согласия в тех случаях, когда оно необходимо, и правила обращения с животными в случаях их использования в работе. Подробная информация содержится в Правилах для авторов.

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Information about authors:

Olga V. Melekhina (e-mail: o.melekhina@mknc.ru), Cand. of Med. Sci., Senior Researcher of Department of Interventional Radiology; *Mikhail G. Efanov* (e-mail: m.efanov@mknc.ru), Doct. of Med. Sci., Head of Department of Hepato-Pancreato-Biliary surgery; *Ruslan B. Alikhanov* (e-mail: r.alikhanov@mknc.ru), Cand. of Med. Sci., Head of Division of Hepato-Pancreato-Biliary surgery; *Victor V. Tsvirkun* (e-mail: tsvirkunvv@mail.ru), Doct. of Med. Sci., professor, Chief Researcher; *Yuliya V. Kulezneva* (e-mail: y.kulezneva@mknc.ru), Doct. of Med. Sci., professor, Head of Department of Interventional Radiology; *Ivan V. Kazakov* (e-mail: i.kazakov@mknc.ru), Cand. of Med. Sci., Senior Researcher of Department of Hepato-Pancreato-Biliary surgery; *Pavel P. Kim* (e-mail: p.kim@mknc.ru), Researcher of Department of Hepato-Pancreato-Biliary surgery; *Andrey N. Vankovich* (e-mail: a.vankovich@mknc.ru), Cand. of Med. Sci., Senior Researcher of Department of Hepato-Pancreato-Biliary surgery; The Loginov Moscow Clinical Scientific Centre of Moscow Healthcare Department, 86 shosse Entuziastov, Moscow, Russia, 11123.