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Brazilian perfusionists and arterial roller pump adjustment: comparison between static and dynamic calibration method

Os perfusionistas brasileiros e o ajuste do rolete arterial: comparação entre a calibração estática e dinâmica

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Abstract

Introduction: Roller pumps play an important role in extracorporeal circulation. However, occlusion of the rollers should be adequately performed and this can be adjusted mainly by two methods: static and dynamic.

Objective: To investigate how the Brazilian perfusionists adjust arterial roller pumps in their services and evaluate the application of a Device to Assist Calibration (DAC) that facilitates roller adjustment by the dynamic calibration method.

Methods: We installed a roller pump with accessories to perform adjustment by drop rate (static calibration) and dynamic calibration methods during the XXVIII Brazilian Congress of Extracorporeal Circulation. Perfusionists were

asked to adjust the roller pump according to the procedure they usually do in their service. After each adjustment pressure was measured by dynamic calibration method with DAC. The research was approved by the Research Ethics Committee of UNICAMP, N° 1144/2010.

Results: There were 56 perfusionists in this study. Pressure average of 56 measurements of dynamic calibration was 434 ± 214 mmHg; 76% of measurements were within the recommended range for the use of the dynamic calibration method (between 150 and 500 mmHg).

Conclusion: Brazilians perfusionists tend to adjust roller pumps with less occlusive settings. The amplitudes of the dynamic calibration pressure tend to be smaller for more experienced perfusionists because their skills increase with

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time. The device can be used by the perfusionists to adjust roller pumps with greater accuracy and mainly repeatability in few minutes.

Descriptors: Extracorporeal Circulation. Pumps. Calibration.

Resumo

Introdução: Bombas de roletes desempenham um papel importante na circulação extracorpórea. No entanto, a oclusão dos roletes das bombas deve ser realizada de forma adequada e estas podem ser ajustadas, principalmente por dois métodos: estático e dinâmico.

Objetivo: Investigar como os perfusionistas brasileiros ajustam as bombas de rolete arterial em seus serviços e testar o uso de um Dispositivo Auxiliar de Calibração que facilita o ajuste pelo método de calibração dinâmica.

Métodos: Foi instalada uma bomba de roletes com os acessórios necessários para a realização de sua calibração pelos métodos de velocidade de queda (calibração estática) e calibração dinâmica durante o XXVIII Congresso Brasileiro

de Circulação Extracorpórea. Foi solicitado aos perfusionistas que ajustassem uma bomba de roletes conforme procedimento normalmente utilizado em seu serviço. Após cada regulação, foi medida a respectiva pressão pelo método de calibração dinâmica com o auxílio do dispositivo. O projeto foi aprovado pelo Comitê de Ética em Pesquisa da UNICAMP, sob N° 1144/2010.

Resultados: Participaram da pesquisa 56 perfusionistas. A média das 56 medidas de pressão de calibração dinâmica foi 434 ± 214 mmHg; 76% das medidas realizadas ficaram no intervalo preconizado para o uso da técnica de calibração dinâmica (entre 150 e 500 mmHg).

Conclusão: Os perfusionistas brasileiros tendem a calibrar bombas de roletes com ajustes menos oclusivos. As amplitudes das medidas de pressão de calibração dinâmica tendem a ser menores para perfusionistas mais experientes. O dispositivo pode ser utilizado por perfusionistas para ajustar bombas de roletes com maior precisão e, principalmente, repetitividade e em alguns minutos.

Descritores: Circulação Extracorpórea. Bombas. Calibragem.

INTRODUCTION

Projections by the World Health Organization (WHO) indicate that cardiovascular diseases remain as the major cause of mortality and disability worldwide by 2020 [1], being considered the main causes of death and disability in Brazil.

Brazil performs about 350 heart operations/1.000.000 inhabitants/year; including implants pacemakers and defibrillators with a high cost in terms of technological, human and financial resources [2].

It is estimated that in Brazil is being served less than a third of the minimum requirement for heart operations to correct birth defects, as these have a higher cost, representing a deficit of 65% [3].

Studies conducted in Brazil on expenses of a heart operation revealed that total costs, approximately 20% were related to perfusion materials [4].

The professionals involved in surgery have sought alternatives that might reduce the use of cardiopulmonary bypass (CPB), as well as the use of new techniques that minimize trauma to the blood cells by the use of CPB [5-9].

It is well established that non-physiological forces during CPB damages the blood and may prolong patient recovery [10,11].

Many advances have been made in CPB. More efficient oxygenators, more biocompatible materials, minimally invasive techniques and usage of new devices and procedures have become safer CPB.

Currently, there are two groups of equipment commonly used as propellants in cardiopulmonary bypass pumps: centrifugal pumps and roller pumps. Centrifugal pumps represent a part of the pumps used in CPB, and are used in a position of arterial pump, responsible for pumping blood. Their great appeal is its alleged least hemolytic characteristics when compared to roller pumps [12,13]. However, studies comparing the two pump models have shown benefits of using centrifugal pumps and are not conclusive [14-16]. As a result, many perfusionists continue to use roller pumps as arterial pumps, which are simple to use and have low cost [17].

The calibration of the rollers is the technique of adjusting the distance between the roller and raceway (occlusion) and its regulation has been seriously compromised in the process of hemolysis [18]. A roller excessively occluded increases blood trauma, and may produce severe hemolysis. A roller with excessive looseness allows reflux, depending on the devices added to the CPB circuit.

They are mainly used two methods for calibrating roller pumps: static method or drop speed and dynamic method

or dynamic calibration [19]. The roller pumps calibrated by the dynamic method, with adjustments within the recommended range from 150 to 500 mmHg are considered by some authors, more repetitive and less hemolytic when compared to the static method [18-20].

In Brazil, most perfusionists use the static method for calibrating roller pumps for use in CPB. The literature recommends to use the static method, the drop speed of 2.5 cm / min for a column of 1000 mm of saline solution [18,19]. For adjustments with the technique of dynamic calibration, it is recommended adjustments of dynamic calibration pressure (DCP) between 150 and 500 mmHg [18].

Although both methods are well known, their relationship is not well established and both present operational difficulties for use in surgical centers [21].

The difficulty of repeatability in the calibration of the roller pumps using the static method along with the experience and training of the perfusionist can bring big differences in the settings of roller pumps.

We developed an assistive device for calibration (ADC) in order to assist perfusionists in adjusting roller pump by the method of dynamic calibration. This device was developed at the Center for Biomedical Engineering (CEB) and tested at the Center for Experimental Medicine and Surgery, both at the University of Campinas (UNICAMP).

Based on microcontroller, it calculates the mean pressure of dynamic calibration and the values of maximum and minimum pressure obtained by the passage of each roller pump. Measurements are performed at the outlet of roller pump with the aid of a disposable pressure transducer commonly used in cardiovascular surgery. The calculated values are shown to the perfusionist through a liquid crystal display, which will then adjust the occlusion pressure until the desired average. The calculations are performed from

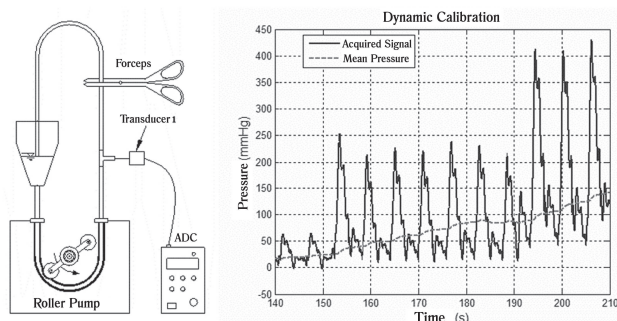


Fig. 1 - Illustration of the use of ADC with the typical response of the pressure signal acquired and mean calculated as a function of time during the dynamic calibration

the acquired signal over time. Figure 1 illustrates the use of the device with pressure transducer and the typical response time of the pressure adjustment during dynamic calibration.

The aim of this study is to investigate how the Brazilian perfusionists adjust the roller pump their services and test the use of assistive device for calibration with the respective measurement by the method of dynamic calibration.

METHODS

Pressure Transducer Calibration

To measure the dynamic calibration, we used a disposable pressure transducer, BX, manufactured by Braile Biomédica (São José do Rio Preto, Brazil). The pressure transducer was tested in the range 0 to 1000 mmHg to 100 mmHg step. Figure 2 illustrates the components used for calibrating the pressure transducer.

Cycles were carried out loading and unloading pressure alternately. Upon reaching the maximum value (1000 mmHg) and minimum (0 mm Hg) of the scale, the pressure was maintained for 5 minutes and then the next cycle was started. The output voltage of the transducer was measured with two multimeters Tek DMM830 of 5 ½ digit Tektronix ®. Six measures were performed, three with pressures ranging from 0 to 1000 mmHg (loading) and three ranging from 1000 to 0 mmHg (unloading).

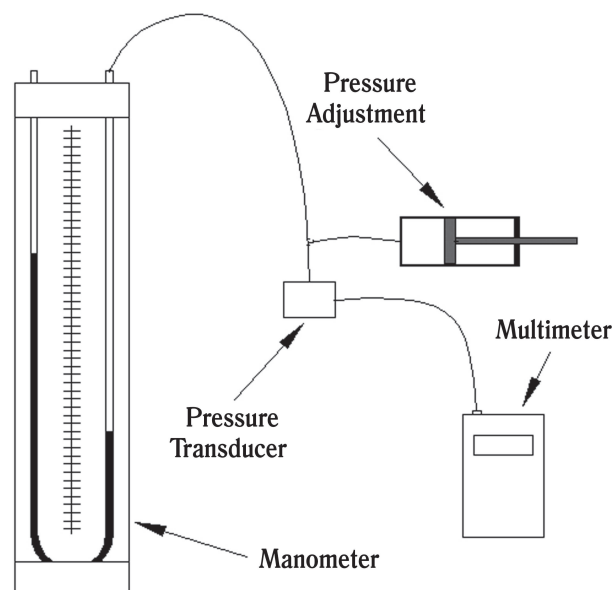


Fig. 2 - Illustration of the main components used to calibrate the pressure transducer

Tests with the ADC

The XXVIII Brazilian Congress of Extracorporeal Circulation, held between December 2 and 4, 2010 in Sao Paulo, Brazil, gathered perfusionists from all regions of Brazil. In this congress was installed a roller pump with accessories needed to perform the calibration methods of drop speed and dynamic calibration.

The project was approved by the Ethics Committee in Research of our institution under N. 1144/2010, and the perfusionists completed and signed the consent form along with a questionnaire attached.

It was required that 56 perfusionists presented at the conference that agreed to participate in the research, that regulated the module arterial roller pump according to the procedure normally used in their service involving CPB procedures.

Silicone tubes were used (typically used in procedures involving CPB in adults) with a diameter of $\frac{1}{2} \times 3/32$ inches used in the raceway of the pump (pocket). After each pump regulation made by a perfusionist, the silicone tube was replaced by a new one to be used for the next perfusionist, a total of 56 new tubes.

After each adjustment made by the perfusionist and before changing the tube, it was made the measure of the mean pressure of dynamic calibration with the use of assistive device for calibration. Figure 3 shows the photographic record of the device.

The dynamic calibration measurements were performed only once after the adjustment made by the perfusionist. Measurements were made with the use of assistive device for calibration, according to procedure:

- Pump circuit already filled with saline solution;
- ADC connected to the pressure transducer;
- Set the offset of the transducer for specific function of the ADC;
- Maintained the adjustment previously made by the perfusionist participating in the research, the pump is set at 10 rpm;
- The measurement was performed by the ADC and the value shown on the display;
- The value of the mean pressure of the dynamic calibration was recorded.

RESULTS

Pressure Transducer Calibration

Figure 4 shows the pressure curve (mmHg) by the voltage (mV) measured on the transducer used in the research. The results reported were calculated as the mean of three tests with three new silicone tubes with a diameter of $\frac{1}{2}$ inch during cycles of loading (left) and three tests during the unloading cycles (right). In each test, there were 12 measures of loading and 12 of downloading. In every



Fig. 3 - Photographic record of the assistive device for calibration (ADC) used for measurements of mean pressure of dynamic calibration

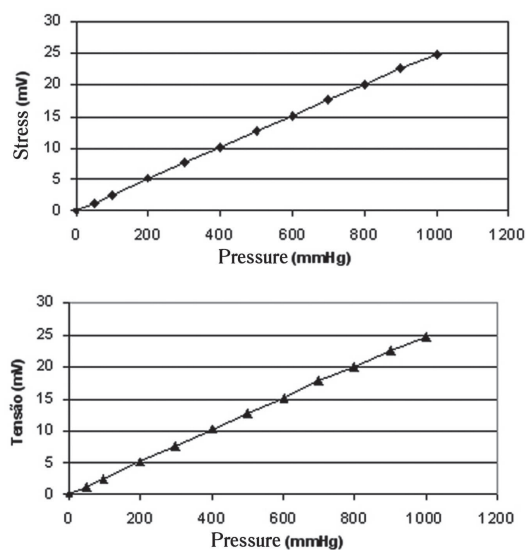


Fig. 4 - Calibration curve for pressure loading cycles (left). Calibration curve for pressure downloading cycles (right)

measure of loading and downloading, two multimeters were used and adopted the same for each of the 12 records the arithmetic mean calculated from measured result of two multimeters. The result of the 72 measures of loading and downloading 72 showed normal distribution by Shapiro-Wilk test ($P > 0.05$).

The comparison between the regressions using analysis of covariance (ANCOVA) showed statistically equal slope coefficients ($P > 0.96$) and intercepts ($P > 0.98$) regressions.

Tests with the assisting device for calibration

Table 1 shows the distribution by region of the perfusionists who participated in the research, as well as the distribution of training in college.

Table 1. Distribution of perfusionists by region and higher education reported

Region	N	%
North	1	0.2
Northeast	11	19.6
Midwest	5	8.9
South	7	12.5
Southeast	32	57.1
Higher education	N	%
Biology	5	8.9
Biomedicine	12	21.4
Nursery	15	26.8
Physiotherapy	3	5.4
Other	4	7.1
No higher education reported	17	30.4

Table 2. Distribution of age and time of experience of perfusionists.

Age (years)	Fi	Percentage
20 — 28	16	34.8%
28 — 36	8	17.4%
36 — 44	12	26.1%
44 — 52	6	13.0%
52 — 60	4	8.7%
Total	46*	100%
Time of experience (years)	Fi	Percentage
0.0 — 4.0	22	40.0%
4.0 — 8.0	6	10.9%
8.0 — 12.0	8	14.5%
12.0 — 16.0	3	5.5%
16.0 — 20.0	5	9.1%
20.0 — 24.0	7	12.7%
24.0 — 28.0	3	5.5%
28.0 — 32.0	—	—
32.0 — 36.0	—	—
36.0 — 40.0	1	1.8%
Total	55*	100%

*Number of perfusionists who reported age and time of experience

Out of 56 of the perfusionists in the survey, 50% were male and 50% female.

Table 2 shows the frequency distribution of ages of perfusionists and the time informed in the profession.

Table 3 shows the distribution of pressure measurements for dynamic calibration of the 56 perfusionists in the survey.

The mean of the 56 pressure measurements for dynamic calibration was 434 ± 214 mmHg (mean \pm standard deviation) and the data were normally distributed ($P > 0.05$).

Table 3. Distribution of mean pressure measurements of dynamic calibration.

Dynamic Calibration Pressure (mmHg)	Fi	Percentage
150 — 300	16	28.6%
300 — 450	17	30.4%
450 — 600	12	21.4%
600 — 750	7	12.5%
750 — 900	2	3.6%
900 — 1050	—	—
1050 — 1200	2	3.5%
Total	56	100%

DISCUSSION

The adjustment of the roller pumps by the method of dynamic calibration is not a new technique. It was originally released in 1997 and several studies have been conducted in an attempt to demonstrate that using this method gives less damage to blood elements [18].

In Brazil, this adjustment technique has been little used, mainly due to operational difficulties or by the unawareness of the method. The main difficulties observed in a study conducted for this purpose were [21]:

- The cyclical characteristics of the pressure roller pumps during the calibration process difficult adjustment;
- The deregulation of the roller, i.e., the difference between the distances of the rollers A and B in relation to the raceway;
- Contamination of devices for measuring pressure;
- Lack of a specific device to aid in the dynamic calibration.

Measurements of the ADC with the use of commercial pressure transducers (Edwards and Braile) showed no variations between cycles of loading and unloading (hysteresis $< 0.26\%$), with measurements made up to 1000 mmHg. The values obtained in the tests are below the tabulated values by the manufacturers for the pressure transducers for linearity and hysteresis ($\pm 1.5\%$).

The technique for adjusting the drop speed is widely used, but in a few cases actually using the methodology recommended in the literature, which is to regulate the pump speed of 2.5 cm / min in a column of saline solution in a tube 1000 mm ¼ inch diameter PVC. This technique also presents operational difficulties for use in the operating room together with the lack of repeatability when performed with silicone tube [20,21].

Figure 5 illustrates the percentage distribution of perfusion in activity by region of Brazil, registered by the Brazilian Society of Extracorporeal Circulation and distribution of those who participated.

The 56 perfusionists in the survey represent approximately 10% of the perfusionists assets in Brazil, according to records in the Brazilian Society of Extracorporeal Circulation (SBCEC). The comparison between the ratio of perfusion region showed a statistically equality in all regions ($P > 0.05$) by the binomial test of proportions.

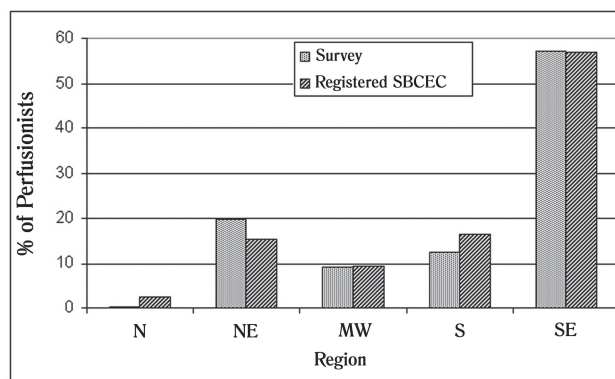


Fig. 5 - Distribution of perfusionists in activity by region of Brazil (source SBCEC) and research participants

Of the 56 perfusionists who participated in the survey, only two used saline solution column above the venous reservoir, installed at the pump. Six perfusionists performed pre-tuning with air, as follows:

- New silicone tube installed in the pump;
- With air, the inlet of the pump was clamped;
- The rollers are pre-adjusted, considering the time of filling (air) of the silicone tube provided in the pocket;
- The circuit was filled with saline solution;
- Conducted a visual measure of the drop speed in the intake tube of the venous reservoir.

A digital timer was provided to assist perfusionists in the settings, however, all measurements were made visually assessing the speed of fall and most were made with the

aid of piping connected to the vessel, which makes it very difficult to accurately and, especially, the repeatability.

The tests were performed with a pump device with simultaneous adjustment of the rollers, so the results are valid for pumps that have built this device. Pumps with individual adjustment of the rollers were not tested, but is understanding of the authors who tested the device can help to calibrate dynamic models of pumps without this type of facility. This is because the device to verify the individual pressure of each wheel and can facilitate the operator to adjust them to have the same pressure at the pump outlet.

The average mean blood pressure values recorded dynamic calibration was 434 mmHg, with standard deviation of 214 mm Hg, and coefficient of variation (CV) of 49.2%. This coefficient may indicate that the static method showed variations inherent to the method, particularly the use of silicone tubes or professionals set the pump with different occlusions.

The total amplitude of the pressure measurements was 1022 mmHg, with minimum of 152 and maximum of 1174 mmHg and 76% of measurements were within the range recommended for measurements of dynamic calibration (between 150 and 500 mmHg) [18].

There were no relationships between measures of Dynamic Pressure Calibration with time or with the profession and informed higher education ($P < 0.05$).

Figure 6 shows the scatter plot of the measured values of Dynamic Pressure Calibration function of time of experience in perfusion reported by perfusionists.

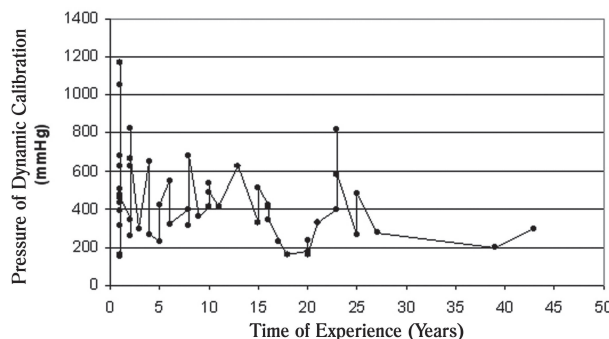


Fig. 6 - Scatter plot of dynamic calibration of pressure versus time of experience in perfusion

The technique used for sampling of the research was for convenience due to the easy access to perfusionists during the XXVIII Brazilian Congress of Extracorporeal Circulation. This technique has the main feature of not using

random selection of forms and, therefore, is classified as non-probabilistic. Although no statistical rigor, is often used when one intends to obtain information quickly and cost-effective, mainly exploratory. It used the sample that you have access, if it could represent the population.

The type of sample used was the only way to measure, with reasonable number of participants, the value adjustments of roller pumps used by perfusionists.

The survey was conducted looking at the possible flaws or biases that might be present in the sample and it is our opinion that the results obtained are a good approximation of the population.

CONCLUSION

The Brazilians perfusionists tend to calibrate the roller pumps with settings between 150 and 500 mmHg, values that are less occlusive than those recommended by the static method (2.5 cm / min).

The amplitudes of the pressure measurement of dynamic calibration tend to be smaller with increasing length of employment.

The device can be used by perfusionists to adjust roller pumps with accuracy and precision and in a few minutes (3 minutes). Careful testing can be started with the device in operative environment.

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