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Comparison of Minimally Invasive Multi-Beat Analysis Method for Cardiac Output Monitoring Versus 2-D Echo Method.

[1.] **Dr Sanjith Saseedharan,** *HOD Criticare Medicine*
[2.] **Co-author: Dr Jayram Navade** *Consultant*
[3.] **Dr Aalia Thinga,** *Registrar*
[4.] **Dr Supriya Pabalkar,** *Registrar.*

Affiliated: S L Raheja Hospital, Mahim, Mumbai 400016

Abstract

Background & Objectives: Hemodynamic monitoring is part of routine ICU care. The last decade has seen the increase in minimally invasive technology in this regard. We aimed to compare cardiac output (C.O) and stroke volume (S.V). obtained by 2d Echocardiography (2d Echo) with minimally invasive multi-beat analysis (MBAtm)technology using the arterial waveform

Methods: 360 patients were screened over 3 months for this observational study. Based on predefined criteria 15 patients were included. Data for cardiac output was collected by tans-thoracic 2d echo, done by a trained cardiologist. The Argos monitor (Retia Medical Systems Inc., White Plains, NY, USA) was used to simultaneously measure Cardiac output and stroke volume by MBAtm. The collected data was then compared.

Results: The data collected for cardiac output and stroke volume by both methods, 2 D echo and MBA, had a p value of 0.0005, which was indicative of a highly significant relationship. The values for intraclass correlation coefficient for stroke volume was 0.967 and for cardiac output by both methods was 0.971 thus showing excellent reliability. Bland-Altman also showed a strong level of agreement.

Interpretation & Conclusions: Across 15 patients with wide-ranging diagnoses, the Argos monitor. showed excellent agreement with 2-D echo measurements. Multibeat analysis appears to be a promising minimally invasive method of cardiac output monitoring requiring less clinical skills, with an easy learning curve and satisfactory accuracy as per the results of this pilot study.

Keywords: hemodynamics, 2D Echo, multibeat analysis, cardiac output

Introduction

Hemodynamic monitoring that involves continuous cardiac output monitoring helps to optimize and personalize the management of critically ill patients. Hemodynamic monitors are useful in aiding the detection, diagnosis, and titration of therapy (fluids or ionotropic support) in response to shock. Technological advancements have helped us to derive these measurements via more and more minimally invasive methods. This has a bearing on the outcome, as minimally invasive technology is known to have much fewer adverse effects like infections, bleeding, hemodynamic compromise, etc. Cardiac output measurement can be done invasively (e.g. Swan Ganz catheterization) or minimally invasively (e.g. transpulmonary thermodilution) or non-invasively (e.g. echocardiography). However, it calls for trained personnel and is unable to provide continuous, real-time hemodynamic monitoring. Ease in obtaining hemodynamic data can provide more information on fluid responsiveness and cardiac output which will further aid in better diagnosis and management of patients [1-3].

In this study, we are comparing data obtained by trans-thoracic 2D Echo with the Argos MBA algorithm, which analyses multiple heartbeats from the blood pressure signal to provide hemodynamic data. This study was presented as a paper at the Mahacriticon conference in Jalgaon, in November

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 08, 2024

2022. The arterial Blood Pressure (ABP) waveform is analyzed and the pulse waveform upstroke is identified from which a cardiac contraction signal is constructed.

The pulse waveform is then analyzed over multiple cardiac cycles and then finds the pure exponential pressure decay without allowing the reflected waves to confound the values. This is then scaled based on the pressure pulse. These values are further used in a proprietary formula along with biometric data to determine the stroke volume [4-6].

According to existing studies, the multi-beat analysis (MBA) has exhibited good performance in assessing the CO variations during hemodynamic challenges compared to trans-oesophageal Doppler, even with the use of vasopressors [7]. CO estimations by multi-beat analysis of the radial arterial blood pressure waveform (Argos Monitor-Retia Medical Systems Inc., White Plains, NY, USA) show 88% agreement compared with CO measured by Pulmonary Artery Thermodilution for post-operative patients [8]. Hence, we decided to compare data obtained from transthoracic 2D Echo and the Argos hemodynamic monitor, using the arterial waveform, to determine the agreement of data obtained from both methods in this pilot study.

Materials & Methods

Objectives

Comparison of multi-beat analysis method for cardiac output monitoring versus the transthoracic 2D Echo method.

Methodology

This observational study was conducted prospectively at the medical intensive care unit of the S.L. Raheja hospital- a Fortis associate, Mumbai, India,

Inclusion criteria:

All consecutive patients over 18 years old and admitted to the medical intensive care unit were included within 2 days of admission. Patients with sepsis requiring no or low-dose ionotropic support (Noradrenaline: 0.025 to 1 mcg/kg/minute, Adrenaline: 0.01 to 0.5 mcg/kg/minute, Vasopressin: 0.01 to 0.04 units/minute) patients.

Exclusion Criteria:

Patients with poor cardiac function (LVEF <0.4), post-cardiothoracic surgery, arrhythmias, and patients requiring high-dose ionotropic support. Ventilated patients were excluded from the study.

A 2D Echo was performed by a trained cardiologist. The patient's stroke volume and cardiac output were recorded. At the same time, the stroke volume and cardiac output were recorded by the Argos monitoring system. This monitoring system uses data derived from an arterial line(femoral /radial) and measures the cardiac output and stroke volume using muti-neat analysis. A green cloth was placed on the monitor while the 2D Echo was being performed to prevent observer bias. The data was collected on the day of admission before any fluid infusion was given.

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 08, 2024

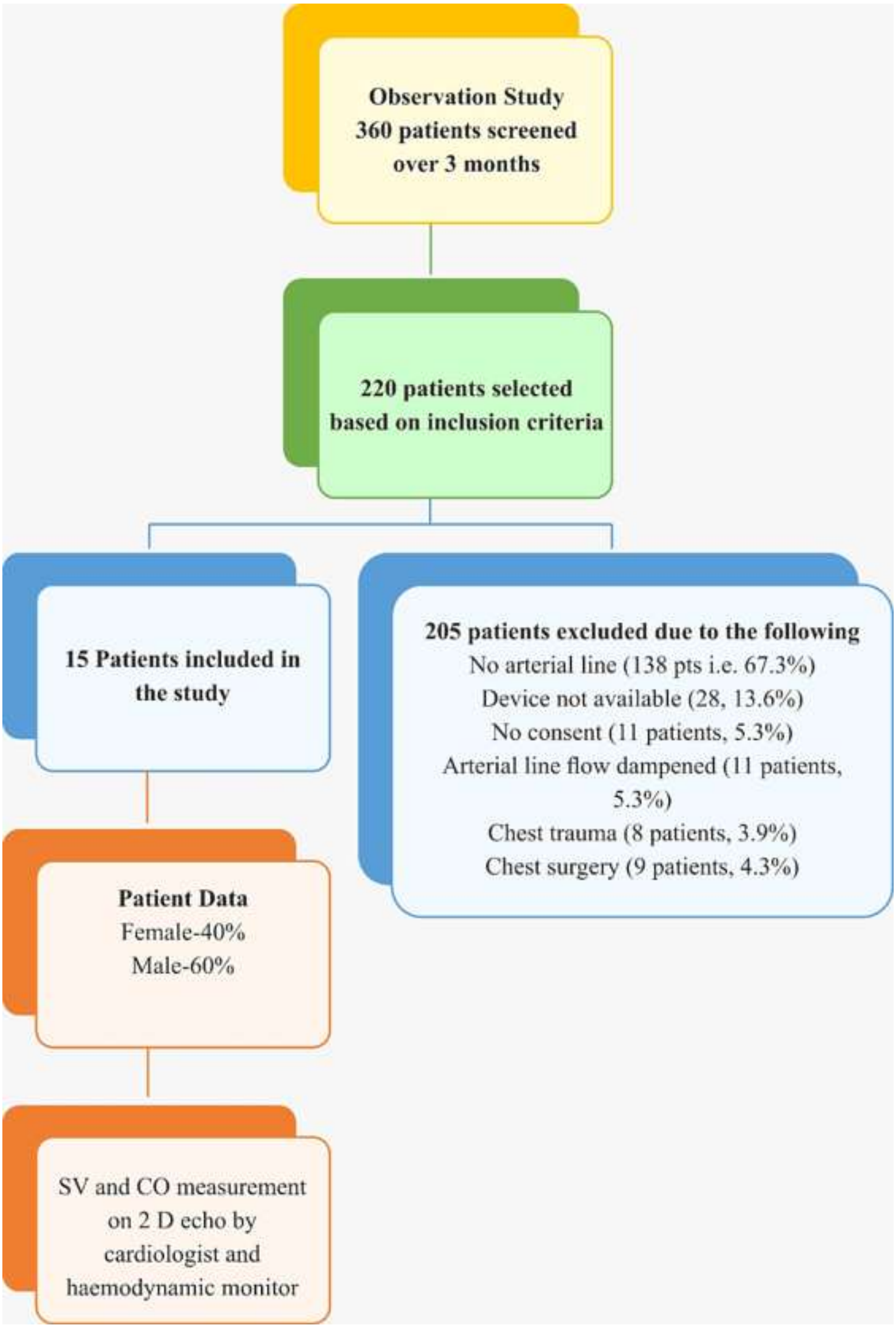


Figure 1: Screening and inclusion scheme

Frequency analysis and percentage analysis were used for categorical variables as these were descriptive. For continuous variables standard deviation and mean were used. Further, a Bland -

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 08, 2024

Altman analysis was used to study the agreement and intraclass correlation between both methods. To find the association of significance in categorical data the Chi-Square test or Fisher's exact test was used. In all the above tools the probability value of .05 was considered significant.

Results

Across 15 patients with a wide range of diagnoses, the Argos monitor showed excellent agreement with 2D Echo measurements. From the patient's tested 40 percent were female and 60% were male. The range of diagnoses was different and included Acute kidney injury, Acute respiratory distress syndrome, Pancreatitis, encephalitis, pneumonia, stroke, urinary tract infection, and cancers (Table *1*).

86% of the patients were not on any ionotropic support, while 13.4% of patients were on lose-dose ionotropic support. (Table *2*)

Diagnosis	Frequency	Percent
Acute kidney injury	1	6.7
Aspiration pneumonia	1	6.7
Gall bladder cancer with neutropenic sepsis	1	6.7
Lung cancer with infective exacerbation of Chronic obstructive pulmonary disease	1	6.7
Rectal cancer with Urinary tract infection	1	6.7
Encephalitis	1	6.7
Lower respiratory tract infection	1	6.7
Left ventricular failure with sepsis	1	6.7
Myocardial infarction in a k/c/o diabetic foot	1	6.7
Pancreatitis	1	6.7
Bacterial pneumonia	1	6.7
Stroke	1	6.7
Infection of urinary tract	1	6.7
Viral pneumonia	1	6.7
Total	15	100

Table 1: This table shows the different diagnoses of the patient included in the study, demonstrating a mixed ICU population.

INOTROPIC SUPPORTS	Frequency	Percent
No	13	86.7
Noradrenaline 8mcg/min	1	6.7
Noradrenaline 9mcg/min	1	6.7
Total	15	100

Table 2: It is a representation of the patient population requiring low dose ionotropic support

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 08, 2024

Through the data obtained and the statistical tools utilized significance was considered with a probability value of .05. A highly significant relationship (p-value of 0.0005) was obtained between both the methods (MBA and 2D Echo for stroke volume and cardiac output). Intraclass correlation coefficient of Stroke volume was 0.967 and cardiac output was 0.971 intraclass correlation was found to be 0.967 and 0.971 respectively by both methods (table *4* and 6). This thus demonstrates very good reliability (Table *3* and 5).

NA	ICC	95% C.I		F Test with True Value 0			
		LB	UB	Value	df1	df2	p-value
Single Measures	0.967[a]	0.903	0.989	58.716	14	14	.0005

Table 3: Intraclass Correlation Coefficient (SV-2D-ECHO and SV-MON)

NA	ICC	95% C.I		F Test with True Value 0			
		LB	UB	Value	df1	df2	p-value
Single Measures	0.971[a]	0.915	0.990	66.870	14	14	.0005

Table 4: Intraclass Correlation Coefficient (CO 2DCHO and CO-MON)

This level of agreement was also demonstrated in the Bland-Altman graph. A new method is said to be acceptable (As per the Critchley and Ceitchley criteria) only if the level of agreement is +/- 30% with the reference method. In our study, the corresponding level was 12.5% signifying a very acceptable level of agreement with the refer (Figure *3* and Figure *4*).

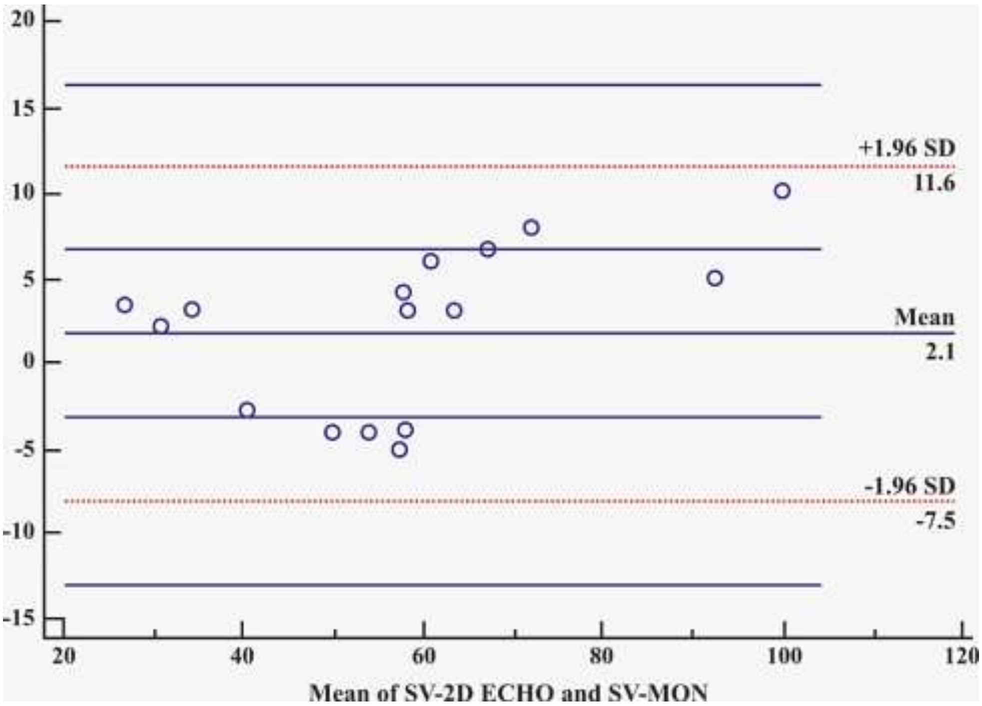


Figure 2: Bland Altman plot to test agreement of stroke volume by 2D Echocardiography (SV-2D ECHO) and the MBA method (CO-MON) The two methods demonstrated a correlation coefficient of 0.967 [0.85 – 0.95] with a Cronbach's Alpha value of 0.983.

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 08, 2024

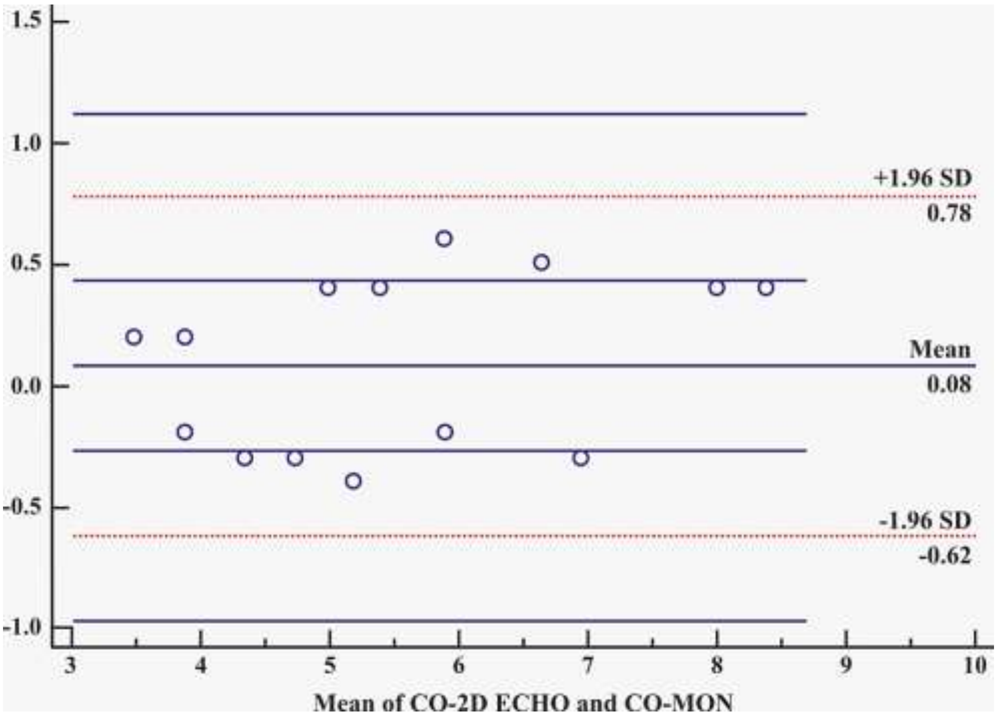
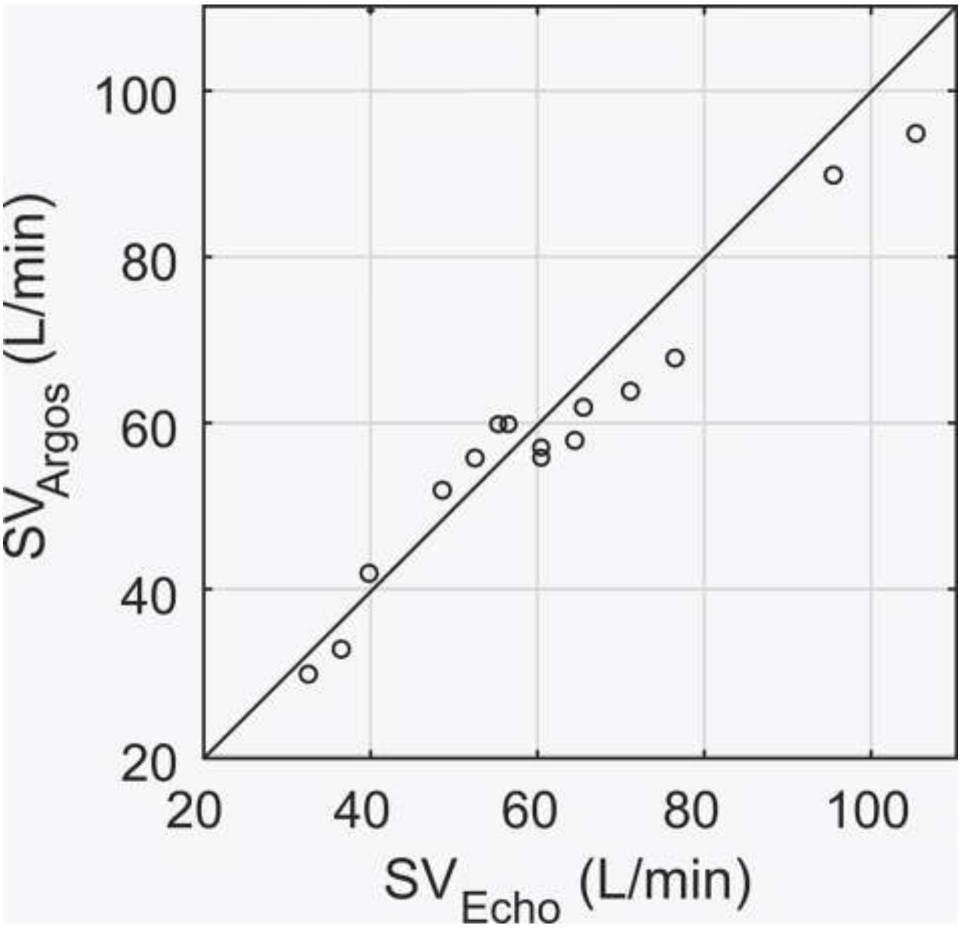


Figure 3: Bland Altman plot to test agreement of cardiac output (CO)between 2D Echo (CO-2dEcho) and MBA method (CO-MON). Correlation coefficient between the both methods was 0.971 [0.85 – 0.95] with a Cronbach's Alpha value of 0.985.



ISSN: 0975-3583,0976-2833 VOL15, ISSUE 08, 2024

Figure 4: Bias = -2.1, Precision = 4.9, Percent Error = 15.7%

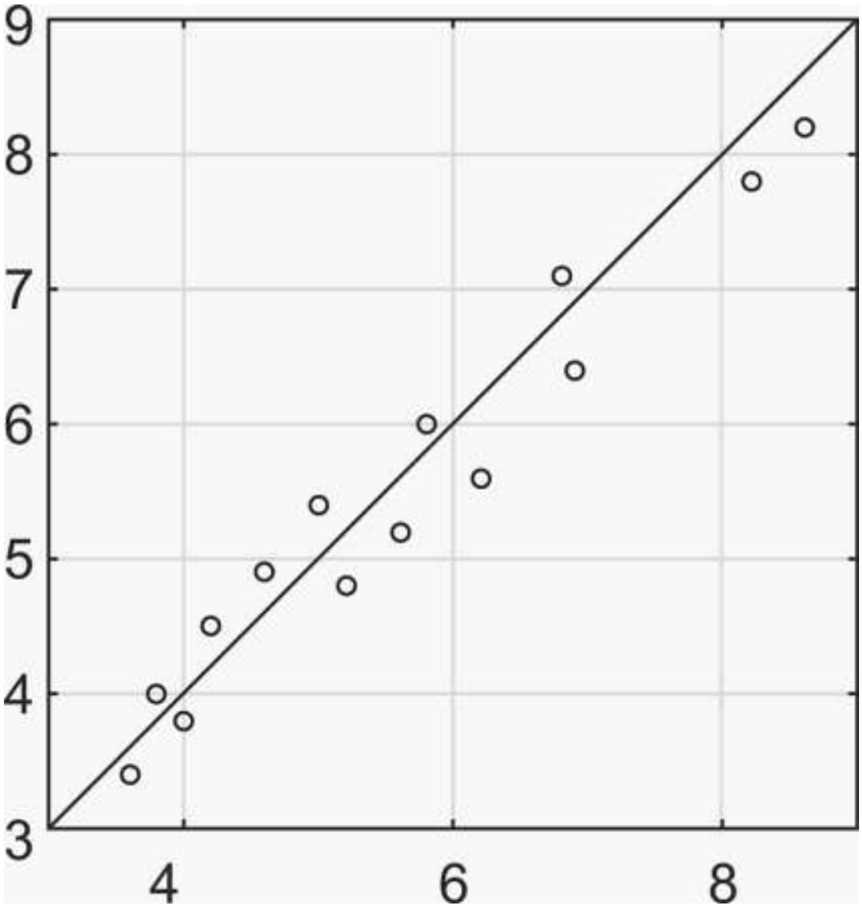


Figure 5: Bias = -0.08 L/min; Precision = 0.34 L/min; Percent Error = 12.5%.

Discussion

In this study, we screened 360 patients and enrolled 15 patients as per our predefined criteria of inclusion and exclusion. Our study found that the level of agreement in the data obtained for cardiac output from the 2D Echo and the Argos monitor was statistically significant. There are several different methods of CO monitoring which include both invasive and non-invasive techniques.

The Swan Ganz catheter (pulmonary arterial catheter) is considered the gold standard device to monitor cardiac output using the thermodilution method [9-10]. However, several complications have been associated with the use of this catheter and this is now rarely used in clinical medicine. These complications have prompted investigators to find alternate and less invasive means to monitor cardiac output [11-12]. The 2D Echo is also considered equivalent to the pulmonary arterial catheter in the monitoring of the stroke volume and the cardiac output [13]. The 2D Echo is also routinely done in an ICU setting and is currently the most conventional method to measure cardiac output. We thus used the 2D echo as a comparison to the MBAtm cardiac output measurement for our study.

Another method is transpulmonary thermodilution, where cold injectate is inserted via a central venous catheter, and mixing of the thermal indicator occurs as it passes the heart, pulmonary circulation, and aorta. Valvular issues like tricuspid regurgitation, and intracardiac shunts will not allow free flow of the injectate causing inaccurate cardiac output measurements [14]. Thermodilution

ISSN: 0975-3583,0976-2833 VOL15, ISSUE 08, 2024

may also be sensitive to changes in injectate temperature, speed of injection, and volume of injectate which may affect the accuracy of measurement [15-16]

The method employed in this study is 2d echocardiography. Imprecision may occur in trans-thoracic echocardiography cardiac output measurements by technical, or operator factors, or due to patient variability [17]. Arrhythmias, low sedation levels, and high-dose ionotropic supports may affect the measurement of CO. In addition changes in the mean airway pressure. We have tried to eliminate these inaccuracies via our exclusion criteria. The data was collected simultaneously from both methods, and it was ensured that non-invasive ventilatory settings or doses of ionotropic support were not changed at that time.

The Multi-Beat Analysis (MBAtm) offers an alternative approach to determining CO accurately without the use of any extra or expensive disposables, the cost consisting of that of an arterial line, which is approximately Rs.1650. However, there remain some limitations of this technology. Any major changes in arterial compliance have the potential to affect the accuracy of this technology [18]. Moreover, it requires a good arterial waveform that is not underdamped or overdamped. Furthermore, it cannot be used in patients with arrhythmias, with an irregular arterial waveform which would lead to incorrect data.

The data obtained through this study showed an excellent level of agreement between the data obtained via 2D Echo and MBA, which is evident in the Bland-Altman plot of agreement (Figure *1* and Figure *2*). Another study done in 2021, which compared data obtained from MBA with TEE showed after various hemodynamic challenges (fluids and vasopressors), the MBA algorithm agreed with TED (concordance) in tracking CO changes 93% of the time [19].

This small study indicates the need to do a larger study to establish the accuracy of this minimally invasive monitor. The benefits of MBA are it is minimally invasive and enables continuous monitoring via a peripheral arterial line. No special training needs to be done to obtain this data, hence it can be used in a smaller healthcare set-up as well. However, the risks of any line insertion remain with this method, and care must be taken to prevent sepsis and other line complications. In our study we did not include patients with a low ejection fraction, therefore these patients should also be included and studied especially if MBA is to be used for the management of cardiogenic shock. Studies can further be done to assess cardiac output while administering fluid boluses and increasing ionotropic supports. Limitation for the study is that it requires trained cardiologist for 2D-Echo.

Conclusions

Multibeat analysis appears to be a promising minimally invasive method of cardiac output monitoring needing very less clinical skills, easy learning curve with a satisfactory accuracy as per the results of this pilot study. However, it is essential to confirm the results of this study with a larger sample size to convincingly prove the accuracy of the method. This minimally invasive monitor when compared to all other monitors in the market would also prove cost effective for the patient as the patient requires only a routine femoral or radial arterial catheter.

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