



Safety and efficacy of a simple cardiotomy suction system as a blood salvage procedure during off-pump coronary artery bypass surgery

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Abstract

The ideal blood-salvaging strategies for off-pump coronary artery bypass graft procedures have not been determined. We developed a new blood-salvaging system that uses a cardiotomy suction. The purpose of this study was to examine the efficacy of this novel method. This was a retrospective study involving 50 consecutive patients undergoing off-pump coronary artery bypass grafting. In 25 patients, a simple cardiotomy suction system was used (cardiotomy suction group). These individuals were compared with 25 historical cohorts who were treating with the conventional cell saver system (cell saver group). There was no in-hospital mortality in either group. In the cell saver group, there was one major complication (stroke) and two minor complications (saphenous vein graft occlusion, superficial wound infection). In the cardiotomy suction group, there was one minor complication (subclinical pulmonary emboli). The cardiotomy suction group received significantly fewer transfused RBC (cardiotomy: 0.56 ± 1.4 units vs. cell saver: 2.46 ± 3.3 units, $p = 0.005$). The serum total protein and albumin levels were significantly higher in the cardiotomy group. Our newly developed simple cardiotomy suction system, when compared with the conventional cell saver system, produced similar clinical results and attenuated postoperative hemodilution. Our system may emerge as a preferable alternative for blood salvage during off-pump coronary artery bypass grafting.

Keywords CABG · Off-pump · Blood transfusion

Introduction

In patients undergoing coronary artery bypass grafting (CABG), perioperative blood transfusion increases morbidity and mortality [1]. Intraoperative blood-salvaging procedures are effective at minimizing the need for blood transfusions [2, 3]. For cardiac surgeries that use cardiopulmonary bypass, blood-salvaging procedures can be classified into two types: direct infusion of salvaged blood with no processing (cardiotomy suction system) and processing of the salvaged blood by centrifugation (cell saver system)

[3]. Studies comparing the two techniques revealed that the cell saver system reduces systemic inflammatory responses [4, 5]. On the other hand, the cell saver system may be associated with excess hemodilution or bleeding secondary to removal of plasma proteins, including coagulation factors and thrombocytes [6]. In off-pump CABG, the cell saver system has been widely used as the standard blood-salvaging procedure. However, because off-pump CABG is associated with neither accentuated inflammatory responses nor bleeding, the efficacy of the cell saver system is questionable, especially given its relatively high cost. In fact, some studies reported that the cell saver system did not reduce transfusion blood during off-pump CABG procedures [7, 8].

We developed a simple cardiotomy system to salvage blood during off-pump CABG procedures. In this system, the intraoperative blood is aspirated with a roller pump, similar to the pump suction of the cardiopulmonary bypass. The salvaged blood is stored in flexible reservoir and returned through a peripheral venous line. The advantage of this system is its low cost and simple assemblage. Moreover, our

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system avoids the risk of excess hemodilution induced by a centrifuge system. The purpose of this study was to investigate the safety and efficacy of our simple cardiotomy system during off-pump CABG procedures.

Materials and methods

Cardiotomy suction system

The outline of this cardiotomy suction system is shown in Fig. 1. The system consists of a flexible sucker, a suction tube, a roller pump (extracorporeal bypass machine), a flexible reservoir, a 40-micron filter, and a peripheral venous line.

The blood aspiration mechanism of the cardiotomy suction system is almost the same as the pump suction of the cardiopulmonary bypass. A flexible sucker is indwelling at the bottom of the pericardial cavity. The bleeding in the operative field is constantly aspirated using negative pressure created with a roller pump. Negative pressure can be adjusted by the rotation speed of roller pump and is kept minimum to avoid damaging the blood cells. The aspirated blood is temporally stored in a flexible reservoir which can be used as an autologous blood volume for the anesthesiologist. The aspirated blood is filtered with a 40-micron

filter to remove small particles in the collected blood. The blood is returned through peripheral venous line via natural instillation.

This cardiotomy suction system was developed as a blood-salvaging procedure for off-pump CABG, and its use was approved for use by the Ethics Committee of Tsuchiura Kyodo General Hospital in 2016 (registration number: 566).

Study design

This was a retrospective cohort study to examine the safety and efficacy of our newly developed blood-salvaging system for patients undergoing off-pump CABG.

The cardiotomy suction system was introduced in December 2016. Between December 2016 and January 2018, we performed off-pump CABG procedures, using the cardiotomy system, in 25 patients. These consecutive 25 patients comprise the cardiotomy suction group. Before introduction of the cardiotomy suction system, we used the cell saver system for off-pump CABG procedures. Between March 2016 and November 2016, 25 patients underwent isolated off-pump CABG using the cell saver system. We retrospectively reviewed the medical records of these consecutive 25 patients which comprised the cell saver group (historical cohort). During the study period, all CABG procedures started with the off-pump procedure, but converted to an on-pump condition in two patients who were

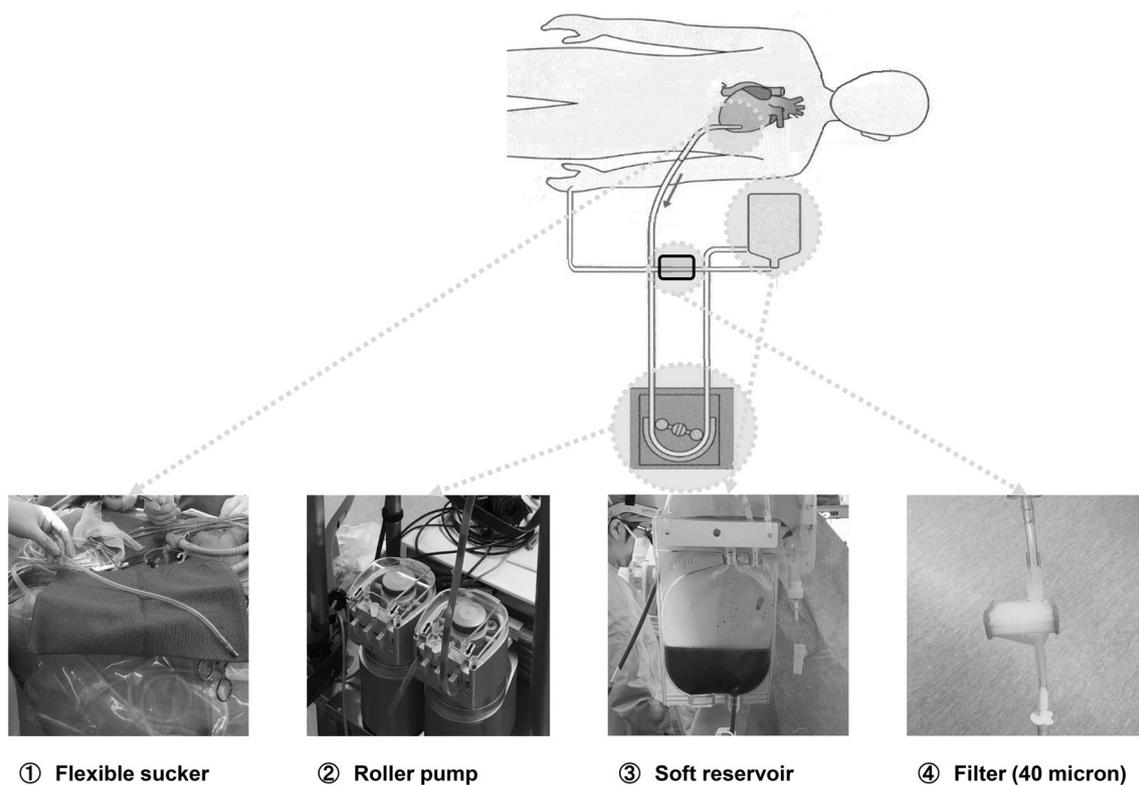


Fig. 1 The outline of cardiotomy suction system

excluded from this study. Clinical outcomes and laboratory data are compared between the cardiomy suction group and the cell saver group. Major postoperative complications are defined as myocardial infarction, low cardiac output syndrome, reoperation due to excess bleeding, stroke, and mediastinitis. All complications other than the major complications were considered minor complications.

Operative strategy

The operative strategy for the off-pump CABG procedures did not change throughout the study period. The operation was performed by a single surgeon. During the distal anastomosis of the bypass graft, the coronary artery proximal to the anastomosis site was snared to achieve a bloodless operative field. The distal site was not snared. The intraluminal coronary shunt tube was selected in instances of excess bleeding from the anastomosis site.

After the graft harvesting, heparin (3.0 mg/kg) was administered intravenously to achieve an activated clotting time longer than 400 s. The heparinization was neutralized at the end of the procedure with protamine sulfate (1.5 mg/kg). Blood salvaging with the cell saver was conducted throughout the operative period; however, with the cardiomy suction system, use was limited during the systemic heparinization. Therefore, cardiomy suction system use started after the confirmation of activated clotting time prolongation and concluded at the time of protamine administration.

Blood transfusions were at the discretion of the anesthesiologist and based on standard indications. There was no *distinct* criteria for the decision to initiate blood transfusion; rather, a liberal (hemoglobin level < 9 g/dl), rather than restrictive (hemoglobin level < 7.5 g/dl), threshold was usually adopted throughout the study period.

Statistical analysis

Continuous variables are reported as means \pm standard deviations and categorical variables as percentages. Fisher's exact test was used to compare categorical variables. The Mann–Whitney test was used to compare continuous variables. Differences in perioperative laboratory data between the two groups were compared by using analysis of variance with repeated measurements. Statistical significance was accepted at $p < 0.05$. All statistical analyses were performed using SPSS statistical software (SPSS version 17.0; SPSS Japan, Tokyo, Japan).

Results

Patients' backgrounds and operations

A comparison of patient backgrounds is presented in Table 1. There were no differences between the two groups with respect to background. The study patients exhibited a relatively high prevalence (30–50%) of acute coronary syndrome, requiring emergent hospitalization. The prevalence of chronic renal failure requiring hemodialysis was high (20–28%). These characteristics resulted in relatively high Euroscore 2 (3.3–3.5) for CABG.

A comparison of the performed operations is presented in Table 2. There were no differences between the two groups with respect to the operations that were performed. Most operations were performed using the bilateral internal thoracic arteries and supplementary use of saphenous vein grafts. The radial artery and gastroepiploic artery were used exclusively.

Clinical outcomes (Table 3)

There was no in-hospital mortality in either group. There were one major complication (stroke) and two minor

Table 1 Patients' characteristics

	Cell saver <i>n</i> = 25	Cardiotomy <i>n</i> = 25	<i>p</i> value
Age (years)	67.0 \pm 11.7	69.6 \pm 8.2	0.763
Male	76% (19)	68% (17)	0.754
Body surface area (m ²)	1.68 \pm 0.17	1.64 \pm 0.21	0.594
Coronary risk factor			
Hypertension	76% (19)	68% (17)	0.754
Diabetes	52% (13)	24% (6)	0.079
Insulin dependent	24% (6)	20% (5)	1.000
Hyperlipidemia	76% (19)	52% (13)	0.140
Smoking	12% (3)	12% (3)	1.000
Old cerebral infarction	28% (7)	16% (4)	0.496
Peripheral vascular disease	8% (2)	24% (6)	0.247
Chronic hemodialysis	20% (5)	28% (7)	0.742
Ischemic heart disease			
Stable angina	64% (16)	48% (12)	0.393
Prior PCI	24% (6)	20% (5)	1.000
No. of diseased vessels	2.6 \pm 0.5	2.8 \pm 0.4	0.061
1 vessel disease	0% (0)	0% (0)	
2 vessel disease	40% (10)	16% (4)	
3 vessel disease	60% (15)	84% (21)	
Ejection fraction (%)	54.9 \pm 12.0	57.0 \pm 11.0	0.409
Euroscore 2	3.45 \pm 4.40	3.31 \pm 4.72	0.655

PCI percutaneous coronary intervention

Table 2 Performed operations

	Cell saver <i>n</i> = 25	Cardiotomy <i>n</i> = 25	<i>p</i> value
Elective surgery	72% (18)	52% (13)	0.244
Reoperation	8% (2)	0% (0)	0.490
No. of anastomosis	2.64 ± 0.70	3.00 ± 0.83	0.056
Operation time (min)	308 ± 56.4	309 ± 50.4	0.816
Operative bleeding (ml)	1259 ± 800	1372 ± 704	0.136
Graft material			
Left ITA	96% (24)	100% (25)	1.00
Right ITA	52% (13)	80% (20)	0.07
SV	72% (18)	84% (21)	0.496
GEA	8% (2)	4% (1)	1.000
RA	4% (1)	0% (0)	1.000

Non-elective surgery, performed within 3 days

ITA internal thoracic artery, SV saphenous vein, GEA gastroepiploic artery, RA radial artery

Table 3 Clinical outcomes

	Cell saver <i>n</i> = 25	Cardiotomy <i>n</i> = 25	<i>p</i> value
In-hospital mortality	0% (0)	0% (0)	1.000
Postoperative complications			
Major	4% (1)	0% (0)	1.000
Minor	8% (2)	4% (1)	1.000
In-hospital stay (days)	13.5 ± 5.2	12.8 ± 5.0	0.806
ICU stay (days)	2.0 ± 0.9	1.6 ± 0.7	0.104
Blood transfusion	60% (15)	12% (3)	0.088
Number of blood products			
RBC (unit)	2.46 ± 3.3	0.56 ± 1.4	0.002
FFP (unit)	0.96 ± 1.8	0.40 ± 1.4	0.148
Body weight gain (kg)	3.14 ± 1.61	3.02 ± 1.08	0.453
Oxygenation duration (days)	4.4 ± 2.7	3.4 ± 2.2	0.096

complications (saphenous vein graft occlusion, superficial wound infection) in the cell saver group. Meanwhile, there was one minor complication (subclinical pulmonary emboli) in the cardiotomy suction group. The durations of in-hospital or ICU stays were not different between the two groups.

Blood transfusion

Fewer patients in the cardiotomy suction group, compared to the cell saver group, underwent homologous blood transfusion, but the difference did not reach statistical significance (cardiotomy suction: 12%: vs. cell saver: 60%, $p = 0.088$). There were significantly fewer RBCs transfused in the cardiotomy suction group (cardiotomy: 0.56 ± 1.4 units vs. cell saver: 2.46 ± 3.3 units, $p = 0.005$).

Laboratory data (Table 4)

The changes in serum total protein concentrations are shown in Fig. 2. In both groups, the total protein concentration decreased immediately after surgery, and recovered slightly by the day after surgery. The total protein concentration was significantly higher in the cardiotomy suction group ($p = 0.029$). Similarly, serum albumin concentrations were significantly higher in the cardiotomy suction group ($p = 0.048$) (Fig. 3). There were no differences in the changes in hemoglobin levels and platelet counts between the two groups.

Discussion

Our newly developed cardiotomy suction system produced clinical results similar to the conventional cell saver system during off-pump CABG procedures. Procedure-related adverse events were not observed. The higher serum protein concentration and need for fewer homologous blood transfusions suggests that our cardiotomy suction system could

Table 4 Laboratory data

	Cell saver <i>n</i> = 25	Cardiotomy <i>n</i> = 25	<i>p</i> value
Total protein (g/dl)			0.029
Admission	6.9 ± 0.8	6.8 ± 0.6	
ICU arrival	4.1 ± 0.9	5.1 ± 1.0	
1 postoperative day	4.8 ± 0.4	5.0 ± 0.6	
Albumin (g/dl)			0.048
Admission	3.8 ± 0.5	3.7 ± 0.4	
ICU arrival	2.3 ± 0.5	2.8 ± 0.5	
1 postoperative day	2.8 ± 0.3	2.8 ± 0.2	
C reactive protein (mg/dl)			0.376
Admission	0.7 ± 1.7	1.3 ± 2.5	
ICU arrival	0.4 ± 0.6	1.3 ± 2.6	
1 postoperative day	6.3 ± 3.4	6.5 ± 4.1	
Hemoglobin (g/dl)			0.870
Admission	12.5 ± 2.1	12.0 ± 1.4	
ICU arrival	9.8 ± 1.5	10.3 ± 1.3	
1 postoperative day	9.7 ± 1.3	9.5 ± 1.2	
White blood cell (/μl)			0.904
Admission	6357 ± 2470	6400 ± 2357	
ICU arrival	12,864 ± 5125	13,060 ± 4161	
1 postoperative day	10,792 ± 3300	10,819 ± 2450	
Platelet ($\times 10^4/\mu\text{l}$)			0.548
Admission	22.4 ± 6.9	18.9 ± 6.9	
ICU arrival	15.0 ± 5.9	15.5 ± 6.1	
1 postoperative day	15.1 ± 4.6	15.1 ± 5.6	

Fig. 2 Changes in total protein concentrations

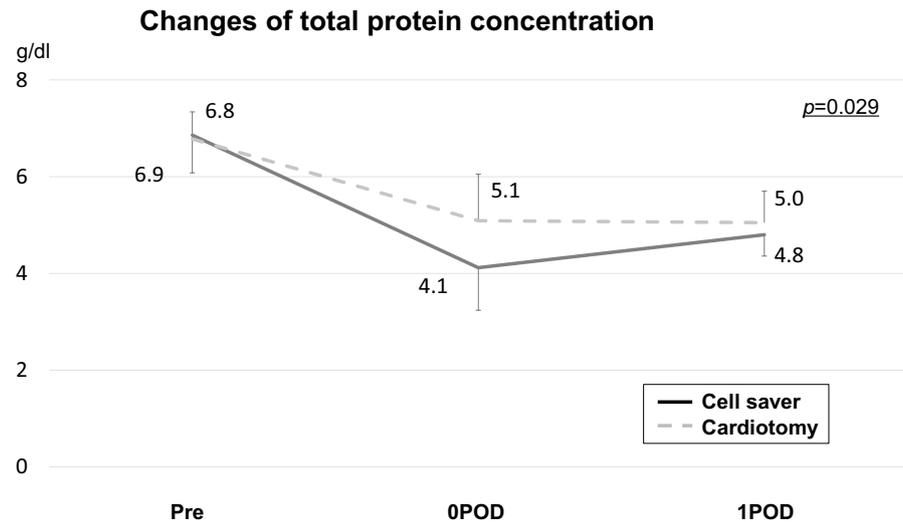
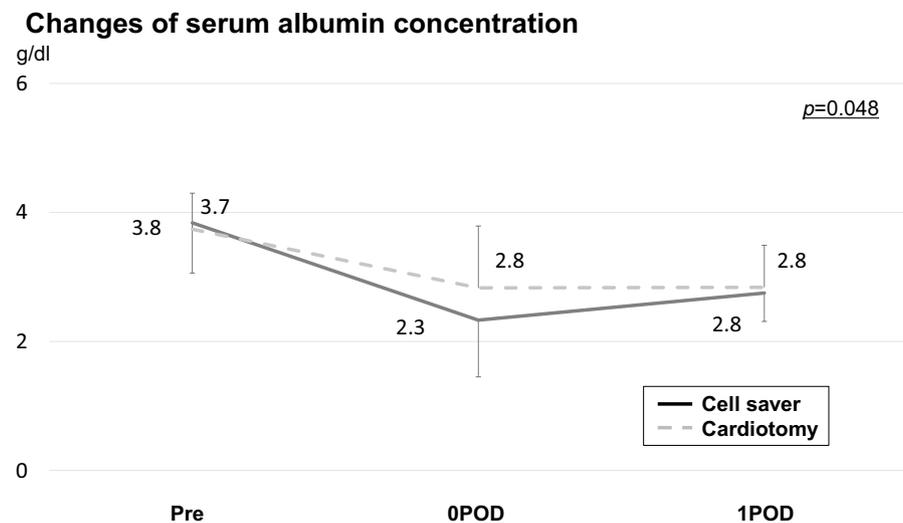


Fig. 3 Changes in serum albumin concentrations



preserve the various blood components more favorably than the cell saver system.

The major benefit of our system is its simplicity. The fundamental mechanism of this is nearly identical to the pump suction of a conventional cardiopulmonary bypass which is familiar to the surgical team. The cardiotomy suction system consists of one series circuit which can be set up within 20 min. The cost is lower than the conventional cell saver system. The only equipment required for the cardiotomy suction system is the roller pump which is usually ready for use during off-pump CABG procedures in the event of an on-pump conversion.

Several blood components were well preserved by the cardiotomy suction system. The blood figure analysis revealed the absence of hemolysis in the peripheral blood in the cardiotomy suction group. The cell saver system inevitably removes or destroys particular blood

components during centrifugation. The relatively potent negative pressure created by the cell saver system may accelerate the destruction of blood components. Therefore, the cell saver system can be associated with an increased risk of excessive blood dilution. The lower postoperative serum total protein and albumin concentration observed in the cell saver group could support this hypothesis. Moreover, the volume of intraoperative homologous blood transfusion was lower in the cardiotomy suction group. These findings are in agreement with the previous prospective randomized study (cardiotomy trial), where blood processing with centrifugation resulted in greater postoperative bleeding and more intraoperative red blood cell transfusion [6]. The cardiotomy suction system can immediately prepare the autologous blood product which can be used as the volume load for anesthesiologists. This rapid preparation of autologous blood can also be helpful for

reducing the volume of intraoperative homologous blood transfusion.

No serious procedure-related adverse events were observed in the study patients. But the postoperative pulmonary embolism in the cardiotomy suction group may arouse concern, because the elimination of centrifugation could increase the risk of contamination of autologous blood products by small particles. In fact, Jewell et al. [9] reported in their prospective randomized study that use of cell saver results in less fat being recycled. The pulmonary embolism was first noticed during routine enhanced computed tomography evaluating the bypass graft, because the postoperative course of this patient was uneventful. An echogram of the lower limbs revealed the existence of a deep vein thrombosis. This deep vein thrombosis may have resulted from the forced bed rest before surgery to avoid the chest symptoms which were previously induced by light exercise. After the diagnosis of pulmonary embolism, anticoagulant therapy was started and completely eliminated the thrombus in the pulmonary artery 1 week after treatment. We have speculated that the patient's pulmonary embolism probably stemmed from the deep vein thrombosis, but we could not rule out the potentially association of this complication with our cardiotomy system.

Study limitations

This study has several limitations. First, all data were retrospectively collected, which may lead to information bias. Second, the control group was a historical cohort; therefore there was a time difference between the medical treatment periods of the two groups. Although the operative strategy did not change throughout the study period, this time difference could affect the clinical outcomes, probably favoring the cardiotomy suction group. Third, our study cohort was relatively small, especially with respect to clinical outcomes evaluation. Further investigations with more patients are necessary if we are to confirm the safety of our cardiotomy system. Fourth, the transfusion criterion was inconsistent among anesthesiologist, which may have influenced the difference in the transfusion data.

Conclusion

Our newly developed, simple cardiotomy system could be used safely during off-pump CABG procedures. The clinical outcomes were similarly compared to the conventional cell

saver system. Hemodilution could be attenuated by our cardiotomy system. Future well-powered studies are mandatory for confirming the safety of this new blood recovery system.

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