Venous anastomosis using a non-penetrating vascular closure system in orthotopic liver transplantation

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Abstract

Background: A non-penetrating vessel closure system (VCS-AnastoClip®) may facilitate vascular anastomosis. The purpose of this study is to explore the utilization of a non-penetrating VCS in orthotopic liver transplantation (OLT).

Methods: From January 2015 to February 2017, patients who underwent OLT were divided into two groups, i.e., those who underwent non-penetrating VCS application for inferior vena cava (IVC) and portal vein (PV) reconstructions and those who underwent hand sewing for these purposes. Clinical data, venous anastomotic times, anhepatic phases, and the recovery of liver function were compared between the groups.

Results: One hundred and fifteen patients underwent OLT (63 in the VCS group and 52 in the suture group). No differences between the two groups were observed in the baseline characteristics. The venous anastomotic time and anhepatic phase in the VCS group were significantly shorter than those in the suture group (\( P < .01 \)). The alanine transaminase and total bilirubin levels in the VCS group were comparable to those in the suture group (\( P = .39 \) and \( P = .06 \), respectively). The complication, mortality, and patency rates of the PV reconstructions did not differ significantly between the two groups.

Conclusions: In OLT, the reconstruction of the PV and IVC with a non-penetrating VCS system is a safe alternative method that has the advantage of shortening the anastomotic time and the anhepatic phase compared to the results of conventional hand suturing. However, the use of this VCS system had no influence on the recovery of graft function.

KEYWORDS
inferior vena cava, orthotopic liver transplantation, portal vein, vascular closure system, venous anastomosis

1 | INTRODUCTION

In the process of liver transplantation, vascular anastomoses, including those of the vena cava, portal vein (PV), and hepatic artery with or without venous-venous bypass, are routinely performed by hand sewing with polypropylene. However, penetrating the vascular wall with a needle belt line for vascular reconstruction induces intimal injury and an antigenic response that can potentially influence the course of anastomotic healing. Non-suture methods have been designed to maintain the integrity of the anastomosis including rings, clips, adhesives, stents, and laser welding. Among these techniques, non-penetrating titanium clips, called
the AnastoClip® vessel closure system (VCS), were approved by the US Food and Drug Administration in 1993. Increasing numbers of studies have been developed to evaluate the safety, efficacy, and potential benefit of this system compared with conventional suturing. A clinical series examining vascular access in hemodialysis revealed that the application of VCS clips is an easy to manipulate, safe, and time-saving method compared with hand-sutured anastomosis. Similar results have been reported for arteriotomy closure after embolectomy, peripheral arterial bypass procedures and graft replacements. Theoretically, the vascular intima is intact, and hyperplasia is absent after achieving anastomosis with non-penetrating clips, as demonstrated in animal experiments. The VCS seems to be a promising alternative device for vascular anastomosis that can even be extended to tubular reconstructions, for example, of the bile ducts and ureters. However, research on the application of this clip in orthotopic liver transplantation (OLT) is rare, and whether the anhepatic phase could be reduced via the use of this device is uncertain. In this study, we present our experience utilizing the non-penetrating VCS system for venous anastomosis in OLT and evaluate its effects on the surgical procedure, recovery of hepatic function and long-term patency of PV compared with the results of traditional suturing.

2 | PATIENTS AND METHODS

2.1 | Recipients and donors

From January 2015 to February 2017, 115 adult patients underwent OLT at the Department of Hepatobiliary Surgery of Beijing Chaoyang Hospital Affiliated to Capital Medical University. The clinical data were collected from the China Liver Transplantation Registry (http://www.cltr.org) and the database of our hospital. The graft livers were harvested from donations after cardiac death and were then allocated by the China Organ Transplant Response System (https://www.cot.org.cn). After the recipient or immediate relatives provided written informed consent for the operation, the liver transplantation was approved by the ethics committee of Beijing Chaoyang Hospital.

The patients were divided into two groups according to venous anastomotic methods, ie, those who underwent reconstructions of the inferior vena cava (IVC) and PV with the non-penetrating VCS (VCS group) and those who underwent venous anastomosis by hand sewing with polypropylene (suture group). The patients’ general conditions, operative parameters, recovery of graft function, and venous patency incidences were compared between the VCS group and the suture group.

2.2 | Surgical management

A modified piggyback technique without venous-venous bypass was performed in the enrolled patients. The processes of exploration and native liver removal were identical between the two groups; only the venous reconstruction method differed. The vascular closure system applied in the current trial was called the AnastoClip VCS®, which is available in four types: small (0.9 mm), medium (1.4 mm), large (2.0 mm), and extra large (3.0 mm). The system includes a clip applier that contains titanium clips, everting forceps and a clip remover for each type of the device.

During the venous reconstructions in the VCS group, the posterior wall of the suprahepatic IVC of the graft was first continuously sutured to the posterior wall of the host vena cava with 4-0 prolene. Then, using forceps, the assistant combined the two anterior edges of IVC and symmetrically everted them. Next, the surgeon applied large-size (2.0 mm) titanium clips to grasp a 1-mm portion of the two layers of the IVC (Figure 1). During the PV reconstruction, two guiding stay sutures were first sewn at the 3:00 and 9:00 o’clock positions of the PV. Then, by pulling the threads gently, the anastomotic orifice was rotated to bring the posterior aspect of the anastomosis forward. After ensuring that the two edges of the graft and recipient PV were everted and folded, the surgeon squeezed the clip applier and attached the medium-size (1.4 mm) clips along the anastomotic line at an interval of less than 1 mm. The same procedure was performed on the anterior aspect, and thus, the anastomosis of the entire PV was achieved with the clips placed in an intermittent pattern (Figure 2). In the suture group, continuous hand suturing was conventionally performed in the vena cava with 4-0 prolene and in the PV with 6-0 prolene, respectively. The venous anastomosis procedures of this study were performed equally by 4 surgeons under the guide of the head of our department. Each of the 4 surgeons was experienced who had completed 30-50 cases of venous anastomosis. Thus, the impact of learning curve on surgical techniques was reduced.

In the arterial reconstructions of the two groups, 8-0 prolene was used with a running suture pattern at the posterior line and in an intermittent manner in the anterior line. A T-tube was not routinely applied, except in cases of high risk for biliary complications. Duct-to-duct intermittent anastomosis with 7-0 prolene was used in the biliary reconstructions.

FIGURE 1  The anterior aspect of an inferior vena cava anastomosis performed using the vessel closure system clips (the arrow denotes the anastomotic line)
2.3 | Postoperative treatments

Doppler ultrasound examination and enhanced computed tomography (CT) angiography were applied to evaluate the hemodynamics of the PV, IVC, and hepatic artery 3 and 7 days after the operation. Anticoagulation therapy was administered using low-molecular-weight heparins during the early stage after the operation, and then, regular oral aspirin was used. A calcineurin inhibitor combined with prednisone and mycophenolate mofetil constituted the immunosuppression regimen, which was adjusted according to plasma concentrations and overall assessments.

2.4 | Statistical analysis

SPSS version 13.0 (SPSS Inc., Chicago, IL, USA) was applied for the analyses, and \( P \) values < .05 were considered significant. Variance analysis and the chi-square test were used to analyze continuous and categorical variables, respectively.

3 | RESULTS

Over an observation period of 2 years, 115 patients who underwent whole adult OLT were enrolled, and among them, 5 retransplantations and 2 liver-kidney transplantations were performed. The VCS was utilized in 63 recipients, and standard hand-sewn sutures were applied in the remaining 52 patients.

The demographic and baseline characteristics are summarized in Table 1. No significant differences were observed between the two groups in terms of sex, age, model for end-stage liver disease (MELD) score, or Child-Pugh grading. The disease spectra were similar: The VCS group included 25 primary carcinomas of the liver, 22 cases of hepatitis B-related cirrhosis, 5 cases of hepatitis C-related cirrhosis, 4 drug-induced hepatic failures, and 2 cases of primary biliary cirrhosis; the suture group included 22 primary liver cancers, 22 cases of hepatitis B-related cirrhosis, 5 cases of hepatitis C-related cirrhosis, 2 drug-induced hepatic failures, and 1 case of primary biliary cirrhosis. The incidences of preoperative portal vein thrombosis (PVT) were comparable between the VCS and suture groups (7/63 vs 7/52, respectively, \( P = .778 \)). The percentages of coronary heart disease and diabetes mellitus were similar in the two groups (16% vs 17%, respectively, \( P = .837 \) and 21% vs 17%, respectively, \( P = .812 \)). The results of the laboratory examinations for hemoglobin, platelets, alanine transaminase (ALT), albumin, total bilirubin (TBil), and creatinine levels were comparable between the two groups. The coagulation functions, including the international normalized ratio and prothrombin activity,

| TABLE 1 | Demographics and baseline preoperative characteristics |
| --- | --- | --- |
| Parameters | VCS group (n = 63) | Suture group (n = 52) | \( P \) value |
| Gender, n | | | |
| Male | 47 | 41 | .379 |
| Female | 16 | 11 | |
| Age, year, mean | 51 | 49 | .3 |
| Score of MELD, mean | 16 | 13 | .07 |
| Child-pugh grade, n | | | |
| A | 17 | 19 | .505 |
| B | 23 | 15 | |
| C | 23 | 18 | |
| Malignancy related, n | | | |
| No | 38 | 30 | .85 |
| Yes | 25 | 22 | |
| Preoperative portal thrombosis, n | | | |
| No | 56 | 45 | .778 |
| Yes | 7 | 7 | |
| Diabetes mellitus, n | | | |
| No | 50 | 43 | .812 |
| Yes | 13 | 9 | |
| Coronary heart disease, n | | | |
| No | 53 | 43 | .837 |
| Yes | 10 | 9 | |
| Preoperative laboratory test, mean (SD) | |
| Hemoglobin, g/L | 106.6 (27.6) | 112.7 (26.6) | .237 |
| Platelet, \( \times 10^9 \)/L | 101.1 (77.3) | 109.3 (80.3) | .579 |
| Alanine transaminase, \( \mu \)mol/L | 121.3 (200.1) | 86 (82.6) | .238 |
| Albumin, g/L | 34.1 (6.0) | 33.5 (6.2) | .546 |
| Total bilirubin, \( \mu \)mol/L | 228.2 (238.2) | 167.8 (222.9) | .166 |
| Creatinine, \( \mu \)mol/L | 76.4 (56.9) | 70.8 (53.3) | .59 |
| INR | 1.68 (1.01) | 1.6 (0.8) | .116 |
| PTA, % | 59.6 (25.3) | 64.6 (25) | .473 |

VCS, vascular closure system; MELD, model for end-stage liver disease; SD, standard deviation; INR, international normalized ratio; PTA, prothrombin activity.
were not different between the two groups ($P = .116$ and $P = .473$, respectively).

The cold preservation times of the donor grafts, operative parameters, and postoperative follow-up results are presented in Table 2. The IVC and PV anastomosis times in the VCS group were significantly shorter than those in the suture group (31 minutes vs 51 minutes, $P < .01$). The anastomotic duration was from the removal of recipient liver to the recovery of PV flow including pruning the anastomotic stoma, double ligations of the short hepatic veins, anastomosing, and hemostasis. Consequently, the anhepatic phase was significantly reduced in the VCS group compared to that in the suture group (36 minutes vs 56 minutes, $P < .01$). The total surgical duration in the VCS group was reduced compared to that in the suture group; however, this difference was not statistically significant (496 minutes vs 530 minutes, $P = .075$). The average volume of blood loss in the two groups was similar (1168 mL vs 1230 mL, $P = .37$).

Twenty-two patients in the VCS group experienced postoperative complications that included the following: 3 cases of acute allograft rejection, 1 case of graft-versus-host disease (GVHD), 3 cases of respiratory infection, 3 cases of abdominal infection, 1 case of abdominal hemorrhage controlled by hemostasis, 2 cases of upper gastrointestinal bleeding, 2 cases of respiratory dysfunction, 1 case of renal dysfunction, 1 case of acute allograft dysfunction, 1 case of multiple organ dysfunction (liver, kidney, and shock), 1 case of acute pulmonary embolism, and 3 cases of intestinal leakage treated with a jejunum stoma. Most of the complications (n = 13) were degree III-V according to the Clavien-Dindo classification of surgical complications. No biliary or venous complications were observed in the VCS group. During the early postoperative period, 6 of the 22 patients died due to acute pulmonary embolism, acute allograft dysfunction, multiple organ failure, GVHD, or severe infection. In the suture group, 17 cases of postoperative complications occurred and included the following: 1 case of GVHD, 4 cases of respiratory infection, 3 cases of abdominal infection, 1 case of abdominal hemorrhage that was managed by hemostasis, 1 case of respiratory dysfunction, 2 cases of renal dysfunction, 2 cases of acute allograft dysfunction, 1 case of multiple organ dysfunction (liver, kidney, and brain), 1 case of incisional hernia treated by herniorrhaphy, and 1 case of gastric leakage cured by gastrotomy. Degree III-V complications were confirmed in 11 cases according to the Clavien-Dindo classification. GVHD, acute allograft dysfunction, multiple organ failure, and severe infection were the causes of 6 deaths among these 17 patients. The rates of postoperative complications, reoperations, and mortality were similar between the two groups (22/63 vs 17/52, $P = .802$; 5/63 vs 4/52, $P = .961$; and 6/63 vs 6/52, $P = .513$, respectively). On day 3 after the operations, ultrasound inspections were conducted to compare the anastomotic diameters and flow velocities in the PV between the VCS and suture groups, and these parameters were found to be comparable (10.9 mm vs 11.3 mm, $P = .21$ and 50.5 cm/s vs 47.2 cm/s, $P = .26$).

### TABLE 2  Operative parameter and postoperative follow-up results

| Parameters                          | VCS group (n = 63) | Suture group (n = 52) | $P$ value |
|-------------------------------------|-------------------|-----------------------|-----------|
| Operative parameters, mean (SD)     |                   |                       |           |
| Cold preservation time, minutes     | 396 (132)         | 369 (146)             | .151      |
| Anastomotic time, minutes           | 31 (6)            | 51 (12)               | < .01     |
| Anhepatic phase, minutes            | 36 (7)            | 56 (12)               | < .01     |
| Operative duration, minutes         | 496 (117)         | 530 (131)             | .075      |
| Blood loss, mL                      | 1168 (759)        | 1231 (1289)           | .37       |
| Postoperative complications, n      | 22                | 17                    | .802      |
| Hemorrhage                          |                   |                       |           |
| Infection                           |                   |                       |           |
| Immune                              |                   |                       |           |
| Organ dysfunction                   |                   |                       |           |
| Others                              |                   |                       |           |
| Clavien-dindo grading, n            |                   |                       |           |
| I, II                               | 9                 | 7                     |           |
| III-V                               | 13                | 10                    |           |
| Reoperation, n                      | 5                 | 4                     | .961      |
| Mortality, n                        | 6                 | 6                     | .725      |
| 3 days postoperation, mean (SD)     |                   |                       |           |
| Diameter of PV, mm                  | 10.9 (2.2)        | 11.3 (1.8)            | .21       |
| Velocity of PV, cm/s                | 50.5 (24.6)       | 47.2 (21.6)           | .26       |
| ALT, µmol/L                         | 301.1 (221.9)     | 288.7 (250.5)         | .39       |
| TBil, µmol/L                        | 114.3 (114.5)     | 83.3 (91.1)           | .06       |
| 7 days postoperation, mean (SD)     |                   |                       |           |
| ALT, µmol/L                         | 141.1 (118.6)     | 128.5 (102.3)         | .555      |
| TBil, µmol/L                        | 78.2 (74.2)       | 62.0 (85.3)           | .285      |
| 4 weeks postoperation               |                   |                       |           |
| ALT, µmol/L                         | 59.9 (47.9)       | 55.1 (70.5)           | .724      |
| TBil, µmol/L                        | 47.9 (73.1)       | 32.5 (44.2)           | .207      |
| 6 months postoperation              |                   |                       |           |
| ALT, µmol/L                         | 56.7 (128.9)      | 94.1 (309.7)          | .586      |
| TBil, µmol/L                        | 24.4 (15.8)       | 46.3 (98.5)           | .289      |
| 6 months patency rate of PV, n (%)  | 54/55 (98)        | 43/44 (98)            | .873      |

SD, standard deviation; ALT, alanine transaminase; TBil, total bilirubin; PV, portal vein.
period, the PV patency rates were similar in the two groups (54/55 vs 43/44, \( P = .873 \)). PVT gradually emerged in 1 case in each group at 6 months postoperatively without requiring invasive treatment in either case.

4 | DISCUSSION

The purpose of a VCS is to intermittently fix the everted vascular intima with titanium clips from outside without penetrating the vessel walls.\(^\text{19}\) Consequently, this device creates minimal lesions in the endothelium, causes a less severe inflammatory reaction and is less likely to lead to intimal hyperplasia than traditional sutures.\(^\text{20}\)

The clinical parameters related to the VCS are focused on the anastomotic time, patency rate, and adverse events. The application of vascular clips has the advantage of shortening the vascular anastomotic time vs traditional suturing according to several large-scale clinical trials involving the construction of an autologous fistula for access for hemodialysis.\(^\text{21-23}\) Furthermore, the 1-year patency rates were similar between these non-penetrating clip and suture groups.\(^\text{10}\) Nilesh performed femoropopliteal artery bypasses with this device and suggested that it optimized the anastomotic time without inducing pseudoaneurysms, dehiscence, or excess bleeding.\(^\text{24}\) In cerebrovascular reconstructions, these non-penetrating arcuate-legged clips have also been proven to reduce the operative time and to elicit less intimal hyperplasia and stenosis in several articles.\(^\text{25-27}\)

In contrast, experimental studies have addressed the healing patterns of anastomosis from macroscopic, microscopic, and pathological perspectives. Scanning electron microscope examinations have revealed that the endothelium at the site of anastomosis is smoother when clips are used than when conventional sutures are used.\(^\text{28,29}\) Another survey revealed reduced fibrin and fewer platelets and white blood cells in the clipped anastomotic lines.\(^\text{16}\) Komori performed femoral vein-artery autogenous reconstruction in canines and reported that the vascular intima close to the anastomotic region was significantly thicker in the suturing group than in the vascular clips group upon pathological examination.\(^\text{30}\) Similar results were presented in Mohamed’s work on carotid arterial anastomosis in goats.\(^\text{31}\) Other series of experiments have demonstrated that the inner diameter, intima thickness, intima-to-media height ratio, and inflammatory reactions associated with anastomosis were not significantly different between VCS clip and sutured anastomosis.\(^\text{32-34}\)

However, liabilities and even disappointing results are associated with the application of VCS clips, especially for arterial anastomosis. In a small-sample pilot study, the speeds of the achievement of anastomosis with VCS clips and sutures were similar, but anastomotic rupture due to clip malfunction and thrombosis occurred in the non-penetrating titanium clips group.\(^\text{14}\) In another clinical experience, two cases of hemostasis problems occurred when carotid arteriotomies were closed using vascular clips.\(^\text{35}\) Some surgeons have suggested that whether this technique should be applied depends on the thickness and characteristics of the artery.\(^\text{19}\) Although positive results were easy to obtain in experimental conditions, the benefit of the VCS was uncertain in patients with atherosclerosis.\(^\text{36}\) After performing 100 vascular anastomosis, Yoshinori proposed that if the arterial wall is heavily calcified and thicker than 2 mm, likely due to atherosclerosis, hand sewing with polypropylene should be regarded as the first choice.\(^\text{15}\) In our opinion, the complications associated with the VCS were reported in the early phase of its usage and likely occurred at the beginning of the learning curve. Furthermore, the sample size of this study was small. Recent and large-sample clinical investigations have displayed the safety, effectiveness, and trend toward choosing this device for vascular anastomosis.\(^\text{37}\)

Unlike bypass access surgery, published articles relevant to the application of a VCS for organ transplantation appear to be rare. In a small sample size study, Jones significantly reduced the anastomotic and warm ischemia times using vascular clips in renal transplantation.
compared with hand sewing without technical complications. In 1998, non-penetrating clips were first applied for pancreatic transplantation by Papalois, who demonstrated similar results. In 2005, Tashiro et al reported 15 cases of PV anastomosis using VCS clips in living-donor liver transplantations. Compared to conventional sutures, the venous reconstruction time in the VCS group was non-significantly decreased; however, this device had the advantage of a low risk of anastomotic stenosis. Experimentally, Maria anastomosed graft renal vessels with recipient aortas and vena cava in piglets. Six months postoperatively, the changes in the luminal diameters at the anastomotic sites were comparable between the VCS and suture groups based on macroscopic observations and angiographic measurements. Two graft failures occurred in the prolene suture group that were caused by early thrombosis, whereas in the VCS clip group, this complication did not appear. In a porcine liver transplantation model, the utilization of arcuate-legged clips failed to reduce the reconstruction time of the hepatic artery and PV but did shorten the bile duct anastomotic time. The above-mentioned articles failed to reveal a positive influence on graft function due to the shortened warm ischemia time. VCS clips have been suggested to be a good fit for transplant practice in creating atraumatic vascular reconstructions; however, transplant surgeons are reluctant to apply this convenient device in vascular reconstruction. The reason for this is that sutures are the safest, most credible, and most trusted method for vessel anastomosis, the two vascular edges are folded and everted before the repair. The crucial step is to ensure that, at the site of anastomosis, the two vascular edges are folded and everted before the application of the clips. Because they are thin and lack smooth muscle, venous walls are readily coapted with clips. No failures occurred in this study, even though in preoperative PVT patients, this procedure was performed satisfactorily after a thrombectomy. The intra-abdominal bleeding risks of the VCS and suture groups were comparable (1/63 vs 1/52, respectively, P = .56). During a reoperation in the VCS group, hepatic arterial anastomotic leakage was confirmed in one case. Anastomotic stenosis of the PV and IVC outflow obstructions were not observed in any of the recipients. Our findings suggest that the outcomes of PV flow as examined by ultrasonography and contrast-enhanced CT scans were not influenced by the titanium clips, even though they were in vivo metallic foreign bodies. The outcomes after 6 months of follow-up revealed that the VCS clips exhibited no advantage over suturing in the prevention of PVT. To the extent of our knowledge, the current research is the first to present the utilization of VCS clips in OLT in adult patients and to provide evidence supporting their application in venous anastomosis.

In the present clinical setting, hepatic artery reconstruction is accomplished by interrupted suturing with 7-0 prolene instead of VCS clips. In our experience, because the average age in the VCS group was 51 years, atherosclerosis was common and even serious in most cases. Furthermore, most of the reported hemorrhagic complications associated with VCS clips occurred in cases of arterial anastomosis. Therefore, because we considered it a technical risk, we were prudent to not apply the VCS clips in arterial anastomosis. Similarly, biliary reconstruction with vascular clips still requires more experimentation, and at least in our view, it is too early to use these clips in this manner in clinical practice.

In conclusion, this non-penetrating VCS is a safe and timesaving alternative anastomotic instrument that is applicable for PV and IVC reconstructions in OLT. The outcomes of our study revealed that, although the anhepatic phase was shortened, utilization of the VCS failed to influence the postoperative graft recovery procedure.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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