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Significance of a soft-coagulation system with monopolar electrode for hepatectomy: A retrospective two-institution study by propensity analysis

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HIGHLIGHTS

- The Aim of this study is to confirm the inferiority or usefulness of the soft-coagulation system.
- This study is a retrospective two-institution study by propensity analysis with 322 cases.
- In the results of propensity-score matching, mild liver dysfunction induced by thermal injury with VIO was induced in a short period after hepatectomy. However, no remarkable increase of postoperative complications was observed.

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ABSTRACT

Background: The VIO soft-coagulation system (VIO) with a monopolar electrode is a novel hemostatic device that provides hemostasis by superficial contact at the bleeding site without carbonization. Because heat injury remains a concern, surgical records and postoperative liver dysfunction were retrospectively evaluated in a cohort study.

Methods: Between September 2010 and March 2016, 322 patients underwent hepatectomy in which hemostatic devices were used at two institutions. Surgical results with use of VIO at one institute (VIO group) were compared with those without use of VIO at a second institute (control group), and propensity analysis was performed.

Results: In limited resection and segmentectomy or sectionectomy performed in the VIO group, the prevalence of liver cirrhosis was significantly higher and the operation time was significantly longer in comparison with the control group ($p < 0.05$). In all hepatectomies, postoperative levels of total bilirubin and aspartate or alanine transaminase tended to be increased and prothrombin activity tended to be lower in the VIO group in comparison with the control group ($p < 0.05$). The prevalence of hepatic failure in the VIO group was significantly higher in comparison with that in the control group ($p < 0.05$). In cases of segmentectomy or sectionectomy, blood loss was significantly increased in the VIO group in comparison with that in the control group ($p < 0.05$) Propensity score matching showed that although the surgical records and outcomes were not significantly different between the groups, postoperative liver dysfunction was significant in the VIO group in comparison with the control group ($p < 0.05$).

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Conclusions: Mild postoperative hepatic thermal injury with VIO was confirmed, and therefore, surgeons should take care when using the VIO system to make frequent wide resected cuts on the surface of the liver.

1. Introduction

Minimization of intraoperative blood loss during hepatic parenchymal transection remains a concern despite recent developments in surgical techniques and devices and perioperative management in liver surgery [1]. The increased amount of blood loss and related transfusion of red blood cells are still risk factors relating to postoperative morbidity or long-term survival in patients with hepatic malignancy who undergo hepatectomy [2,3]. The tendency for increased blood loss is influenced by the severity of the chronic liver injury, the related functional liver reserve, functions of hemostatic devices or the operators' skill [4,5]. Transfusion of red blood cells is necessary after blood loss of over 850–1000 ml, which might affect patient survival [3,6,7]. The crush clamping method used for hepatic parenchymal transection is a well-known traditional blunt transection procedure that continues to remain a useful and rapid operative procedure [8,9]. Advanced crushing devices such as the Cavitron Ultrasonic Surgical Aspirator (CUSA) or water-jet dissector have been used worldwide [10,11], and furthermore, various hemostatic coagulation cutting devices have improved over recent decades [8,9,12,13]. Therefore, the operator's skill might be aided by use of these advanced devices to avoid hepatic bleeding. Although we continue to use these devices, hepatic venous bleeding or uncontrollable oozing of blood at the transection planes is still experienced. Even with the use of the above coagulation devices or suturing, hemostasis can still be difficult at times. To reduce hepatic venous bleeding, further improvements of hemostatic devices or surgical techniques such as vena cava clamping methods are necessary [9–14].

A soft-coagulation system, the VIO 300 D system (Erbe, Elektromedizin GmbH, Tübingen, Germany) is a novel hemostatic device that delivers a computer-controlled low voltage without electrical discharge, and heat is transferred to the deeper areas of the liver without hemostatic surface carbonization. No sparks are generated due to the absence of an electric discharge, which allows use not only for pinhole bleeding but also for major trunk bleeding [15–19]. The electrical tip of the VIO system can drip saline to prevent the attachment of blood clots, and therefore, it can be applied in narrow gaps. Thus, it can be applied directly to achieve hemostasis. This system is effective both for pinpoint hemostasis and for hemostasis over a wider area of the cut surface. To overcome the limitations of procedures using the previous forceps-style devices, we began to apply a combination technique using the VIO soft-coagulation system in hepatic resection in 2010. However, heat injury to the remnant liver caused by VIO soft coagulation remains a concern when coagulation is widely applied on the cut surface and which depends on the surgeon's decision. It is thus necessary to confirm the inferiority or usefulness of the soft-coagulation system in comparison with the conventional method without soft-coagulation devices. Although a few investigators have reported the usefulness of the soft-coagulation system in reducing blood loss in liver surgery [16–19], sufficient clinical advantages of this new device have not been fully clarified at present.

Therefore, the present cohort study retrospectively examined patient demographics, surgical records and patient outcomes in patients who underwent hepatectomy and compared the results between patients in whom the VIO soft-coagulation system was used and patients in whom the system was not used. We compared the surgical results between these two groups for each type of hepatectomy and equally compared the results by the propensity score matching method.

2. Materials and methods

2.1. Patients

We retrospectively and historically examined 322 patients with liver disease who underwent hepatic resection in two Japanese institutions between September 2010 and March 2016. The present cohort study compared patient demographics, preoperative liver functional parameters and liver damage grade [20], background liver status, type of hepatectomy, surgical records and postoperative course between the VIO group (n = 209), comprising all patients treated in one institute, in whom the VIO system was used, and the control group (n = 113), comprising all patients treated at the second institute, in whom the VIO system was not used. All patients' inpatient data was consecutively collected during the follow-up periods. No patient selection or matching criteria were applied: all patients were consecutively enrolled in the present study. Informed consent for data collection and use of hemostatic devices was obtained by the opt-out method on the homepage of the respective surgery departments and the information board at the outpatient clinics in both hospitals. The study design was approved by the ethics review board at both institutions.

2.2. Operative procedures

For open laparotomy, the procedure basically included clamping of the hepatoduodenal ligament to occlude total inflow to the liver during transection. A combination of an ultrasonic dissector (Nagasaki University: USU MH-207; Olympus, Tokyo, Japan; University of Miyazaki: CUSA EXcel, Valleylab, Boulder, CO, USA) and forceps fracture procedure was basically applied for transection of the liver parenchyma. In the crushing method using a forceps clamp, the hepatic parenchyma was gently crushed, and confirmation was obtained that the remnant vessels and tiny vessels ($\leq$2 mm in diameter) were divided by the vessel sealers [3,4]. Larger vessels ($\geq$3 mm in diameter) were tied using absorbable braid (Ethicon, Somerville, NJ, USA). Glissonian branches of the first or secondary trunk were doubly tied. The isolated large hepatic vein was ligated by various vascular staplers.

The vessel sealers used were 1) the Harmonic Focus® Curved Shears (ultrasonic coagulator dissector; Ethicon Endo-Surgery) and 2) the LigaSure Small Jaw Instrument (LF1212; Surgical Solutions Group, Boulder, CO, USA). The Harmonic Focus® Curved Shears include an automatic cutting function during coagulation. The power supply level was fixed within the range of 3–5. A Harmonic Device Generator 300 system was operated using a hand switch (Ethicon) as a full-featured high-frequency mechanical energy system. The sealing time is only a few seconds, providing fast, powerful sealing [4,21–23]. The LigaSure Small Jaw Instrument has a built-in cutting function. The power supply level was fixed at level