Original papers

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Hemolytic Characteristics of Three Suctioning Systems for Use with a Newly Developed Cardiopulmonary Bypass System

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Abstract:

Introduction

We have been developing a closed-circuit cardiopulmonary bypass (CPB) system ("Dihead CPB") for application during coronary artery bypass grafting (CABG) and valve surgery. To strive for minimal hemolysis during Dihead CPB, we compared the hemolysis caused by three different suction systems, and performed a clinical study with the newly applied suction system.

Materials & Methods

We evaluated the hemolysis caused by roller pump suction, SmartSuction® Harmony® and wall suction systems with respect to suction speed and compared among the systems by means of in vitro studies. A clinical study was also performed on 15 volunteers to assess hemolysis and the sufficiency of the newly applied suction system with Dihead CPB.

Results

Pressure inside the suction cannula was −22.5 ± 0.1 mmHg at maximum flow of 1.5 L/min for roller pump suction and −43.4 ± 0.1 mmHg at −150 mmHg of the set vacuum pressure of wall suction. With SmartSuction, the pressure inside the cannula varied from −76.3±1.0 to −130.3 ± 1.5 mmHg depending on suctioning conditions. Suction speed (to suction 50 ml of blood) was fastest with SmartSuction (69.7 ± 3.58 s), whereas with roller suction it was 117.3 ± 8.47 s and with wall suction 96.9 ± 7.10 s. SmartSuction had the highest hemolysis rate (2.00 ± 0.33%) vs. 0.61 ± 0.10% for roller suction and 0.41 ± 0.11% for wall suction ($P < 0.001$). The clinical study with wall suction showed no significant increase in plasma-free hemoglobin during or after CPB compared with before surgery.

Conclusions

Wall suction had less hemolysis than roller suction or SmartSuction in the in vitro study, and the clinical study with wall suction showed efficient suction speed and acceptable hemolysis, suggesting that Dihead CPB with wall suction is feasible for CABG.

Key Words Free hemoglobin—Hemolysis—Cardiopulmonary bypass—Closed circuit—Negative pressure

INTRODUCTION

Closed-circuit cardiopulmonary bypass (CPB) is reported to induce less activation of the coagulation and inflammation cascade than conventional CPB because it does not have an open reservoir, which facilitates blood–air contact.[1-3] Closed-circuit CPB, however, is unable to maintain blood flow when massive bleeding suddenly occurs during surgery and the circulating blood volume is quickly lost. Hence, it is applicable only for cardiac surgery in which unexpected sudden bleeding is rarely predicted, such as coronary artery bypass grafting (CABG). In order to facilitate closed circuit CPB, with the added benefit of low-hemolysis suction of surgical blood, we have been developing a novel CPB system in which there is a soft reservoir in the closed circuit and an open hardshell cardiotomy reservoir, creating a dual-reservoir circuit, appearing visually as a two-headed (i.e. Dihead) CPB circuit. The open reservoir is connected to a suction system that drains blood from the surgical field into the reservoir. The Dihead CPB is applicable for aortic surgery, valve replacement and repair, and coronary artery bypass grafting, where blood loss can be managed via suction, with the benefit of a concurrent closed CPB system (Fig. 1).

Clinically available suction systems for the open reservoir are wall suction, roller suction, and SmartSuction® (Haemonetics, Braintree, MA, USA). There are sparse reports actually comparing the methods to each other, but the main cause of hemolysis is reported as air exposure together with negative pressure in a suction roller[4,] We therefore evaluated hemolysis caused by suction in various systems to optimize the open reservoir and suction of our newly developed Dihead CPB.

MATERIALS AND METHODS

Dihead CPB Circuit

The Dihead CPB circuit consists of an LIX system[5] (http://www.mera.co.jp/mera_e/b_seihin/b01_1_d03.html; Senko Medical Instrument, Tokyo, Japan) and a hard-shell blood reservoir (Senko). The LIX system is a combination of Excelun (Senko), which is a membrane oxygenator composed of hollow propylene fibers coated with ultrathin layers of silicone and heparin, and a centrifugal Gyro Pump (Medtronic, Minneapolis, MN, USA). A left ventricular vent tube is directly connected to the drainage tube (venous line) and an arterial filter and soft reservoir are incorporated into the circuit. The whole circuit is then coated with heparin. Blood was suctioned from the surgical field to the hard-shell cardiotomy reservoir using a suction system.

Pressure measurement

The roller pump suction system consists of a roller pump (HAD11-E; Senko Medical Instrument) and ¼-inch polyvinyl chloride tubing (Fig. 2A). The closing pressure of the tubing was set in accordance with JIS_T1603-1995.[6] The wall suction can change the vacuum pressure from 0 to −150 mmHg, using a wall-mounted pressure regulator. SmartSuction automatically regulates pressure inside the tubing by alternating the vacuum pressure (Fig. 2B). When air is detected in the suction cannula, it automatically decreases the vacuum pressure. The flow rate varies from 0.5 to 4.0 L/min. [7, 8] In this study, negative pressure inside the suction tubing was measured in a mock circuit that consisted of a macro suction cannula (DLP® Cardiac Suction Tubes; Medtronic, Grand Rapids, MI, USA),

polyvinyl chloride tubing (1.5 m long, ¼ inch diameter), a hard-shell reservoir (Fit Fix; Daiken, Osaka, Japan), and a metal tray. A stopcock was interposed between the cannula and the tubing, and the pressure was measured using a gas flow analyzer VT Plus HF (Fluke Biomedical, WA, USA). The metal tray was filled with 33 vol% glycerin water solution [9, 10] maintained at 20°–22°C in a hot water tub. The roller pump was driven at 35, 71, 107, 144, and 180 rpm to produce flow rates of 0.3, 0.6, 0.9, 1.2, and 1.5 L/min, respectively. For wall suction, the vacuum pressure was set at −30, −60, −90, −120, and −150 mmHg using the wall-mounted regulator. For SmartSuction, there were three suctioning conditions established to mimic clinical use. First, the suction cannula was fully immersed in the solution, then semi-immersed, then placed in air. These measurements were repeated three times for each suction system.

Tests for hemolysis and suction speed

Hemolysis was evaluated with a mock circuit composed of a metal blood pool of 250 × 200 × 50 mm, a DLP macro suction cannula, and a blood collection tube. Polyvinyl chloride tubing (1.5 m long, ¼ inch diameter) connected the blood tray and the blood collection tube. The roller pump was placed between the blood tray and the collection tube with occlusion in accordance with JIS_T1603-1995 (Fig. 2A).[6] Wall suction and SmartSuction were connected to the collection tube by polyvinyl chloride tubing (1.5 m long, ¼ inch diameter) (Fig. 2B). Fresh bovine blood (50 ml) with 13.0 vol% of acid citrate dextrose solution was used in the experiment. The blood was spread in the blood pool and maintained at 25°C. To evaluate hemolysis with the highest suctioning rate in clinical

usage, the blood was suctioned at 1.5 L/min at 180 rpm for roller suction and at −90 mmHg of vacuum pressure with wall suction with abandoned air to obtain a skimming condition. The blood was spread and suctioned again after all the blood was suctioned into the blood-collection tube. This suction sequence was repeated 5 times. Hemoglobin concentration (Hb), hematocrit (Hct), Plasma-free hemoglobin (fHb), and potassium levels; indicators of hemolysis, were measured before and after the 5 suction sequences. The experiment was repeated 10 times with different blood in each suction system. The suction speed required to aspirate 50 ml of blood was also measured for each suction system during the suction sequences. The I-STAT system (Abbott Park, IL, USA) provided the diagnostic reagents for determining Hct, Hb, and potassium levels. The fHb was measured by a photometric assay (Hemo Cue Plasma/Low Hb hotometer®; HemoCue, Ångelholm, Sweden). The fHb, total Hb, and Hct were measured before suction sequences. The hemolysis rate was calculated using the following equation for each experimental session: [11]

$$\text{Hemolysis rate} = (\text{fHbA} - \text{fHbB}) \times (1 - \text{HctB}) \times 100 / (\text{HbB})$$

where suffixes A and B indicate the measurement after and before suction, respectively. the fHb and Hb are expressed in grams per deciliter, and hematocrit is expressed as a decimal.

Clinical study

The clinical study was approved by the ethical review committee of Nagano Red Cross Hospital. Fifteen consecutive patients who underwent elective coronary artery bypass graft (CABG) were enrolled in the study. We performed CABG with Dihead CPB and the wall suction system, which consisted of a macro suction cannula (DLP® Cardiac Suction Tubes,

Medtronic) and polyvinyl chloride tubing (3.5 m long, ¼ inch diameter). Vacuum pressure was set at −90 mmHg using the wall-mounted regulator. Cardiac arrest was achieved with Miotecter (Analogue of St. Thomas solution; Mochida Pharmaceutical, Tokyo Japan.) in all patients. We measured fHb before CPB, 1 h after starting CPB, and 24 h after the surgery by photometric assay (HemoCue Plasma/Low Hb Photometer) and compared between before CPB, 1 h after starting CPB, and 24 h after the surgery.

Statistical analysis

All statistical analyses were performed with SPSS Statistics 22 software (SPSS, Inc., Chicago, IL, USA). Data are expressed as means ± standard deviation. Differences between three groups were assessed with analysis of variance followed by the Games–Howell test and Tukey's test. The fHb and potassium concentrations were compared using Student's t test. A value of $P<0.05$ was considered to indicate statistical significance.

RESULTS

Pressure measurements

With roller pump suction, the pressure inside the suction cannula decreased with increased flow rate and was −22.5 ± 0.1 mmHg at the maximum flow of 1.5 L/min (Fig. 3A). For wall suction, the pressure inside the suction cannula decreased almost linearly with decreasing vacuum pressure, reaching −43.4 ± 0.1 mmHg at −150 mmHg of the set vacuum pressure (Fig. 3B). For SmartSuction, the pressures inside the tubing were −76.3 ± 1.0 and

−84.3 ± 0.4 mmHg in air and the semi-immersed condition, respectively, and −130.3 ± 1.5 mmHg in the fully immersed condition (Fig. 3C).

Tests for hemolysis and suction speed

Before the hemolysis test, the fHb was 0.04 ± 0.01 g/dl with SmartSuction, 0.06 ± 0.01 g/dl with roller pump suction, and 0.09±0.01 g/dl with wall suction. After the test, fHb significantly increased to 0.36 ± 0.04, 0.15 ± 0.02, and 0.15 ± 0.01 g/dl with SmartSuction, roller pump suction, and wall suction, respectively (Fig. 4A). The hemolysis rate was also 2.00 ± 0.33% with SmartSuction, which was significantly higher than 0.61 ± 0.10% with roller pump suction and 0.41 ± 0.11% with wall suction. Thus, wall suction had the lowest hemolysis rate among the three systems (Table 1). Potassium increased after suctioning with all three systems, although the increase with the roller pump system was apparently less than that with the other two suction systems (Fig. 4B).

The suction speeds are shown in Table 1. It took 69.7 s to suction 50 ml of blood with SmartSuction, and 117.3 and 96.9 s with roller pump and wall suction, respectively. Smart Suction thus had the greatest speed of the three systems.

Clinical study

Patients' mean ± SD age was 63.3 ± 11.44 years. The study group included one woman and six men with a mean of 3.1 ± 0.81 distal anastomoses. Operation time, CPB time, and cardiac arrest time were 445.8 ± 79.9, 151.3 ± 25.7, and 82.9 ± 23.0 min, respectively. The participants experienced no mortality or morbidity during the study period. No mechanical

trouble was observed with Dihead CPB during the surgery. Figure 5 shows the changes in fHb, which increased 1 h after CPB started and decreased below the preoperative value 24 h after the surgery, although the changes were not significant.

DISCUSSION

Whilst hemolytic characteristics of some of the individual suction methods compared in this study have been reported, there are sparse reports actually comparing the methods to each other. This study revealed that, among three suction systems, wall suction caused the least hemolysis, with SmartSuction causing the most. It has been reported that suction-induced hemolysis increases with the increase in vacuum pressure—more than doubling when the vacuum pressure rose from −150 mmHg to −300 mmHg.[11]

SmartSuction varies the vacuum pressure from −20 to −150 mmHg depending on the liquid–air contamination in the suction cannula and produces suctioning flow of 0.5 – 4.0 L/min.[7, 8] In this study, the negative pressures inside the SmartSuction cannula were −76.3 ± 1.0, −84.3 ± 0.4, and −130.3 ± 1.5 mmHg in the air, skimming, and fully immersed conditions, respectively. Maximum negative pressure was −22.5 ± 0.1 mmHg at the maximum flow of 1.5 L/min for roller pump suction and −3.4 ± 0.1 mmHg at −150 mmHg of the set vacuum pressure for wall suction.

The hemolysis rate was significantly higher with SmartSuction than with wall or roller suction, which is attributed to the high negative pressure with SmartSuction. We performed the hemolysis test with the skimming condition (semi-immersed condition), which severely affected hemolysis in this study. In a previous study, hemolysis increased 10-fold when blood was mixed with air compared with blood alone.[11] The skimming condition was

chosen for the hemolysis test in this study because we sometimes skim blood during anastomosis in the clinical setting, and this severe condition for hemolysis more significantly elicited hemolytic characteristics of the three suction systems.

A vacuum pressure below −150 mmHg is recommended to reduce blood trauma, [12, 13] and it is not necessary to suction at negative pressures above −150 mmHg. We set the vacuum pressure at −90 mmHg for the hemolysis test to obtain −23 ± 0.1 mmHg of the pressure inside the suction cannula with wall suction. This negative pressure of −22.5 ± 0.1 mmHg is equivalent to the maximum flow rate of 1.5 L/min with roller suction and is considered sufficient for suctioning blood from the surgical field.[14-16] A suction time lag was not observed with−90 mmHg of vacuum pressure during wall suction in the seven patients in the clinical study, although the suction speed was 96.9 s, which was slower than that of SmartSuction in the suction speed test. Hemolysis rate was 0.41 ± 0.11% and the lowest with −90 mmHg of vacuum pressure. It is thought that −90 mmHg of vacuum pressure is suitable for wall suction.

The suction speed for removing 50 ml blood was 117.3 ± 8.47 s with roller suction and 96.9 ± 7.10 s with wall suction. These speeds were significantly different, although the mean negative pressures measured were almost the same at −22.5 to −23.0 mmHg inside the cannula of each suction system. With the roller pump, the negative pressure inside the tubing fluctuated because the pressure inside the tube becomes positive when the roller separates from the tubing during roller rotation. The actual suctioning time was shorter with the roller pump than with wall suction because of this transient positive pressure inside the tubing.[16] Therefore, suction speed was lower with roller suction, although the mean

negative pressure was almost the same in both suction systems.

The clinical study showed no significant increase in fHb during or after CPB. No mechanical trouble or suction time lag was experienced. These results suggest that Dihead CPB with wall suction is feasible for CABG. However, we included only a small number of cases. The application of Dihead CPB for valve surgery was not investigated here. Thus, further study is needed to evaluate this newly developed technique.

CONCLUSION

Wall suction was associated with less hemolysis than roller suction or SmartSuction. In addition, it provides sufficient suction speed, as shown in both the in vitro and clinical studies. Thus, Dihead CPB with wall suction is feasible for CABG without a suctioning time lag, although further study is needed to evaluate the technique.

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Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Authors' Contributions

Yuki Michinaga designed the study, performed in the vitro studies, and wrote the initial draft of the manuscript. Tamaki Takano analyzed and interpreted data and designed the study. Takamitsu Terasaki performed the clinical study. Souma Miyazaki and Noritoshi Kikuchi collected data. Kenji Okada directed the study.

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Legends

FIG. 1. Dihead cardiopulmonary bypass (CPB) circuit

FIG.2. Circuit for hemolysis test. Blood was suctioned into a collecting tube. (A) Roller pump suction was connected bellow the collecting tube. (B) Wall suction or SmartSuction was connected bellow the collecting tube.

FIG. 3. Negative pressure in the cannula. Roller pump suction (A), wall suction (B) and SmartSuction (C).

FIG. 4. (A) Changes in free hemoglobin levels with the three suction systems. (B) Changes in potassium with three suction systems.

FIG. 5. Free hemoglobin levels before CPB (pre), 1 h after starting CPB (1h), and 1 day (24 h) after surgery.

TABLE 1. Variables measured with the SmartSuction® Harmony®, roller pump, and wall suction devices

Variable	SmartSuction	Roller Pump (1.5 L/min)	Wall Suction (-90 mmHg)	P Value
Pressure (mmHg)	-84.3 ± 0.4	-22.5 ± 0.1	-23.0 ± 0.1	-
Hemolysis rate (%)	2.00 ± 0.33	0.61 ± 0.10	0.41 ± 0.11	<0.001
Suction speed (sec)	69.7 ± 3.58	117.3 ± 8.47	96.9 ± 7.10	<0.001

Results are given as means ± SD

Figure 1

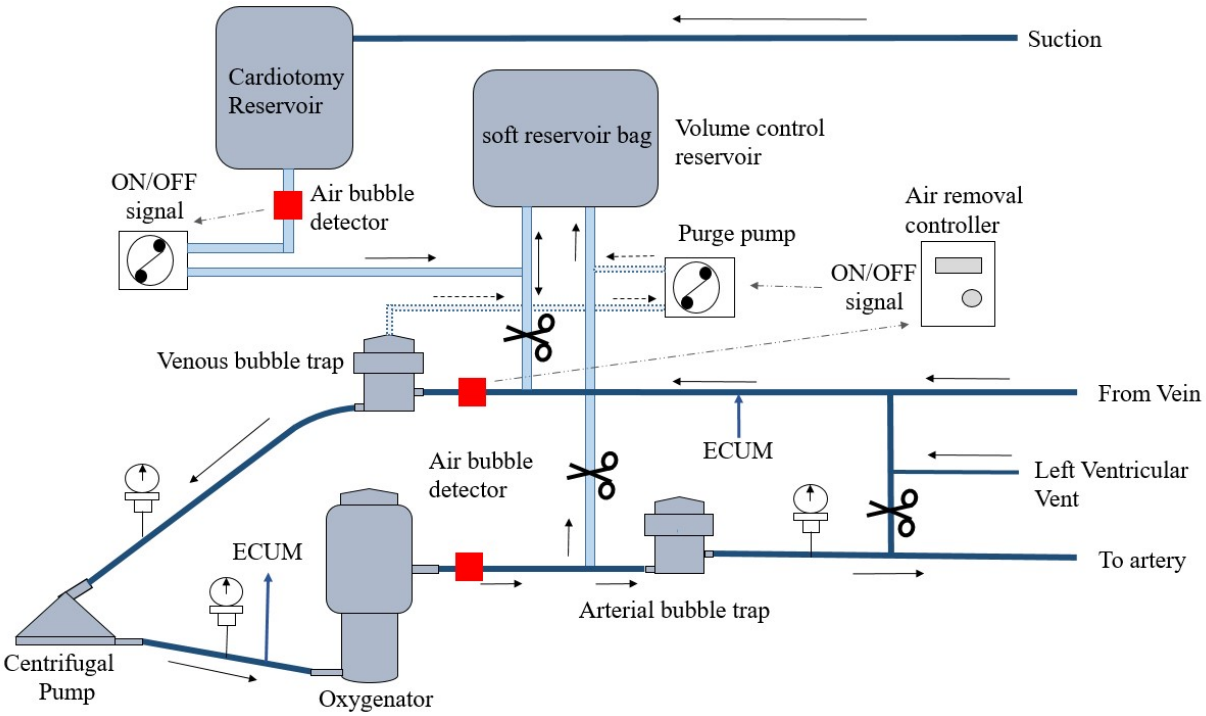
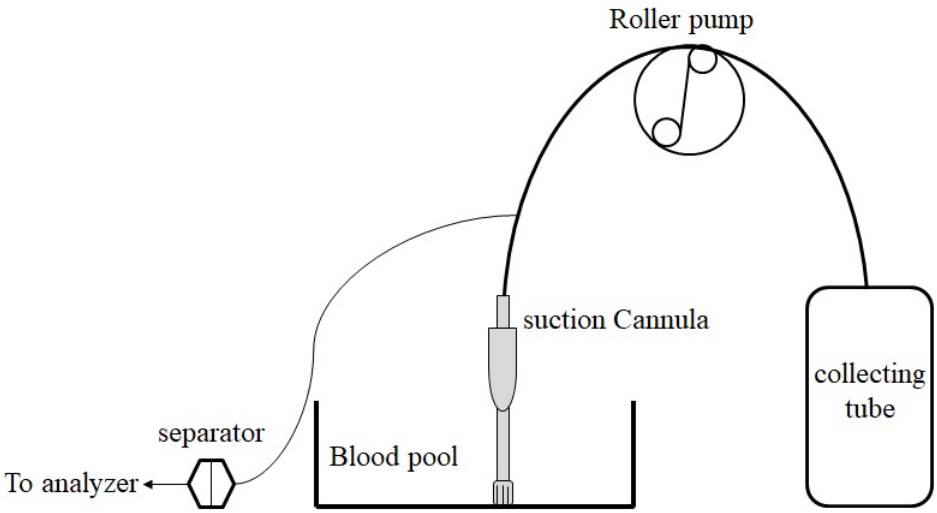
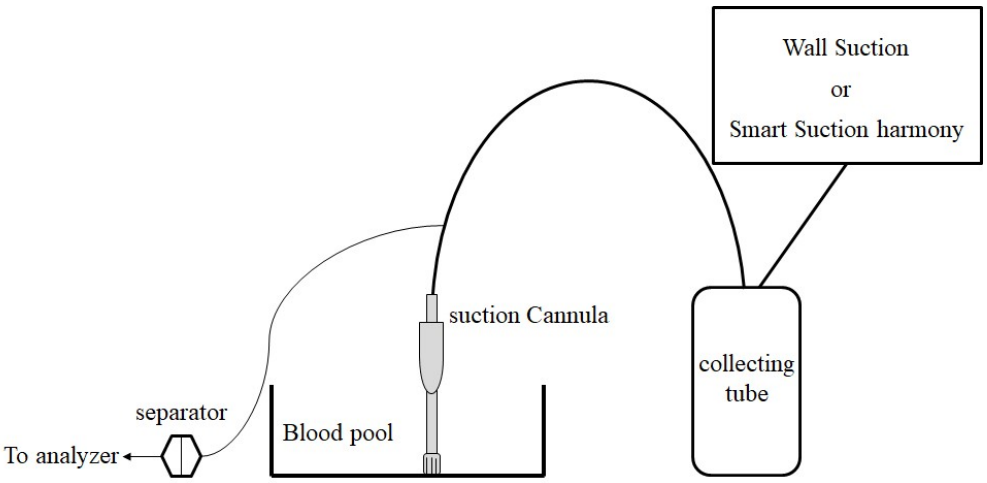

Suction
Cardiotomy Reservoir
soft reservoir bag
Volume control reservoir
ON/OFF signal
Air bubble detector
Purge pump
Air removal controller
ON/OFF signal
Venous bubble trap
From Vein
ECUM
Air bubble detector
Left Ventricular Vent
ECUM
To artery
Arterial bubble trap
Centrifugal Pump
Oxygenator

Figure 2


Roller pump
suction Cannula
collecting tube
separator
Blood pool
To analyzer

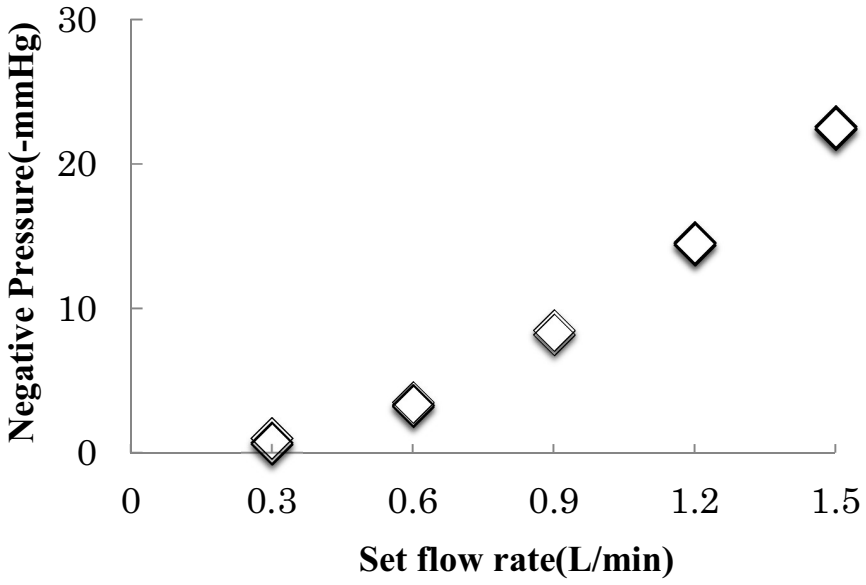
(A)

Figure 2


Wall Suction
or
Smart Suction harmony
suction Cannula
collecting
tube
separator
To analyzer
Blood pool

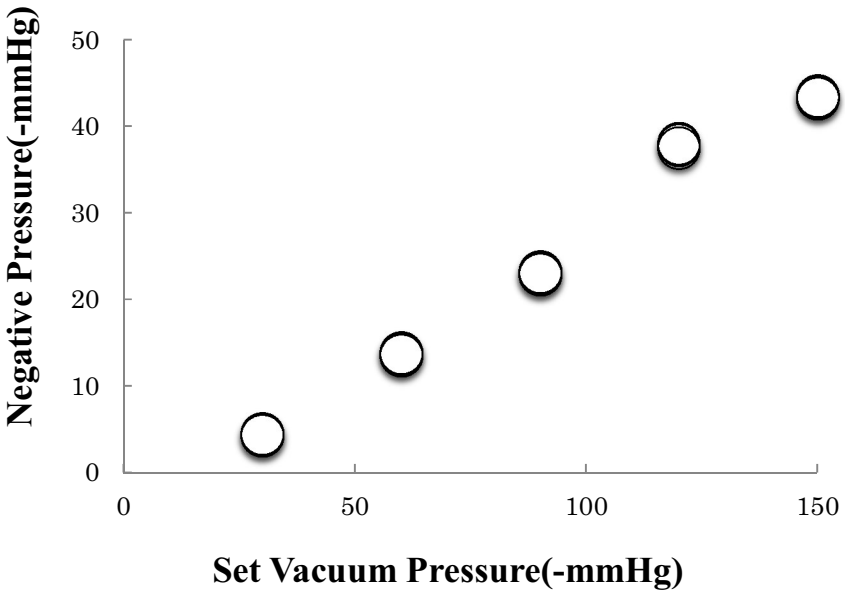
(B)

Figure 3


Negative Pressure(-mmHg)
30
20
10
0
0
0.3
0.6
0.9
1.2
1.5
Set flow rate(L/min)

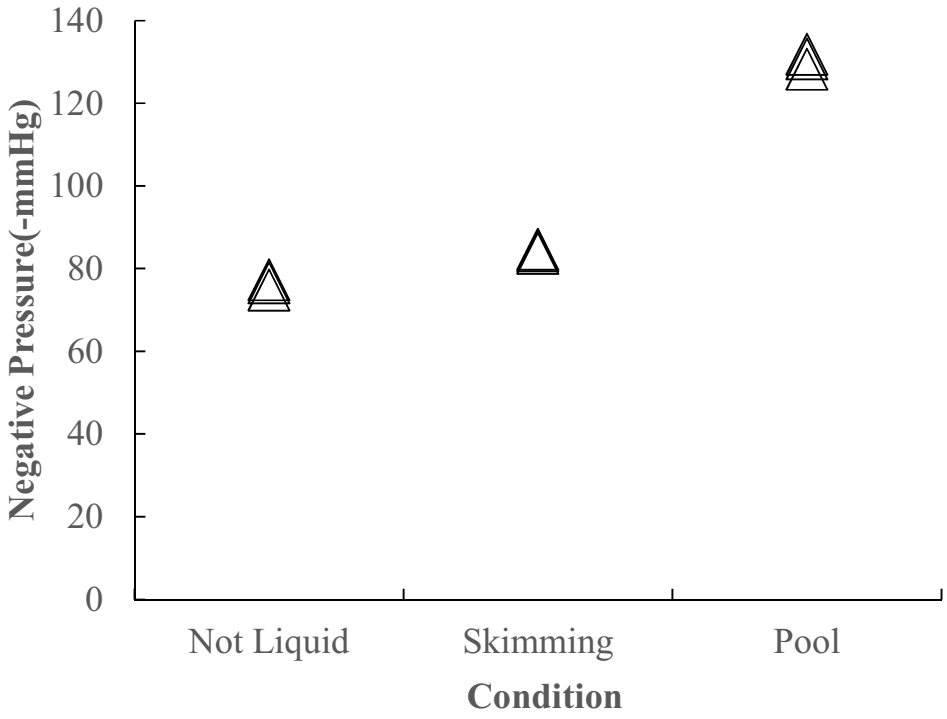
(A)

Figure 3


Negative Pressure(-mmHg)
50
40
30
20
10
0
0
50
100
150
Set Vacuum Pressure(-mmHg)

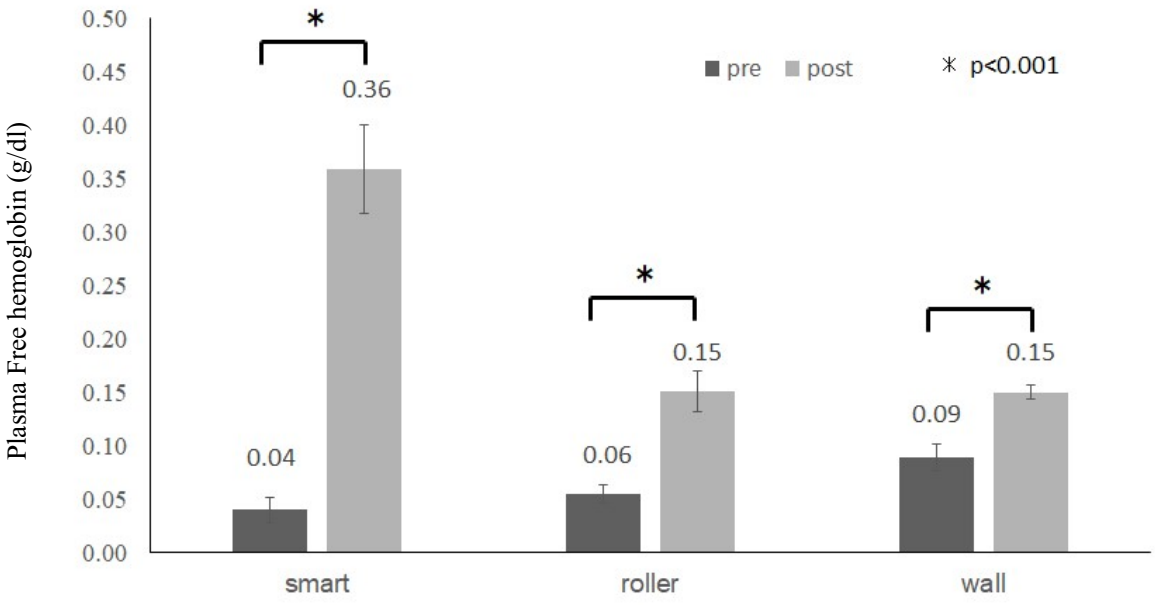
(B)

Figure 3


140
120
100
80
60
40
20
0
Negative Pressure(-mmHg)
Not Liquid
Skimming
Pool
Condition

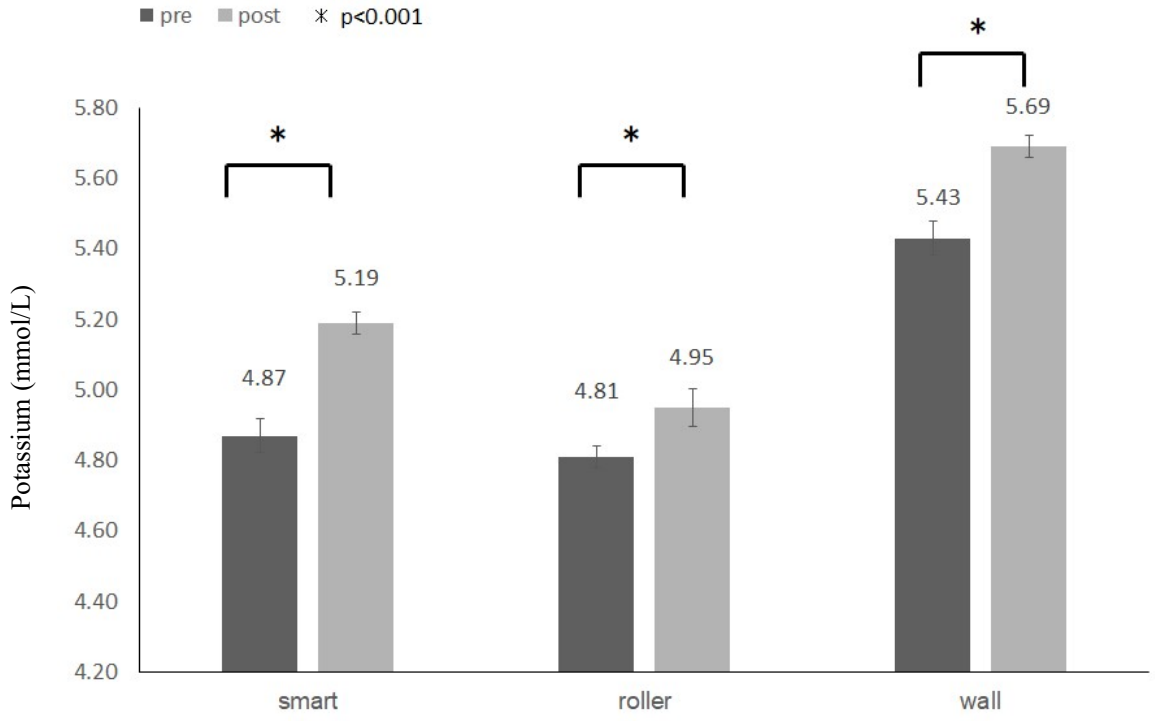
(C)

Figure 4


Plasma Free hemoglobin (g/dl)
0.50
0.45
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
pre
post
* p<0.001
*
*
*
0.36
0.04
0.15
0.06
0.15
0.09
smart
roller
wall

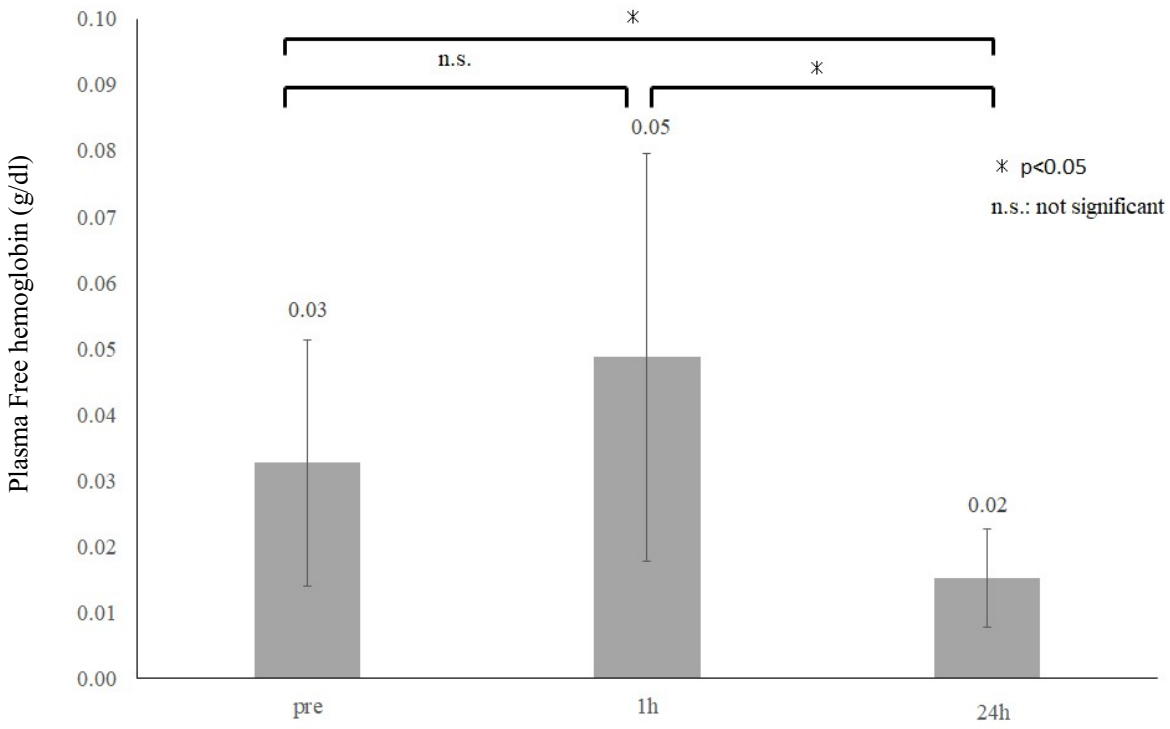
(A)

Figure 4


pre
post
* p<0.001
Potassium (mmol/L)
5.80
5.60
5.40
5.20
5.00
4.80
4.60
4.40
4.20
*
*
*
4.87
5.19
4.81
4.95
5.43
5.69
smart
roller
wall

(B)

Figure 5


Plasma Free hemoglobin (g/dl)
0.10
0.09
0.08
0.07
0.06
0.05
0.04
0.03
0.02
0.01
0.00
*
n.s.
*
0.05
* p<0.05
n.s.: not significant
0.03
0.02
pre
1h
24h