

Calibration of the Stockert SIII Double Headed Pump for the Adult and Pediatric Sorin Vanguard 4:1 Blood Cardioplegia Delivery System

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Abstract

At B. C.'s Children's Hospital the Sorin Pediatric Vanguard 4:1 for Blood Cardioplegia Delivery (BCD) includes a buretrol on the crystalloid inlet to accurately measure the delivered dose of cardioplegia to the myocardium. This is done as the suggested calibrations for the Stockert SIII double headed pump were off. On quantifying the error in the Stockert published calibration factors to Sorin Canada, they repeated the same study on their machine. Sorin agreed that the combination of the SIII double headed pump and the Pediatric Vanguard 4:1 BCD over delivered volume. The initial study was repeated to include the Adult Vanguard 4:1 BCD and to determine if the preload pressure from the oxygenator was the cause of the over delivery. The volumes delivered were not affected by preload or after load when tested within the normal clinical delivery ranges. The adult BCD over delivered volume by 15% for the blood tubing and 17% for the crystalloid tubing. The pediatric BCD over delivered volume by 18% for the blood tubing and 44% for the crystalloid tubing. The correct calibration settings for the four tubing sizes used were defined.

Introduction and Background

At BC Children's Hospital, a 150 ml buretrol (Buretrol Add On Set-JC7565, Baxter Corporation, Toronto ON Canada) on the crystalloid inlet tubing of the blood cardioplegia delivery (BCD) set is used to ensure precise and accurate delivery of cardioplegia to neonatal and pediatric hearts.

Initially, cardioplegia was delivered using the Sorin Vanguard Pediatric 4:1 BCD set and a single Stockert SIII pump with both tubings through the raceway (blood on the bottom and crystalloid on top). There were two buretrols on the crystalloid inlet tubing of the BCD for the high and low potassium cardioplegia solutions. The pump RPMs were the same for both tubings during cardioplegia delivery.

On the SIII single roller pump there are tubing size selections of 1/4", 3/8", 1/2", 5/8", F1 and F2. On the SIII double headed pump there are tubing size selections of 1/4", 5/16", F1 and F2. The F1 and F2 are two free registers that allow a fine calibration for non-listed tubing sizes (SIII Operating Instructions – Version 04 / 2001 – Page 5-41).

Subsequently the cardioplegia pump was changed to an SIII double headed pump. There was only one buretrol on the crystalloid inlet tubing of the BCD for the high potassium cardioplegia solution. The blood to crystalloid ratio was adjusted upward on the cardioplegia control module for lower potassium delivery. Pump A had the 3/16 inch

blood tubing with an F1 fine calibration of 3.2 mls/revolution (ml's/R) (Stockert). Pump B had the 3/32 inch crystalloid tubing with an F1 fine calibration of 0.8 mls/R (Stockert). Pump A and B's RPM's were the same for both tubings during cardioplegia delivery. The SIII cardioplegia control module on the pump was used to control the double headed pump for cardioplegia delivery. Pump B's flow control knob was turned on to maximum. Pump A's flow control knob was used to initiate and adjust flow for both pumps A and B.

It was noted that the cardioplegia volume delivery display on the cardioplegia control module did not correspond with the actual cardioplegia volume delivered to the patient as measured by the buretrol.

The following is a discussion of the process used to recalibrate the double headed pump for the pediatric / adult Vanguard 4:1 BCD sets so that the volume delivery display on the cardioplegia control module aligned more closely with the actual cardioplegia volume delivered to the patient as measured by the buretrol.

Method

Stockert Instrumente GMBH (Munich, Germany) supplied the fine calibration factors for the SIII double headed pump and the four tubing sizes used with the adult / pediatric Vanguard 4:1 BCD set (Sorin Group, Toronto ON Canada). The F1 fine calibration factors are: 1/4 inch x 1/16 inch (blood - adult set) - 0 mls/R; 1/8 inch x 1/16 inch (crystalloid - adult set) - 1.6 mls/R; 3/16 inch x 1/16 inch (blood - pediatric set) - 3.2 mls/R; 3/32 inch x 1/16 inch (crystalloid - pediatric set) - 0.8 mls/R. See figure 1 for a diagram of the circuit used.

The pediatric / adult Vanguard 4:1 BCD sets were mounted on the SIII double headed pump. The Vanguard 4:1 BCD sets were primed with Plasmalyte A solution (Baxter Corporation, Mississauga ON Canada). Occlusions on the double headed pump were set at 100%. A variety of flows ranging from 50 – 400 mls/min were used for the tests to simulate the normal clinical range for cardioplegia delivery to the patient. Delivered volumes were measured directly using a graduated metric 500 ml laboratory beaker with 5 ml increment markers (Nalgene Labware, Rochester New York USA).

For each flow and calibration setting - the after load pressures were measured post Vanguard BCD on the patient cardioplegia delivery line and were controlled by a resistance thumb clamp set to be 200 mmHg \pm 10 mmHg as measured on a DLP Pressure Display 60000 and DLP Pressure Display Set 61000 (Medtronic Canada, Mississauga ON).

For each flow and calibration settings the pre load pressures (simulated pressure from the oxygenator) were set at 0 & 100 mmHg as measured on a DLP Pressure Display set. The preload pressure was measured on the blood inlet tubing to the Vanguard BCD. The pre load pressure from the oxygenator was simulated by attaching a one liter bag of Plasmalyte A crystalloid solution to the blood inlet tubing of the BCD set. To simulate 0 mmHg preload pressure the crystalloid bag was kept at the same level as the pump. To simulate 100 mmHg preload pressure the crystalloid bag was raised to the appropriate height above the pump.

BC Children's Hospital BCP delivery Circuit

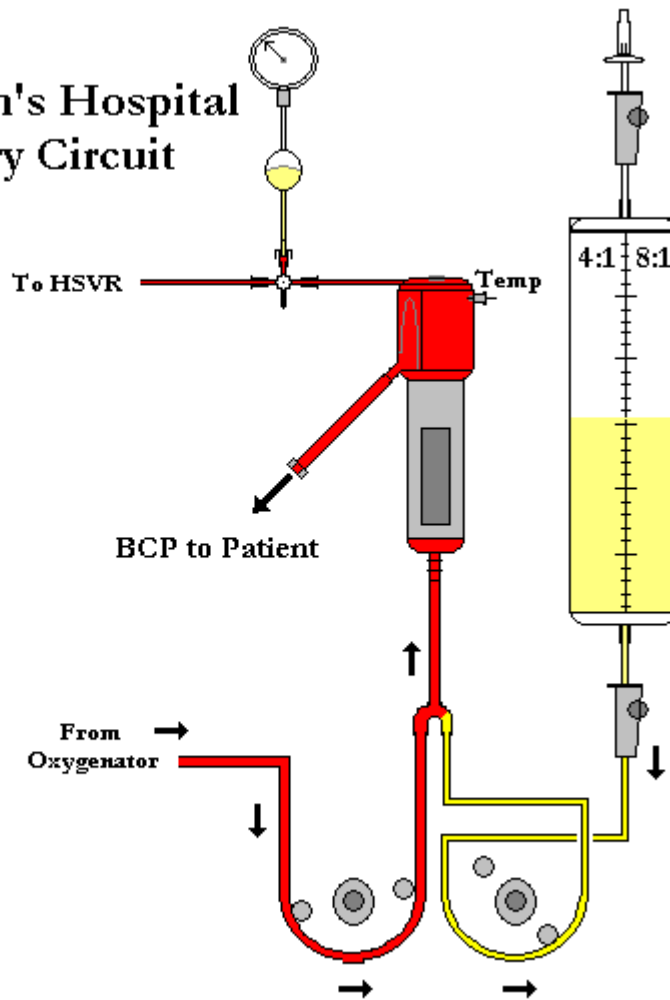


Figure 1.

The volume of fluid delivered to the measurement beaker during testing was measured “slip stream”. The pump was turned on, the flow rate was set & the volume was delivered to a recirculation vessel. Then the delivery line was moved to the measurement beaker while simultaneously starting the stop watch timer. After one minute the delivery line was moved from the measurement beaker to the recirculation vessel. This eliminated any delay errors in volume measurement associated with turning the pump on/off or adjusting the flow rate.

Once the Stockert fine calibration settings for the double headed pump were fully assessed, the fine calibrations were adjusted until the flow rates matched the delivered volumes.

Initially each tubing size was assessed individually for both the adult and pediatric Vanguard 4:1 BCD sets. For the 3/16 inch (blood) tubing on the pediatric Vanguard BCD set the F1 fine calibration factor of 3.2 ml's/R was set on the double headed pump being used. The pump flow was set at 100 ml's/minute (ml's/min). Using a stop watch – the volume of fluid delivered to the beaker over one minute was measured at 118 ml's. The F1 fine calibration factor was then adjusted upward by 0.1 ml's/R increments and retested following the above procedure for 3.3, 3.4, 3.5, 3.6, 3.7, 3.8 and 3.9 ml's/R until the measured volume of fluid in the beaker was 100 mls at a flowrate of 100 mls/min. It was established with this process that an F1 fine calibration factor of 3.8 ml's/R was the precise calibration for the 3/16 inch blood tubing.

On the same double headed pump the fine calibration factor of 3.8 mls/R for the 3/16 inch blood tubing was entered. The same testing procedure was repeated using a different pediatric Vanguard 4:1 BCD set. The volume of fluid measured in the beaker at each of the designated flow rates was accurate for that flow rate.

On a different double headed pump the fine calibration factor of 3.8 mls/R for the 3/16 inch blood tubing was entered. With the same pediatric Vanguard 4:1 BCD set the same procedure was repeated. The same results were reproduced verifying the accuracy of the test.

The whole process was repeated individually for each of the other tubing sizes (3/32 inch crystalloid - pediatric set, 1/4 inch blood – adult set, 1/8 inch crystalloid – adult set) until the precise F1 fine calibration factors were established. Next the precise established F1 fine calibration factors for the above tubing sizes were retested on the same double headed pump but with different adult and pediatric Vanguard 4:1 BCD sets. The same results were achieved. Once this was completed the established F1 fine calibration factors for the above tubing sizes were retested on a different double headed pump but with the same adult and pediatric Vanguard 4:1 BCD sets. The results were reproduced.

After this – the pediatric Vanguard 4:1 BCD set was tested as a unit. The 3/16 inch blood tubing was loaded in pump A with an F1 fine calibration set at 3.8 ml s/R and the 3/32 inch crystalloid tubing was loaded in pump B with an F1 fine calibration set at 1 ml/R. The same procedure was used for testing. The volume of fluid measured in the beaker at each of the designated flow rates was accurate for that flow rate. The whole process was repeated again on the same double headed pump but with a different pediatric Vanguard 4:1 BCD set. The same results were achieved. The whole process was repeated again on a different double headed pump but with the same pediatric Vanguard 4:1 BCD set. The results were reproduced.

Finally the adult Vanguard 4:1 BCD set was tested as a unit. The 1/4 inch blood tubing was loaded in pump A with an F1 fine calibration set at 7.0 mls/R and the 1/8 inch crystalloid tubing was loaded in pump B with an F1 fine calibration set at 1.9 ml's/R. The same procedure was used for testing. The volume of fluid measured in the beaker at each of the designated flow rates was accurate for that flow rate. The whole process was repeated again on the same double headed pump but with a different adult Vanguard 4:1 BCD set. The same results were achieved. The whole process was repeated again on a different double headed pump but with the same adult Vanguard 4:1 BCD set. The results were reproduced.

A second investigator repeated the testing again for the entire project. The second investigator reproduced the study results confirming accuracy of testing.

Results

All the testing confirmed the following as the correct calibrations for the tubing sizes 3/16 inch blood – pediatric set – 3.8 mls/R, 3/32 inch crystalloid – pediatric set – 1 ml/R, 1/4 inch blood – adult set – 7 mls/R, 1/8 inch crystalloid – adult set – 1.9 mls/R.

Preload of 100 mmHg in the arterial line post oxygenator had no effect on the cardioplegia volume delivered.

After establishing and documenting the double headed pump fine calibration settings for the tubing sizes of the pediatric / adult Vanguard 4:1 BCD sets as seen in figure 3 further work was done.

The results were verified mathematically by calculating the volumes delivered by each tubing size. The pump raceway length was measured for one complete revolution from occlusion take up point to release over the effective course of the two rollers.

See figure 2 for the comparison of the calculated, measured (actual) and Stockert published fine calibration settings.

Tubing ID		Calculated				Actual	Published
		Radius	Cross sectional volume	Tubing raceway length	volume/R		
Imperial	Metric	mm	πr^2	length	mls	mls/R	mls/R
inches	mm	mm	mm	± 0.005 m	mls		
1/4" x 1/16"	6.35	3.18	31.66	0.22	6.97	6.98	6.25
1/8"x1/16"	3.18	1.59	7.94	0.22	1.75	1.9	1.6
3/16"x1/16"	4.76	2.38	17.79	0.22	3.91	3.85	3.2
3/32"x1/16"	2.38	1.19	4.45	0.22	0.98	1.06	0.8

Figure 2. Comparison of calculated, measured & Stockert published fine calibration settings.

The calculated volumes delivered by each tubing size were similar to the measured actual fine calibration results. This reinforces the fact that the Stockert published fine calibration mls/R were off enough to inversely affect the delivered volumes. The lower the fine calibration mls/R the higher the delivered volume.

	Tubing size		Calibration ml/R	rpm	Set flow mls/min	Actual flow mls/min
Pediatric Vanguard BCP Set	3/16" x 1/16"	Stockert	3.2	31	100	118
		Corrected	3.8	26	100	99
	3/32" x 1/16"	Stockert	0.8	60	50	72
		Corrected	1	47	50	50
Adult Vanguard BCP Set	1/4" x 1/16"	Stockert	0	48	300	345
		Corrected	7.0	43	300	300
	1/8"x1/16"	Stockert	1.6	46	70	82
		Corrected	1.9	39	70	70

Figure 3. Comparison of Stockert published versus measured determined pump fine calibrations factors and their effect on delivered volumes.

Figure 3 is a comparison of the Stockert published versus the measured correct fine calibrations and illustrating how these affect the delivered volumes at set flow rates.

Once the measured correct fine calibration settings on the double headed pump were established for the pediatric/adult Vanguard 4:1 BCD tubing sizes, the results were confirmed. Figure 4 illustrates the accuracy of the delivered measured volumes at specific flow rates. It also reaffirms that with the correct fine calibrations the Vanguard BCD 4:1 tubing ratios and tubing tolerances were appropriate.

	3/16" x 1/16"		3/32" x 1/16"		
Set flow	Flow	rpm	Flow	rpm	Measured volume
mls/min	mls/min		mls/min		mls
50	40	11	10	8	50
100	80	21	20	17	98
150	120	32	30	27	150
250	200	53	50	47	249
375	300	80	75	68	375

Figure 4. Sorin Pediatric Vanguard 4:1 BCD set with correct fine calibrations on the SIII double headed pump.

Once the newly defined F1 fine calibration factors for the double headed pump and the pediatric Vanguard 4:1 BCD set were confirmed they were put into use clinically. For the first five clinical cases the ratios were tested by measuring potassium (K+) in the patient and the delivered blood cardioplegia (BCP). The BCP K+ was measured using a 50% dilution with normal saline 0.9% to dilute the delivered BCP K+ to within the measurable range of the blood gas analyzer. The delivered BCP K+ was as calculated therefore indicating that the pump tubing flows supported the change in fine calibrations.

SIII double headed pump	1/4" ID x 1/16" PVC	1/8" ID x 1/16" PVC	3/16" ID x 1/16" PVC	3/32" ID x 1/16" PVC
Stockert published fine cal setting	1/4" fine cal 0	F1/F2 fine cal 1.6 ml/R	F1/F2 fine cal 3.2ml/R	F1/F2 fine cal 0.8ml/R
Measured actual calibration setting	1/4" fine cal+7.0ml/R	F1/F2 fine cal 1.9 ml/R	F1/F2 fine cal 3.8ml/R	F1/F2 fine cal 1.0ml/R
% error delivery vol. using Stockert fine cal settings	+15%	+17%	+18%	+44%

Figure 5. Differences between the Stockert published and measured correct fine cal.'s and % error of BCP over delivery using the published values.

Looking at figures 5 and 6, although the differences between the Stockert published and the measured correct fine calibrations may seem negligible - the affect they have on the BCP delivered volumes indicates otherwise. Both figures 5 and 6 illustrate the % error of BCP volume over delivery for the tubing sizes of the pediatric/adult Vanguard BCD sets using the Stockert published fine calibration settings on the double headed pump.

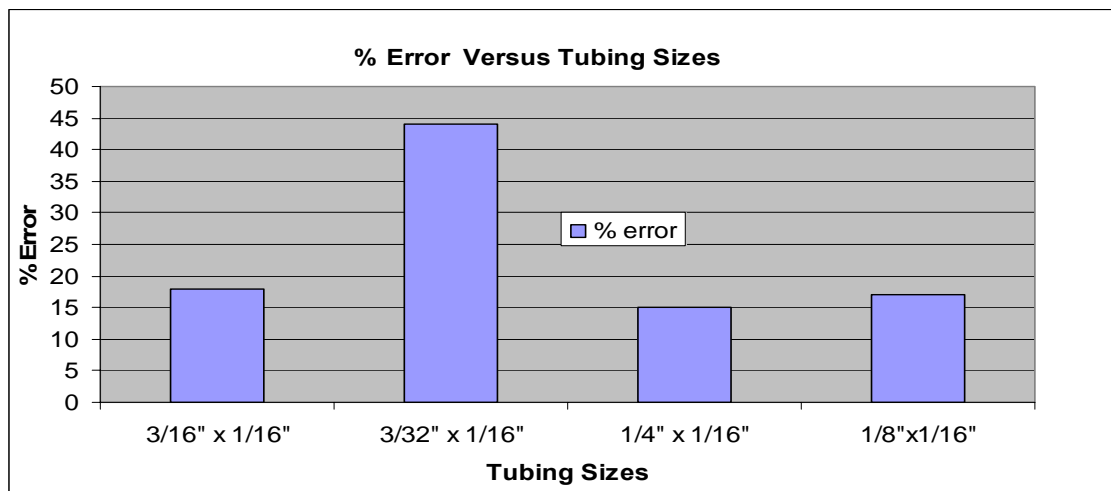


Figure 6. % Error of BCP over delivery for tubing sizes using Stockert published fine cal.'s.

Discussion

The % error of the BCP volume over delivery using the pediatric Vanguard 4:1 BCD set and the double headed pump with the Stockert published fine calibrations was discussed with the Sorin Canada Group in Toronto. Their technical support department proceeded to conduct the same experiments. Through testing, they confirmed the variance between published fine calibration settings and the delivered volumes. Sorin Canada Group also kindly donated some adult Vanguard 4:1 BCD sets for this study.

The results of this study were also shared with Stockert Germany. Their response was a well stated reminder for all perfusionists. It is stated in the SIII Operating Instructions (Version 04 / 2001 – Page 5-43): “The firmware in the SIII pumps uses standard factors for the calculation and display of the flow rate which have been measured on an ideally set reference system using standard tubing. During routine operation however, variations in the user adjustment of the pump occlusion as well as tubing tolerances are likely, causing a

slight change in the display of the flow rate. Therefore perform the fine calibration of the SIII pumps prior to the first usage and upon each change of the tubing material or diameter. In this manner, the deviations can be compensated for and the displayed and actual flow rates will once again correlate. Inexact displays are an avoidable risk during operation”.

Using the single roller pump with both BCD tubings through the same raceway the cardioplegia volume delivery display on the control module was less than the volume actually delivered to the patient as measured on the buretrol. This occurred because the pump fine calibrations were off. Also the calibration took into account only one tubing size yet there were two tubings going through the same pump race way. The pump RPM's were the same for both tubings during BCP delivery. There was an over delivery of volume and K^+ .

To improve the accuracy of cardioplegia delivery the pump was changed to a double headed pump. Therefore the blood and crystalloid tubing each had there own pump race way and the ability to set the fine calibration for each pump for the tubing size used. Using the Stockert fine calibration settings the cardioplegia volume delivery display on the control module was less than the volume actually delivered to the patient as measured on the buretrol. The pump RPM's were also the same for both pumps during BCP delivery. There was also an over delivery of volume and K^+ .

In reviewing figure 5 and 6, it was noted that for the adult Vanguard 4:1 BCD set the BCP volume over delivery percentages were 15% for the 1/4 inch blood tubing and 17% for the 1/8 inch crystalloid tubing. Since the percentage of volume over delivery was fairly close for both tubings the actual concentration of potassium delivered to the myocardium was also constant. For some adults the over delivery of cardioplegia probably will not have an adverse effect.

However, for the pediatric Vanguard 4:1 BCD set - the BCP volume over delivery percentages were 18% for the 3/16 inch blood tubing and 44% for the 3/32 inch crystalloid tubing. Since the percentage of volume over delivery was more than double for the crystalloid tubing compared to the blood tubing the actual concentration of potassium delivery to the myocardium was relatively higher. For an infant the over delivery of cardioplegia volume and K^+ could potentially have an adverse effect on the patient's ECG rhythm and prolong the bypass time to flush volume / hemoconcentrate for removal of excess potassium.

Once the correct measured fine calibration settings were established for the double headed pump and the pediatric / adult Vanguard 4:1 BCD sets, it was noted that the pump RPM's were different - see figures 3 and 4. Pump A (blood) had higher RPM's than pump B (crystalloid) during cardioplegia delivery. This indicates that there is more blood diluting the crystalloid and less K^+ delivery to the myocardium which is beneficial using the pediatric BCD set. As well – both pumps A (blood) and B (crystalloid) turned at lower RPM's indicating less volume delivery to the myocardium. The Stockert fine calibrations were too low for the ml's/R and correcting these made delivery volumes / K^+ accurate.

The testing was performed on several different adult and pediatric Vanguard 4:1 BCD sets with the results being reproducible for each of the same sets. This indicates there were minimal variations in the Sorin tubing tolerances and 4:1 tubing ratios.

When producing data for patient fluid balances or research, there is clearly a need for the pump fine calibrations to be checked. In most cases more cardioplegia is better than less. The flow rate and volume delivered are only two parameters measured of several that give information on the quality of myocardial preservation. If these parameters are inaccurate this could lead to complications when dealing with fragile neonatal or adult ischemic myocardiums.

Conclusion

Using a buretrol on the crystalloid inlet tubing of the Vanguard BCD set ensures accurate delivery of cardioplegia volume regardless of the accuracy of pump fine calibration and cardioplegia delivery display.

Accepting the pump manufacturer's suggestions for tubing size calibration is a reference base to start with. Testing revealed that the calibrations were off enough to provide over delivery of cardioplegia volume and additional potassium in the pediatric Vanguard 4:1 BCD device. As the SIII Operating Instructions suggest, performing fine calibration of the pump can help eliminate deviations between the displayed volumes and flow rates. Although the testing required to establish pump fine calibrations were extremely time consuming - the resulting accuracy during usage was well worth the effort.

The mathematical calculation of the volume delivered by each tubing size of the adult and pediatric Vanguard BCD sets validates the experimental results achieved in this study for pump fine calibration.

Sorin tubing tolerances and 4:1 tubing ratios were acceptable for the Vanguard BCD sets.

Preload of 100 mmHg in the arterial line post oxygenator had no effect on delivered cardioplegia volume.

A special thanks goes out to the Sorin Canada Group and Stockert Germany for their help, acknowledgement and correspondence during this study.

At this stage of the perfusion profession much of the development of equipment has already occurred. Questioning the minor assumptions is what keeps things safe and enables advancement.