

# A New Closed-system Using Partially Frozen Injectate for Thermodilution Cardiac Output Determinations

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The FI (partially frozen injectate) system, a new closed-system devised by the authors for thermodilution cardiac output determinations, has two major features: 1) it needs no ice-filled receptacle to keep injectate cold because it uses partially frozen injectate, and 2) it can go without monitoring the injectate temperatures during the whole process of cardiac output determinations. The author evaluated the accuracy and reproducibility of cardiac output determinations with the FI system in 10 critically ill patients, as compared with another closed-system (which is commercially available) and the standard open method. The injectate temperatures in the FI system were also measured in vitro. The mean injectate temperature in the FI system was  $0.71 \pm 0.26^{\circ}\text{C}$  and 80% of the injectate temperatures were lower than  $1.0^{\circ}\text{C}$ . Even when no monitoring of injectate temperatures was made, the predicted error in the calculated cardiac output resulted as low as 2% with the FI system. The mean cardiac output values were not statistically different between the FI system and the other two systems. (Key words: cardiac output, thermodilution determination, catheter)

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Nowadays thermodilution cardiac output (CO) determination is one of the standard monitoring procedures in the care of critically ill patients<sup>1</sup>. The standard open-system manual injection thermodilution method (S system), however, has some inherent disadvantages such as risk of contamination, elevation in injectate temperature, and an increased variability in the rate of injectate administration<sup>2,3</sup>. For eliminating these disadvantages, some

closed-system thermodilution methods have been introduced<sup>4,5</sup>. One of them is commercially available CO-Set (Model 93-500, American Edwards Laboratories, Santa Ana, CA). This closed-system uses a reservoir bag or a coil which is mounted in a specially designed receptacle filled with ice. This receptacle is complex in structure and, furthermore, it can be an obstacle in the ICU or the operation room. The authors devised a simple closed-system (FI system) which uses partially frozen injectate, needs no receptacle, and yet can keep the injectate cold. This study was performed in an attempt to compare between the FI system and two other systems in 10 critically ill patients.

## Methods

### 1) FI system

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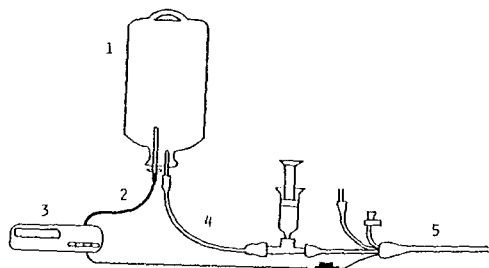


Fig. 1. Illustration fo FI system

1. partially frozen D5W in i.v. bag
2. temperature probe
3. cardiac output computer
4. male to male i.v. extension tube connected to the 18G needle
5. pulmonary artery catheter

The schematic diagram of the FI system is shown in figure 1. A 500 ml bag containing 5% dextrose in water (D5W) was completely frozen at  $-25^{\circ}\text{C}$  in a refrigerator. Then the frozen D5W was partially defrozed by putting the i.v. bag in a microwave oven for 3 min and the thawed portion of D5W was separated. The microwave oven was used to accelerate the defreezing process.

The injectate temperature was determined with a temperature probe (Model 9850A, American Edwards Laboratories, Santa Ana, CA) inserted into the partially frozen i.v. bag through a specially designed introducer. The introducer was removed from the i.v. bag and the probe was fixed in a way not to cause leakage of the solution. An 18G needle was inserted into the i.v. bag. A male to male i.v. extension tube (X1-LM10, TOP Inc., Tokyo), 0.1 ml in volume and 12 cm in length, was connected to the 18G needle. After connecting a 3-way stopcock to a 10 ml syringe, the i.v. extension tube was connected to the side port of the stopcock. The third port of the stopcock was connected to a 7F pulmonary artery catheter.

## 2) Protocol

### A) Measurement of cardiac output

The study was performed in 10 adult patients with a variety of respiratory failures which were treated with mechanical ventilation. All of them underwent pulmonary artery catheterization for hemody-

namic monitoring. Five consecutive CO determinations for three different systems (FI system, CO-Set, S system) were performed manually in one patient, which made fifteen determinations in each patient. The injectate volume was 5 ml of D5W for all three systems. Before the injection, the injectate was aspirated into the syringe and then returned to the i.v. bag for the FI system and CO-Set and to a beaker in a cold bath for the S system. This "pumping" procedure was conducted twice to get a constant temperature of the injectate and chill the syringe as well. The thirdly aspirated injectate was used for actual CO determinations. A cardiac output computer (Model 9520A, American Edwards Laboratories, Sant Ana, CA) was used for the CO determinations. All CO determinations were performed by the same investigator. Injections were initiated at end-exhalation in mechanical ventilation<sup>7</sup>. The computation constant of the cardiac output computer was changed when CO-Set was used, because the injectate temperature of CO-Set varied between 8 and  $14^{\circ}\text{C}$ .

### B) Measurement of injectate temperatures in the FI system

In the FI system, the injectate temperatures both in the i.v. bag (t-B) and at the entrance to the pulmonary artery catheter (t-C) were determined in vitro to investigate the degree of the injectate warming and the effect of pumping. One temperature probe was inserted into the i.v. bag as previously described. An i.v. tube in place of the pulmonary artery catheter was connected to the 3-way stopcock. Then another temperature probe (Model 6000, Mon-a-therm Inc., St. Louis) was inserted into the i.v. tube close to the 3-way stopcock. Injectate temperatures were determined in four different groups: Group 1 (G1) with no pumping; Group 2 (G2) with two pumpings followed by injection of aspirated solution; Group 3 (G3) with four pumpings; Group 4 (G4) with six pumpings. Five consecutive determinations of injectate temperatures were performed for each group using only one i.v. bag. In total, six i.v. bags were used. In all, 30 determinations for each group were

**Table 1.** Comparison of cardiac output (L/min), SD and range among three systems

		FI system	CO-Set	S system
Cardiac Output	(n=50)	5.79±0.40	5.59±0.39	6.16±0.48
SD	(n=10)	0.37±0.06	0.42±0.08	0.54±0.10
Range	(n=10)	0.90±0.15	1.02±0.17	1.28±0.22

Mean ± SE

Cardiac output values were not statistically different between the FI system and the other two systems. Neither was there any statistical difference among three systems in SD or range.

**Table 2.** The data on injectate temperature (°C) in FI system

Group	G1 (n=30)	G2 (n=30)	G3 (n=30)	G4 (n=30)
t-B	0.64±0.53*#	0.06±0.09	0.07±0.09	0.05±0.07
t-C	2.38±0.93*#	0.71±0.26*	0.60±0.23	0.49±0.23
difference	1.74±0.53*#	0.65±0.22*#	0.53±0.21	0.45±0.21
max. t-C	4.3	1.3	1.1	1.1
min. t-C	1.3	0.3	0.2	-0.1

Mean ± SD

# =  $P < 0.05$  compared with G3; \* =  $P < 0.05$  compared with G4; t-B = the injectate temperatures in i.v. bag; t-C = the injectate temperatures at the entrance to the pulmonary artery catheter; difference = t-C minus t-B; max. t-C = the maximum temperature in t-C; min. t-C = the minimum temperature in t-C.

performed in all.

### 3) Statistics

A) Five consecutive CO determinations were used for each system to calculate the mean value, the standard deviation (SD) and the range (the highest value minus the lowest value). This calculation was done in 10 patients. In all, 50 CO determinations were performed for each system and 10 SDs and as many ranges were calculated for each system. The reproducibility was evaluated on the basis of the SD and the range of the five consecutive CO determinations in each subject. The data were analyzed by comparing the collection of SDs and ranges by analysis of variance. The population of the mean values of the CO determinations was also compared by analysis of variance.

B) Six sets of five determinations of the injectate temperatures in the in vitro study were used to calculate the mean value of

the injectate temperatures and the difference (t-C minus t-B). They were compared by analysis of variance.

Significance was determined at  $P < 0.05$ .

### Results

A) There was no significant difference in the measured values of cardiac output among the three systems (table 1). And there was no significant difference between the FI system and the other systems in the reproducibility, although the FI system showed less variableness than the other two systems.

B) The data on injectate temperatures of the FI system are summarized in table 2. Both t-B and t-C were decreased as the number of pumping times was increased. The mean t-C in G2 was 0.71°C and 80% of t-C in G2 were lower than 1°C. All of t-B in G2, G3 and G4 were within the range of 0 to

0.5°C. More than 50% of t-B in G2, G3 and G4 were 0°C. Maximum and minimum t-C for each group were as shown in table 2.

### Discussion

The standard open system for measuring thermodilution cardiac output has some inherent disadvantages, which include rise in the injectate temperature, variability in the rate of injectate administration and risk of contamination. In an effort to overcome or eliminate these disadvantages, some closed-systems have been introduced. In these closed-systems, however, a reservoir bag or a coil has to be mounted in a specially designed, ice-filled receptacle of a complex structure. On the other hand, there are some reports recommending a system with no such receptacle, in which the injectate at room temperature is used<sup>8-10</sup>. However, the use of cold injectate has been advocated for patients with high cardiac output, low body temperature, or those requiring mechanical ventilatory support, because it improves the signal/noise ratio<sup>11,12</sup>. Hence, a simple system which uses injectate maintained cold is useful. The authors introduced a closed-system which uses partially frozen 5% dextrose in water in an i.v. bag and a small volume i.v. extension tube, thereby constantly furnishing cold injectate without using any special receptacle for the i.v. bag.

The present study demonstrated that the receptacle-free FI system is comparable with a closed-system with receptacle and the standard open procedure both in the mean cardiac output value and in the reproducibility.

In this study, pumping was done twice when cardiac output was measured, and in vitro study indicated that the mean t-C was 0.71°C and that of t-C minus t-B was 0.65°C in G2, the group subjected to two pumpings. An error of 2.86% in the calculated cardiac output can be predicted from the standard indicator-dilution equation for each degree (°C) of temperature error in the blood/injectate gradient<sup>13</sup>. In the FI system, a 0.65°C change in delivered injectate temperature in G2 would produce a 1.86% error. Even if the temperature probe is not

connected to the cardiac output computer, the cardiac output will be calculable on the assumption that the injectate temperature is 0°C. In the FI system, an error of 2% in the calculated cardiac output was predictable without connecting the temperature probe because the mean value of t-C was 0.71°C. One methodological disadvantage in the FI system is that insertion of the temperature probe requires a special introducer. In emergency cases, however, with low and constant injectate temperature assured, the FI system can do without such temperature monitoring.

This study demonstrated the importance of "pumping" in securing cold injectate and in minimizing the difference between t-C and t-B. The FI system is virtually free from otherwise possible contamination resulting from pumping, since all parts of it are sterilized and there is no possibility of the injectate coming into contact with air or any other thing not sterilized. There have been no infectious cases attributable to the use of the FI system in our institution. Injectate would remain cold enough when pumping were done twice, judging from the fact that there was no significant difference in t-C among G2, G3 and G4.

The FI system is a simple method of determining thermodilution cardiac output in that it requires no receptacle for keeping the injectate cold. A number of i.v. bags of D5W are always stored in refrigerators in our institution. Thus, in emergency situations, CO determinations can be performed without monitoring injectate temperatures.

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