

Non-occlusive Condition with the Better-Header Roller Pump: Impacts of Flow Dynamics and Hemolysis

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Purpose: Impacts on hemolysis and backflow using a non-occlusive setting with the Better-Header (BH) roller pump were investigated.

Methods and Results: Pump flow of a non-occlusion setting was measured with a pump speed of 3 L/min and 5 L/min against various after-loads. With the non-occlusive setting (BH-NO350), backflow was less than 10% if the pump pressure head was <300 mmHg. When the outlet line is occluded, 80% of the set flow was shunted through the pressure relief valve and outlet pressure did not develop hazardous overpressure. During surgery with the BH-NO350, flow loss was <5% while the pump pressure was maintained at approximately 200 mmHg. An *in vitro* hemolysis test was conducted at 5 L/min against 350 mmHg, using the standard occlusion (BH-SO), the non-occlusion (BH-NO350), and the centrifugal pump (CP). The CP demonstrated less hemolysis than the other two groups; the BH-SO and the BH-NO350 had similar hemolytic characteristics. During cardiopulmonary bypass, no significant differences in hemolysis were seen among the BH-SO, the BH-NO350, and the CP.

Conclusion: Possible flow loss of the non-occlusion setting with the BH should be almost negligible in most clinical situations. The BH-NO350 demonstrated hemolytic characteristics similar to those of the BH-SO, but not as good as those of the CP. (*Ann Thorac Cardiovasc Surg* 2004; 10: 357–61)

Key words: Better-Header roller pump, non-occlusive setting, hemolysis test

Introduction

A Better-Header (BH) roller pump has been developed to prevent over-pressurization of a roller pump consequence. The BH consists of a Starling-like pressure relief valve connected across the inlet and the outlet of roller pump tubing. As long as arterial line pressure at the pump outlet remains below a set limit, the valve is closed. If line pressure approaches the pressure limit, the valve opens and shunts blood from the pump outlet to the inlet. Since the occlusion condition is adjusted by dynamic

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methods in the BH, a constant non-occlusive setting is easily obtained. If a non-occlusive setting is applied, hemolytic characteristics may be altered and flow loss generated.

In order to clarify the impacts of a non-occlusive setting with the BH on the aspect of flow dynamic features and hemolysis, *in vitro* and *in vivo* studies were conducted.

Materials and Methods

Conventionally, an occlusion setting for roller pumps is adjusted as a static condition (non-dynamic method) with a drop rate of 2.5 cm from a 100 cm height. In contrast, a non-occlusion setting is adjusted by a dynamic method: a slowly rotating pump generates a prescribed pressure when the pump outlet tubing is clamped. In detail: (i) air is infused to the pressure relief valve. The desired pres-

sure of the pressure relief valve (P set) is set, for example 350 or 500 mmHg. (ii) While an outlet tube is clamped, pumping is started with 5 rpm (210 ml/min) in a half inch ID tube. Roller occlusion is gradually closed until the pressure relief valve opens (shunt flow generated). (iii) Just before the valve opens, the desired P set non-occlusion setting is obtained. It is not necessary to stop the pump during this dynamic procedure. P sets of 350 and 500 mmHg equivalent drop rates of 20-40 and 40-60 cm/min/100 cm, respectively.

Study 1. In vitro flow dynamic test

When the flow was set at 3 L/min and 5 L/min followed by pump rotation speed, the actual pumped flow was measured with a flow meter (HD-800, Hayashi Denki CO, Ltd., Japan) while the total head pump pressure changed from 0 to 500 mmHg. The flow meter was located on the outflow line but distal to the shunt line. Human MAP blood (Ht 24%) was used as a solution. Pump inlet and outlet pressures were monitored with pressure transducers, and prescribed pressure differences across the pump were imposed with an adjustable screw clamp on the pump outlet tubing.

Experiments with the BH roller pump were performed under the following three conditions:

- a) Standard occlusive condition: (BH-SO)
- b) Non-occlusive condition with P set of 500 mmHg: (BH-NO500)
- c) Non-occlusive condition with P set of 350 mmHg: (BH-NO350)

In addition, shunt flow through the pressure relief valve and outflow pressure were measured while outflow was occluded in BH-NO500 and BH-NO350.

Study 2. In vitro hemolysis test

The in vitro hemolysis was conducted. The circuits were conducted with 3/8 and 1/2 inch Tygon tubes, a soft reservoir, and a blood pump. Fresh heparinized slaughterhouse bovine blood from a single donor was divided among the circuits, 500 ml each respectively. The pumping condition was set at 5 L/min against a total pressure head of 350 mmHg. Blood temperature was maintained at 28°C. The following three conditions were examined:

- a) BH roller pump with the standard occlusive setting (BH-SO) (n=4)
- b) BH roller pump with a non-occlusive setting (BH-NO350) (n=4)
- c) Centrifugal pump (BP-80, Medtronic Bio-Medicus, Inc., Eden Prairie, MN) (CP) (n=4)

For each experiment, plasma hemoglobin was determined hourly for 6 hrs. The normalized index of hemolysis (NIH = milligram of hemoglobin liberated per 100 L of blood pumped) was calculated for each pump according to the followings.

$$\text{NIH (g/100 L)} = [\Delta\text{Hb}/\Delta t \times \text{volume} \times (1-\text{Ht})]/\text{flow}$$

where $\Delta\text{Hb}/\Delta t$ = rate of increase in plasma free hemoglobin (mg/dl/min); volume = blood volume of each circuit (ml); Ht = hematocrit (expressed as fraction of 1); and flow = blood flow rate (L/min).

Differences in the NIH among the three groups were tested using multiple t-tests (paired two samples for means); p values <0.05 were considered statistically significant.

Study 3. In vivo flow study

During clinical cardiopulmonary bypass (CPB) with the BH roller pump, actual pump flow was determined and compared to the set flow, which was calculated by pump rotation speed. Subjects on whom the BH pump was used included 15 cases of elective coronary artery bypass graft surgery. A P set of 350 mmHg was applied. Radial artery pressure, pump outflow pressure, pump set flow, and actual flow were determined at 1 min, 5 min, 10 min, 30 min, 60 min, and 90 min into CPB, and in the weaning period (10 min before CPB termination).

A 2-way repeated-measures analysis of variance and unpaired Student's t-test were used to analyze the measured values. A p value of <0.05 was considered statistically significant.

Study 4. In vivo hemolysis test

Thirty cases of elective coronary artery bypass were randomly divided into three groups:

- a) BH roller pump with the standard occlusive setting (BH-SO) (n=10)
- b) BH roller pump with a non-occlusive setting (BH-NO350) (n=9)
- c) Centrifugal pump (CP) (n=11)

Plasma free hemoglobin was measured at pre CPB, at 60 min into CPB, at the end of CPB, and at 2 hr after CPB termination.

A 2-way repeated-measures analysis of variance and unpaired Student's t-test were used to analyze the values. A p value of <0.05 was considered statistically significant.

The protocol was approved by the institutional review board and affirmation that informed consent was obtained from each patient.

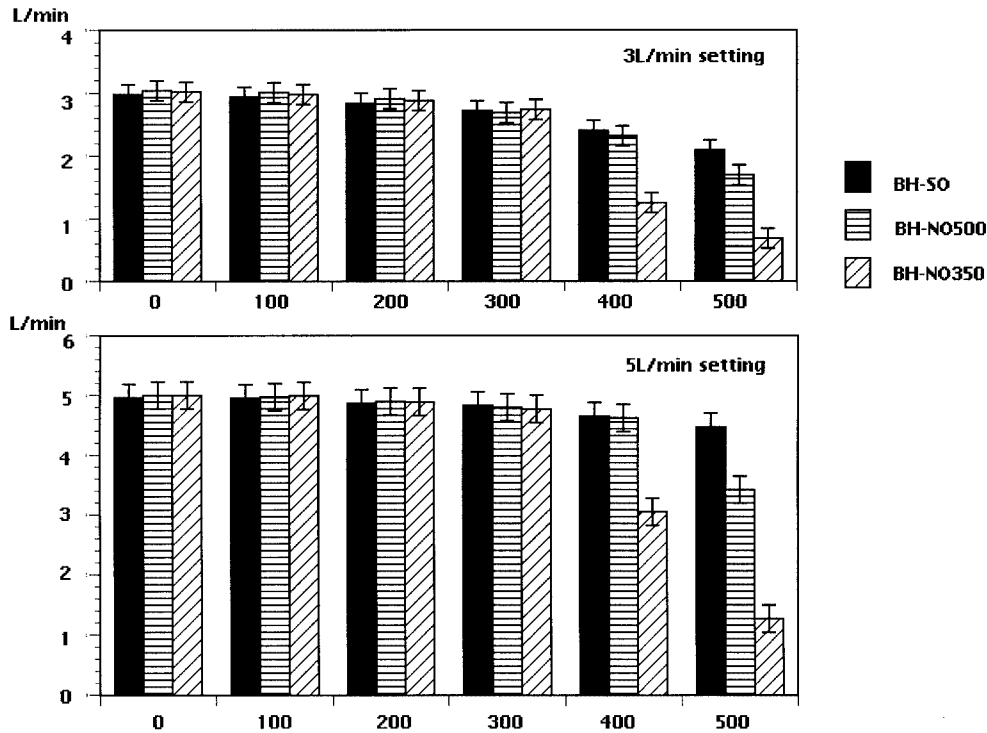


Fig. 1. In vitro flow dynamic test. Actual pump flow against various after-loads (pump pressure of 0-500 mmHg). Even in the BH-NO350, which has greater backflow than BH-NO500, differences between the set flow and the actual flow were less than 10% when the total pressure head was less than 300 mmHg. However, significant flow loss developed when the total pump pressure head exceeded 400 mmHg, whether at 3 L/min or 5 L/min.

Results

Study 1

Even in BH-NO350, which has greater backflow than BH-NO500, differences between the set flow and the actual flow were less than 10% if the total pressure head was less than 300 mmHg (Fig. 1). However, significant flow loss was developed if the total pump head pressure reached 400 mmHg or higher. This tendency was seen in both 3 L/min and 5 L/min conditions.

While outflow was occluded, approximately 80% of set flow was shunt through the pressure relief valve (Table 1). In addition, it prevented over-pressurization in the outlet line.

Study 2

The NIH levels of BH-SO, BH-NO350 and CP were 0.019±0.003, 0.017±0.005, and 0.008±0.002, respectively. No significant difference was seen between BH-

SO and BH-NO350. In addition, CP demonstrated the significantly lowest hemolysis among three (p<0.01).

Study 3

During stable flow conditions in patients undergoing CABG during CPB, the average BH pump head pressure was 200 mmHg and only occasionally reached 300 mmHg, while radial artery pressure was maintained at nearly 50 mmHg. The difference between the set flow and the actual measured flow was negligible (less than 5%) at any time during CPB (Fig. 2).

Study 4

Regarding plasma free hemoglobin levels during various stages of CPB in patients undergoing CABG, the levels at the end of CPB were the highest in all three groups. However, no statistically significant differences were seen between the three groups at any time (Fig. 3).

Table 1. Shunt flow though the pressure relief valve during outflow

	Pump set flow	Shunt flow (L/min)	Outlet pressure (mmHg)
BH-NO350	3 L/min	2.4±0.2	382 mmHg
	5 L/min	4.2±0.2	435 mmHg
BH-NO500	3 L/min	2.5±0.2	540 mmHg
	5 L/min	4.3±0.2	615 mmHg

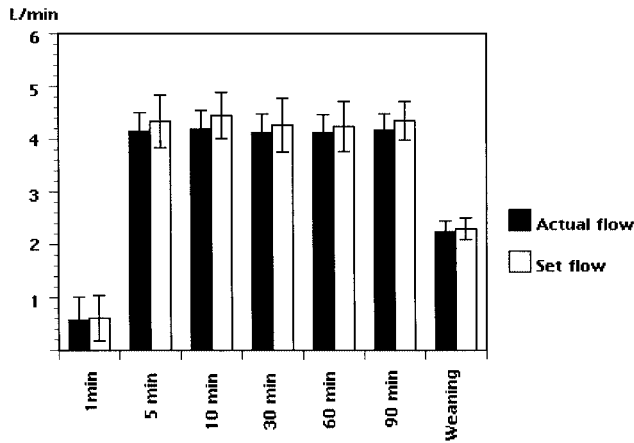


Fig. 2. In vivo flow dynamic test.

During cardiopulmonary bypass, no significant differences were seen between actual measured flow and set flow.

Discussion

Traditionally, roller pumps are almost always set at standard occlusion, because of the concern that retrograde flow through a non-occlusive gap would cause errors in calculating pump flow from pump speed. The same non-occlusive settings would be difficult to achieve using the standard drop rate technique.

The BH has been developed as a safety device to automatically prevent accidental over-pressurization of the roller pump without requiring electrical connections to the pump. If line pressure approaches the pressure limit, the pressure relief valve opens by shunting blood from the pump outlet to its inlet. Actually, both BH-NO350 and BH-NO500 prevented dangerous over-pressurization with nearly 80% of pump flow through the pressure relieved valve.

This device provides a simple, reproducible, and precise non-occlusive setting through a dynamic method. With this method, an occlusion setting can be achieved at any time before starting bypass, whereas the drop method must be carried out before the circuit is connected because the length of tubing is open to the atmosphere. Since occlusion is set while the rollers are rotating, variations in tubing wall thickness, roller extension, and raceway symmetry, all affecting the accuracy of the static drop rate technique, are averaged out with the dynamic method. The same non-occlusive settings would be difficult to achieve using the standard drop rate technique.

A less occlusive setting may be beneficial in terms of hemolysis because of lower shear stress in the roller

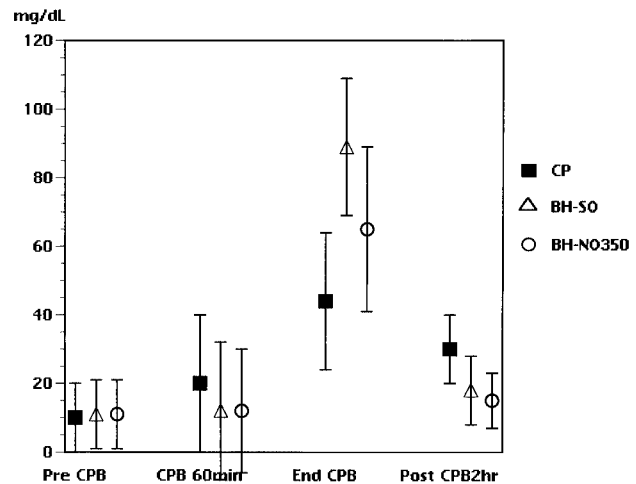


Fig. 3. In vivo hemolysis test.

During cardiopulmonary bypass, no significant differences were seen among the centrifugal pump, standard occlusive and non-occlusive (P set of 350 mmHg) Better Header.

pump.¹⁻⁶⁾ On the other hand, increased pump rotational speed due to higher backflow may increase hemolysis. This study was conducted in order to clarify the features of BH relating to flow dynamics and hemolysis.

The in vitro flow dynamic study demonstrated that flow loss of BH-NO350, which has greater backflow than BH-NO500, was less than 7-10% of forward flow with a total pressure head of less than 300 mmHg, whether pump flow was 3 L/min or 5 L/min.

The in vivo study demonstrated that the pump head pressure could be maintained at around 200 mmHg and only occasionally reached 300 mmHg. It indicated that possible flow loss could be negligible or less than 10% with usual usage of the BH. At most, 5% additional pump speed application would be enough to achieve the desired pump flow. It should be remembered that the accuracy of most clinically used flow meters is specified as $\pm 10\%$ of the reading or ± 100 ml/min. On the other hand, if pump pressure exceeds 300 mmHg, significant backflow will be generated. Anyhow, we recommend direct flow monitoring by a flow meter during the clinical induction of this new BH device because a perfusionist has a better sense of the actual flow loss with a flow monitor. Continuous monitoring of mixed venous oxygen saturation is also helpful, of course.

Generally, a roller pump is considered to be more hemolytic than a centrifugal pump.^{7,8)} A less occlusive setting in the roller pump is supposed to lessen hemoly-

sis. There have been some reports that less occlusive roller pumps resulted in lower hemolysis than the CP.^{9,10} However, this tendency is not absolute, probably due to differences in test settings. According to our results, even if the non-occlusion setting may be beneficial in terms of hemolysis, this effect may not be so great in most clinical situations. In addition, the effect of cardiotomy suction blood can not be overlooked, which may be a principle source of plasma free hemoglobin.

Conclusion

A simple safety device of the BH easily achieved a reliable non-occlusion setting through a dynamic method. In most clinical uses, flow loss of the non-occlusion setting was negligible or less than 10% with a P set greater than 350 mmHg. But if pump pressure exceeds 300 mmHg, significant backflow develops. While the non-occlusion setting may decrease hemolysis to some extent, this effect is minimal and not as great as with the centrifugal pump.

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