A novel internal cold circulation radiofrequency-assisted device for liver transection

Yanzhao Zhou, Jingzhong Ouyang, Zhengzheng Wang, Xun Chen, Ruili Zhu, Qingjun Li and Jinxue Zhou

Department of Hepatopancreatobiliary Surgery, The Affiliated Tumor Hospital of Zhengzhou University, Henan, People’s Republic of China

ABSTRACT

Purpose: To evaluate the safety and efficacy of a new internal cold circulation bipolar radiofrequency compared with Habib-4X bipolar radiofrequency device in the resection of liver tumors.

Methods: A total of 85 patients with hepatocellular carcinoma who received radiofrequency-assisted liver resection from February 2017 to January 2020 were retrospectively enrolled in our study, in which 45 patients received the new internal cold circulation bipolar radiofrequency (New-RF) and 40 patients received Habib-4X bipolar radiofrequency (Habib-4X). Primary outcome measures were the speed of liver transection, the width of coagulation tissue, hemorrhage volume, blood transfusion rate, and operation time.

Results: The baseline characteristics of patients in the New-RF and Habib-4X groups had no significant difference \( p > 0.05 \). Compared to Habib-4X, the New-RF had a faster average speed of liver transection \( (4.81 \pm 1.20 \text{ cm}^2/\text{min} \text{ vs } 3.64 \pm 1.08 \text{ cm}^2/\text{min}, p < 0.001) \), a narrower width of coagulation tissue \( (1.42 \pm 0.23 \text{ cm}^2 \text{ vs } 1.81 \pm 0.20 \text{ cm}^2, p < 0.001) \), a less operation time \( (55.04 \pm 16.12 \text{ min} \text{ vs } 64.02 \pm 15.09 \text{ min}, p = 0.010) \), a lower rate of needle path bleeding \( (13.3\% \text{ vs } 35.0\%, p = 0.019) \), and a lower carbonization rate of electrode needle \( (22.2\% \text{ vs } 77.8\%, p < 0.001) \). Hemorrhage during the transection \( (85.0 \text{ ml} \text{ vs } 105.0 \text{ ml}, p = 0.438) \) and hemorrhage per square centimeter \( (3.28 \pm 0.86 \text{ ml/cm}^2 \text{ vs } 3.60 \pm 1.12 \text{ ml/cm}^2, p = 0.141) \) in the New-RF group were smaller than those in Habib-4X group with no significant difference.

Conclusion: The new internal cold circulation bipolar radiofrequency was a safe and efficacious auxiliary device for liver resection with a faster speed of resection, lower carbonization rate of electrode needle, and more precise range of coagulation.

Introduction

Hepatectomy is the first-line therapy for primary and secondary liver tumors, especially for hepatocellular carcinoma (HCC), liver metastases of colorectal cancer, and hepatobiliary carcinoma [1–3]. The application of advanced equipment can retain more liver tissue to decrease intraoperative hemorrhage and transfusion, reduce risks of liver failure and other complications, and provide the opportunity of re-excision after tumor recurrence [4].

Recently, auxiliary liver resection devices such as Cavitron ultrasonic aspirators [5], Tissuelink [6], and BiClamp [7] are developed to increase the safety of hepatectomy and reduce the hemorrhage. Besides, the advancement of vascular occlusion techniques and the application of low central venous pressure (CVP) anesthesia minimize the risk of hemorrhage during the operation [8–10]. However, these interventions will reduce the blood perfusion of the liver, leading to regional ischemia. Previous studies revealed that ischemia and reperfusion were the main causes of liver injury or liver failure after surgery [11,12], and they could increase risks of early recurrence [13]. Therefore, multiple techniques are developed to reduce intraoperative hemorrhage and transfusion, and avoid ischemia liver injury caused by blood reflux occlusion. For example, radiofrequency devices such as Habib-4X [14], Tissuelink, and InLine [15] can coagulate tissues before the resection to excise the liver tissue without bleeding. The radiofrequency energy released by electrodes is conducted to adjacent liver tissue, leading to the oscillation of intracellular ions and generation of heat. This mechanism can cause the coagulation and necrosis of the liver tissue and seal blood vessels and biliary ducts with a diameter of 3–7 mm through collagen fusion [16,17], thereby reducing the need of Pringle operation (extended intermittent clamp of the hepatic portal) and blood transfusion [18,19].

Weber et al. firstly applied a unipolar internal cold radiofrequency ablation electrode for the hepatectomy, reducing the intraoperative hemorrhage to 30 ± 10 ml [20]. With the advancement of technology, the coagulation range of unipolar electrode radiofrequency increased, and multiple electrodes such as internal cold circulation electrode [21,22],...
bipolar electrode [23], and cluster electrode [15,18] were developed to extend the coagulation range by regulating the deposition of radiofrequency energy in tissues. Although the cluster electrode could extend the coagulation range by overlapped effect, the increased risk of electrode-related puncture wounds cannot be ignored [18]. Therefore, we designed a new internal cold circulation bipolar radiofrequency (New-RF) device by combining a bipolar radiofrequency electrode and an internal cold device, to minimize the damage of puncture wounds without affecting the efficiency of tissue coagulation. Previous studies suggested that an internal cold electrode had a high coagulation efficiency with a repeatable coagulation range [16,24-27]. Besides, the internal cold circulation electrode was demonstrated to have a higher coagulation efficiency compared to the cluster electrode both in theory and in vivo [16,28]. Cluster electrode (Habib-4X) has been safely and efficaciously used for decades with the advantage of reducing the need for Pringle operation and intraoperative hemorrhage [14,15,18]. Although the unipolar internal cold circulation radiofrequency device is used in the assistance of hepatectomy [29,30], few research have explored the efficacy of the bipolar one in the open hepatectomy. This study was conducted to assess the efficacy of the New-RF compared to Habib-4X in the assistance of hepatectomy by analyzing the intraoperative hemorrhage, blood transfusion, and complications in the perioperative period.

Materials and methods

Enrollment of patients

A total of 85 patients with HCC who received radiofrequency-assisted liver resection from February 2017 to January 2020 were retrospectively enrolled in our study, in which 45 patients received the new internal cold circulation bipolar radiofrequency (New-RF) and 40 patients received Habib-4X bipolar radiofrequency (Habib-4X) (Figure 1). Written informed consent was obtained from each patient and the study was approved by the Ethics Committee of The Affiliated Tumor Hospital of Zhengzhou University. All procedures were conducted in accordance with the Declaration of Helsinki. The inclusion criteria are as follows [1]: patients diagnosed as primary liver cancer by two imaging examinations combined with the clinical conditions before surgery and diagnosed as HCC by postoperative pathology [2]; operable liver tumor with sufficient liver tissue remaining [3]; no extrahepatic metastasis [4]; Child–Pugh classification A or B [5]; ECOG (East Coast Oncology Group) Scale of Performance Status ≤2. The baseline characteristics of patients in the New-RF and Habib-4X groups had no significant difference (p > 0.05) (Table 1).

Ablation device

The ablation is conducted by an internal cold circulation radiofrequency ablation system (Taishang Lide LDRF-120S Mianyang Lide Electronics Co., Ltd. Mianyang, China). The system is composed of a radiofrequency generator with a maximum power of 200 W and a frequency of 400 kHz, a bipolar radiofrequency electrode, and a cold circulation pump. The length of the bipolar electrode is 10.0 cm, the distance between the needles is 1.2 cm, and the length of the tip of the needle (the exposed part for electric conduction) is 3.0 cm. The two-needle electrode contains dual channels that can pump cold saline through a cold circulation pump. The working temperature of the cold circulation electrode is maintained between 10–20 °C to dissipate the heat energy generated in the tip of the needle. The generator produces radiofrequency energy when the impedance ranges from 25 Ω to 30 Ω, in manual or automatic modes. The Habib-4X can control the output power in the impedance feedback mode, in which the coagulation will continue until the impedance rises to 35 Ω [31].

Operation process

The patient was treated using a laparotomy under general anesthesia. The liver was associated based on the location and range of the lesion. The relationship between the lesion and important anatomical structures such as blood vessels and biliary ducts was revealed by the ultrasound examination. Blood vessels to be preserved and the liver to be resected were marked under ultrasound guidance. The electrode was inserted along the marked line to coagulate the liver tissue, forming a ‘no blood circulation’ tissue plane (Figure 2). Then, we used vascular forceps or tissue scissors to excise the liver along the ‘no blood circulation’ tissue plane, close to and parallel to the outer edge of the liver tissue that needed to be preserved, remaining an ablation edge of about 0.8 cm (Figure 3). Blood vessels and biliary ducts with relatively large diameters were identified and ligated. Little hemorrhage was detected during the excision. A limited number of sutures or clips were required to control the blood flow of the trunk or the branches of the portal vein. Although there was no need to clamp the inflow and efflux channels, we still preset a blocking band at the hepatic portal as a backup. The process obeyed the sequence of ‘coagulation to excision’, which
318 patients received radiofrequency-assisted liver resection between February 2017 and January 2020. 152 patients received the New-RF assisted liver resection, 166 patients received the Habib-4X assisted liver resection. A total of 85 patients who received radiofrequency-assisted liver resection and diagnosed as HCC by postoperative pathology enrolled in our study. 233 patients were excluded because they were not diagnosed as HCC by postoperative pathology (including colorectal metastases, cholangiocarcinoma, gallbladder cancer, benign tumor, and some other liver lesions).

There were 26 males and 19 females with average age of 52 years received the New-RF assisted liver resection enrolled (n=45)

40 patients with HCC received the Habib-4X assisted liver resection were selected with matching the similar types of liver resection, age and gender (n=40)

Figure 1. Flow chart of the study.

Table 1. Baseline characteristics of enrolled patients.

| Variables               | New-RF group (n = 45) | Habib-4X group (n = 40) | p-Value |
|-------------------------|-----------------------|-------------------------|---------|
|                       | Male                  | Female                  |         |
| Gender                 | 26 (57.8%)            | 19 (42.2%)              | 0.797a  |
| Age (years old)        | Mean ± SD 52.04 ± 3.26| Median, (Range) 54 (28–75) | 0.165c  |
| Liver function         |                       |                         |         |
| Child-Pugh grade A     | 39 (86.7%)            | 35 (87.5%)              | 0.909a  |
| Child-Pugh grade B     | 6 (13.3%)             | 5 (12.5%)               |         |
| ICGR-15 (%)            | Mean ± SD 6.45 ± 2.83 | Median, (Range) 43.5 (37.7–44.6) | 0.920c  |
| Albumin (g/l)          | Mean ± SD 43.06 ± 5.22| Median, (Range) 43.5 (37.7–44.6) | 0.528c  |
| TBIL (umol/l)          | Mean ± SD 13.11 ± 4.76| Median, (Range) 11.5 (8.2–22.3) | 0.149b  |
| PT (s)                 | Mean ± SD 11.78 ± 0.82| Median, (Range) 12.0 (10.5–12.6) | 0.084b  |
| ALT (IU/l)             | Mean ± SD 27.50 ± 18.20| Median, (Range) 23 (9–75) | 0.168b  |
| AST (IU/l)             | Mean ± SD 36.40 ± 21.61| Median, (Range) 28.5 (17–72) | 0.180b  |
| AFP (µg/l)             | Mean ± SD 276.60 ± 495.55| Median, (Range) 34.35 (2.24–1210) | 0.832b  |
| Etiology               | HBV 31 (68.9%)        | HCV 3 (6.7%)            | 0.882a  |
|                        | Others 11 (24.4%)     |                         |         |
| Liver cirrhosis        | With 17 (37.8%)       | Without 28 (62.2%)      | 0.791c  |
| Tumor number           | Single 40 (89.9%)     | Multiple 5 (85.0%)      | 0.594a  |
| Tumor diameter (cm)    | Mean ± SD 6.22 ± 1.60 | Median, (Range) 6.9 (2.3–9.6) | 0.306c  |

Note. *the proportion of the groups is compared using χ² test; bdata obeying skewed distribution. Wilcoxon rank sum test is used for comparison between groups; cdata obeying normal distribution with consistent population variance. Student’s t-test is used for comparison between groups. Skewness data is represented by median and range within parentheses.

ICGR-15: 15-min indocyanine green retention rate; TBIL: total bilirubin; ALT: alanine aminotransferase; AST: aspartate aminotransferase; PT: prothrombin time; AFP: alpha-fetoprotein; HBV: hepatitis B virus; HCV: hepatitis C virus.
allowed us to change the direction during the liver excision according to the position, size, and shape of the tumor (Figure 4). Besides, sufficient liver tissue would be preserved during the liver resection in this way.

**Outcome measures**

Patients received examinations such as liver function, kidney function, and blood routine before surgery and 1, 3 and 7 days after surgery. Each patient would be followed up for at least 3 months. The safety of the New-RF device was evaluated based on the incidence of complications and mortality after surgery; its feasibility was assessed by the speed of liver transection per square centimeter (cm²/min) and hemorrhage per square centimeter (ml/cm²). Resection time was defined as the time from the beginning to the end of the transection. The hemorrhage was evaluated by the weight of the suction fluid, blood-soaked cotton pads, and gauze pieces subtracting the weight of lavage fluid, dry blood-soaked cotton pads, and gauze pieces (1 g = 1 ml). A piece of sterile paper was stuck on the surface of the liver as a mark of the resection area. After surgery, the contour of the sterile paper was duplicated to a piece of dry white paper. Then, an identical white paper was used to calculate the surface area of the liver section (cm²) [7]. The resection speed was defined as the resection area divided by resection time (cm²/min). The width of coagulation tissue was measured directly using a sterilized steel ruler in centimeters. Needle path bleeding was defined as continuous bleeding in the needle path when the electrode needle was inserted into and pulled out from the liver tissue. The carbonization of the needle tip was defined as the adhesion of burnt tissue in the tip of the electrode needle. The biliary fistula was defined as the bilirubin concentration in the effluent after surgery at least 3 times the serum bilirubin concentration, or bile accumulation or biliary peritonitis that required surgical intervention [32]. Indications for blood transfusion were intraoperative hemorrhage >1500 ml or hemoglobin <70 g/l. Surgery-related death was termed as death within 30 days after hepatectomy. Primary outcome measures were the speed of liver transection, the width of coagulation tissue, hemorrhage volume, blood transfusion rate, and operation time. Secondary outcome measures were total hospitalization time, 30-day mortality rates, and complications such as biliary fistula, abdominal abscess, pleural effusion, and liver failure after surgery.

**Statistical analysis**

All statistical analyses were conducted using SPSS 25.0. Quantitative data obeying Gaussian distribution were represented by the mean ± standard deviation; the comparison of differences was performed by student’s t-test. Quantitative data disobeying Gaussian distribution were represented by the median with range in the parentheses; the comparison of differences was performed by Mann–Whitney U test. Qualitative data were represented as rates (%) or proportion; Pearson Chi-square test, Pearson continuous correction Chi-square test, or Fisher exact probability test was used to
compare the differences. Two-sided $p < 0.05$ was considered statistically significant.

## Results

### Intraoperative data of enrolled patients

In the New-RF group, 33 (77.3%) patients received minor liver resection (<3 liver segments) whereas 12 (26.7%) patients received major liver resection ($\geq$3 liver segments); in the Habib-4X group, 33 (77.3%) patients received minor liver resection whereas 12 (26.7%) patients received major liver resection (Table 2). No significant difference was detected between the two groups ($p = 0.861$). Compared to Habib-4X, the New-RF had a faster average speed of liver transection ($4.81 \pm 1.20 \text{ cm}^2/\text{min}$ vs $3.64 \pm 1.08 \text{ cm}^2/\text{min}$, $p < 0.001$), a narrower width of coagulation tissue ($1.42 \pm 0.23 \text{ cm}^2/\text{min}$ vs $1.81 \pm 0.20 \text{ cm}^2/\text{min}$, $p < 0.001$), a less operation time ($55.04 \pm 16.12 \text{ min}$ vs $64.2 \pm 15.09 \text{ min}$, $p = 0.010$), a lower rate of needle path bleeding ($13.3\%$ vs $35.0\%$, $p = 0.019$), and a lower carbonization rate of electrode needle ($22.2\%$ vs $77.8\%$, $p < 0.001$). However, no significant difference was detected in the total hemorrhage, hemorrhage during the transection, hemorrhage per square centimeter, total operation time, device usage time, Pringle operation rate, and blood transfusion rate between the two groups. As a result, most patients in the two groups had no necessary to receive blood transfusion, whereas very few patients received the transfusion of no more than six units of red blood cells.

### Lab examinations of patients after surgery

The total bilirubin (TBIL), prothrombin time (PT), alanine aminotransferase (ALT), and aspartate aminotransferase (AST) of patients in the two groups were elevated one day after surgery and returned to normal three to seven days after surgery. However, the TBIL, PT, ALT, and AST of patients in the two groups were elevated one day after surgery and returned to normal three to seven days after surgery. Although non-anatomical liver resection can preserve more liver tissue, it also leads to more hemorrhage compared to anatomical liver resection [33]. It is hard for patients with liver cirrhosis to choose anatomical or non-anatomical liver resection since these patients need more liver tissue to be preserved. However, the radiofrequency can assist the liver resection to decrease intraoperative hemorrhage and blood transfusion rates while preserving more liver tissue as much as possible, thereby reducing the risks of liver failure after surgery and accelerating the recovery of the organ [34]. In the meantime, the reduction of hemorrhage and blood transfusion was also helpful for patients receiving preoperative chemotherapy [35]. A previous study suggested that complications such as ascites, transient liver failure, and transient renal failure are more common in patients receiving blood transfusions [36]. Therefore, minimized hemorrhage and blood transfusion are the primary objective of hepatobiliary surgery.

### Complications of patients after surgery

The total incidence of complications of patients in the New-RF group was lower than those in the Habib-4X group but with no significant difference ($p = 0.256$) (Table 3). Moreover, intensive care unit (ICU) time (0 vs 0.5 days, $p = 0.604$), total hospitalization time ($14.61 \pm 2.52$ vs $15.40 \pm 2.84$ days, $p = 0.178$), and 30-day mortality rates (0.0% vs 2.5%, $p = 0.953$) of patients in the two groups had no significant difference. Notably, one patient in the Habib-4X group was transferred to ICU due to liver failure with a continuously deteriorated condition on the 5th day after surgery. On the 7th day after surgery, he died of multiple organ dysfunction syndrome (MODS); therefore, the mortality in the perioperative period of Habib-4X was 2.5% (1/40). However, no patient died in the New-RF group within 30 days after surgery.

### Discussion

Surgical resection of liver tumors is required to minimize intraoperative hemorrhage and prevent liver dysfunction after surgery. Although non-anatomical liver resection can preserve more liver tissue, it also leads to more hemorrhage compared to anatomical liver resection [33]. It is hard for patients with liver cirrhosis to choose anatomical or non-anatomical liver resection since these patients need more liver tissue to be preserved. However, the radiofrequency can assist the liver resection to decrease intraoperative hemorrhage and blood transfusion rates while preserving more liver tissue as much as possible, thereby reducing the risks of liver failure after surgery and accelerating the recovery of the organ [34]. In the meantime, the reduction of hemorrhage and blood transfusion was also helpful for patients receiving preoperative chemotherapy [35]. A previous study suggested that complications such as ascites, transient liver failure, and transient renal failure are more common in patients receiving blood transfusions [36]. Therefore, minimized hemorrhage and blood transfusion are the primary objective of hepatobiliary surgery.

Initially, the development of radiofrequency device was to treat unresectable liver lesions by local thermal ablation, but the application of radiofrequency energy gradually extended to conventional liver resection [20]. The invention of the Habib-4X bipolar radiofrequency device, by Professor Habib, for the assistance of liver resection has further promoted the application of radiofrequency technology in liver resection [14]: firstly, the Habib-4X can coagulate the liver tissue and occlude the blood vessels, reducing intraoperative hemorrhage and the number of ligation and hemostasis processes, leading to a shortened operation time; secondly, there is no need to completely dissociate the liver and occlude blood vessels using Habib-4X, so that it is possible to alternatively perform the heptectomy; thirdly, the bipolar electrode of Habib-4X can avoid the occurrence of complications during electrical conduction [19,31,37]. However, we found that the range of coagulated tissue was wide and carbonized tissues would be attached on the tip of the electrode needle, which damages normal liver tissues and cause the needle path bleeding, leading to the decreased efficiency of liver resection.

Our study revealed that the New-RF had a lower carbonization rate of electrode needle ($22.2\%$ vs $77.8\%$, $p < 0.001$) and a faster average speed of liver transection ($4.81 \pm 1.20 \text{ cm}^2/\text{min}$ vs $3.64 \pm 1.08 \text{ cm}^2/\text{min}$, $p < 0.001$) compared to the Habib-4X device. One reason was that the internal cold circulation in the New-RF device reduced the heat concentrated at the tip of the electrode needle, which could decrease the carbonization of tissue. The carbonized tissue could act as an insulator to increase the impedance and reduce the energy deposition at the tip of the electrode needle [38]. Therefore, the internal cold radiofrequency device empowered the sufficient diffusion of the radiofrequency energy by reducing the carbonization rates. In contrast, although the Habib-4X had an extra electrode needle, it would contact with more liver tissues, which increased the tissue carbonization and dispersed the energy deposition at
### Table 2. Intraoperative data of enrolled patients.

| Variables                                      | New-RF group (n = 45) | Habib-4X group (n = 40) | p-Value |
|------------------------------------------------|------------------------|-------------------------|---------|
| Liver resection                                | 33 (77.3%)             | 30 (75.0%)              | 0.861a  |
| Minor liver resection (<3 segments)            | 13 (28.9%)             | 10 (25.0%)              | 0.502a  |
| Major liver resection (≥3 segments)            | 12 (26.7%)             | 4 (9.8%)                | 0.050a  |
| Wedge resection                                | 20 (44.4%)             | 21 (52.5%)              | 0.458a  |
| Segment resection                              | 12 (26.7%)             | 4 (9.8%)                | 0.050a  |
| Hemihepatectomy                                | 6 (13.3%)              | 4 (10.0%)               | 0.890a  |
| 3 liver segments resection                     | 2 (4.4%)               | 1 (2.5%)                | 1.000a  |
| Pringle operation                              |                        |                         | 1.000a  |
| Yes                                            | 3 (6.7%)               | 4 (10.0%)               |         |
| No                                             | 42 (93.3%)             | 36 (90.0%)              |         |
| Total hemorrhage (ml)                          | 319.09 ± 422.44        | 362.50 ± 436.75         | 0.698b  |
| Mean ± SD                                      | 165 (50–1550)          | 187.5 (55–1525)         |         |
| Median, (Range)                                | 85 (10–735)            | 105 (10–850)            |         |
| Hemorrhage during transection (ml)             | 124.09 ± 205.55        | 152.00 ± 248.30         | 0.438b  |
| Mean ± SD                                      | 28 (1.8–5.6)           | 32 (2.1–6.0)            |         |
| Average hemorrhage per square centimeter (ml/cm²) | 3.28 ± 0.86           | 3.60 ± 1.12             | 0.141c  |
| Blood transfusion                              |                        |                         |         |
| Yes                                            | 5 (11.1%)              | 3 (6.7%)                |         |
| No                                             | 40 (88.9%)             | 16 (33.3%)              |         |
| Total operation time (min)                     | 157.72 ± 53.64         | 178.00 ± 61.92          | 0.323b  |
| Mean ± SD                                      | 145 (60–275)           | 170 (75–295)            |         |
| Median, (Range)                                | 11 (5–40)              | 16 (5–50)               |         |
| Operation time of transection (min)            | 17.09 ± 11.67          | 17.60 ± 12.29           | 0.778c  |
| Mean ± SD                                      | 12.6 (11.4–13.4)       | 13.6 (12.3–15.6)        |         |
| Median, (Range)                                | 1.42 ± 0.23            | 1.81 ± 0.20             |         |
| Average transection speed (cm²/min)            | 4.81 ± 1.20            | 3.64 ± 1.08             | <0.001c |
| Width of coagulation tissue (cm)               | 1.42 ± 0.23            | 1.81 ± 0.20             |         |
| Mean ± SD                                      | 1.2 (0.8–1.8)          | 1.6 (1.4–2.2)           |         |
| Needle path bleeding                           | 6 (13.3%)              | 14 (35.0%)              | 0.019a  |
| Yes                                            | 39 (86.7%)             | 26 (65.0%)              |         |
| No                                             | 35 (77.8%)             | 15 (37.5%)              |         |
| Carbonization of electrode needle              |                        |                         |         |
| Yes                                            | 10 (22.2%)             | 25 (62.5%)              |         |
| No                                             | 35 (77.8%)             | 15 (37.5%)              |         |

Note. a the proportion of the groups is compared using χ² test; b data obeying skewed distribution. Wilcoxon rank sum test is used for comparison between groups; c data obeying normal distribution with consistent population variance. Student’s t-test is used for comparison between groups. Skewness data is represented by median and range within parentheses.

### Table 3. Lab examinations of patients after surgery.

| Variables                  | New-RF group (n = 45) | Habib-4X group (n = 40) | p-Value |
|----------------------------|------------------------|-------------------------|---------|
| TBIL (umol/l)              |                        |                         |         |
| 1 day after surgery        | 14.3 (8.2–30.4)        | 17.4 (5.2–55.3)         | 0.378b  |
| 3 days after surgery       | 20.7 (9.3–33.3)        | 28.9 (9.4–49.6)         | 0.260b  |
| 7 days after surgery       | 15.8 (11.0–30.8)       | 15.4 (4.7–40.5)         | 0.944b  |
| PT(s)                      |                        |                         |         |
| 1 day after surgery        | 14.5 (13.0–20.1)       | 15.4 (12.2–21.3)        | 0.573b  |
| 3 days after surgery       | 13.4 (11.9–16.7)       | 14.9 (11.6–18.7)        | 0.324b  |
| 7 days after surgery       | 12.6 (11.4–13.4)       | 13.6 (12.3–15.6)        | 0.056b  |
| ALT(IU/l)                  |                        |                         |         |
| 1 day after surgery        | 251 (125–1010)         | 364 (5–983)             | 0.360b  |
| 3 days after surgery       | 104 (59–252)           | 130 (2–382)             | 0.778b  |
| 7 days after surgery       | 64 (27–141)            | 50 (5–100)              | 0.888b  |
| AST(IU/l)                  |                        |                         |         |
| 1 day after surgery        | 276.5 (127–535)        | 359 (161–497)           | 0.360b  |
| 3 days after surgery       | 42.5 (24–95)           | 51 (20–143)             | 0.698b  |
| 7 days after surgery       | 34.5 (13–51)           | 30 (18–47)              | 0.944b  |

Note. a data obeying skewed distribution. Wilcoxon rank sum test is used for comparison between groups. Skewness data is represented by median and range within parentheses.

TBIL: total bilirubin; PT: prothrombin time; ALT: alanine aminotransferase; AST: aspartate aminotransferase.
the tip of the electrode needle. Another reason was that during the application of Habib-4X, sometimes we had to suspend the operation and wipe the carbonized tissue. When the electrode was taken out of the liver, the electrode needle was likely to stick to the tissue and cause the hemorrhage [19]. These would bring extra operations and we might need to reinsert the electrode to stop bleeding, which reduced the efficiency of liver transection and affected the clarity of surgical field. Besides, our study found that the needle path bleeding rate of the Habib-4X was significantly higher than that of the New-RF device (35.0% vs 13.3%, \( p = 0.019 \)), which suggested that the New-RF could significantly reduce the needle path bleeding rate. Since the continuous needle path bleeding could blur the boundary between the cross-sectional liver tissue and the critical ducts and the vision of surgical field, the application of the New-RF could facilitate the delicate operation and endow the operators with confidence. Moreover, the width of coagulation tissue of the New-RF was significantly narrower than that of Habib-4X (1.42 ± 0.23 cm\(^2\) vs 1.81 ± 0.20 cm\(^2\), \( p < 0.001 \)), which suggested that the isolation band for coagulation tissue of the New-RF was narrower. This could improve the safety of operation, meet the requirement of precise liver resection, and reduce risks of damaging important anatomical structures such as blood vessels, inferior vena cava, and gallbladder, etc. Additionally, hemorrhage during the transection (85.0 ml vs 105.0 ml, \( p = 0.438 \)), hemorrhage per square centimeter (3.28 ± 0.86 ml/cm\(^2\) vs 3.60 ± 1.12 ml/cm\(^2\), \( p = 0.141 \)) and transfusion rates (11.1% vs 12.5%, \( p = 1.000 \)) exhibited no significant difference in the two groups, which indicated that although the width of coagulation tissue of the New-RF was lower than that of Habib-4X, the application of the New-RF could block the ducts with high efficiency. In fact, the significance of radiofrequency-assisted device for liver transection was to induce a coagulation plane with no blood circulation and facilitate the isolation of the liver tissue. Therefore, there was no need to make a wide coagulation plane.

A previous study revealed that the remaining coagulated necrotic tissue after surgery increased the risk of abdominal infection [31]. In our study, the incidence of abdominal infection of the New-RF was lower than that of Habib-4X (2.2% vs 7.5%, \( p = 0.526 \)). Although there was no significant difference, the incidence of abdominal infection was lower than a previous study [37]. Therefore, further studies are required to investigate the correlation between residual coagulated necrotic tissues and the risk of abdominal infection. Besides, the incidence of biliary fistula in the two groups was relatively low (2.2% vs 5.0%, \( p = 0.917 \)), which suggested that both devices had potent abilities in tissue coagulation and pipe sealing. Moreover, the incidence of complications, ICU time, total hospitalization time, and 30-day mortality rates in the two groups were relatively low with no significant difference. Therefore, the safety of the New-RF was consistent with Habib-4X.

There are several limitations in our study. The effects of the New-RF on tumor recurrence and metastasis and long-term survival rate of patients require further investigation. Besides, the sample size of our study is limited. The large-scale and multicenter studies are needed to determine the efficacy of the New-RF device.

To sum up, we developed a new internal cold circulation bipolar radiofrequency device, of which the safety and efficacy were demonstrated in our study. This would provide a potential therapeutic approach with high efficiency in the assistance of liver resection.

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**ORCID**

Yanzhao Zhou [http://orcid.org/0000-0001-6612-5648](http://orcid.org/0000-0001-6612-5648)

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