# Validation Study on Cardiac Output and Index Determination in Impendence Cardiography on Postoperative Cardiac Patients in Critical Care

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**Abstract**

The gold standard in determination of cardiac output is highly invasive and expensive in use. An accurate and reliable method, non-invasively and cheap, would improve hemodynamic management. This study is for validation of a new module in impedance cardiography to improve the accuracy in cardiac patients. Heart rate (HR) Cardiac output (CO), index (CI) and stroke volume (SV) have been determined simultaneously by thermodilution (Swan Ganz, right heart catheterisation) and impedance cardiography (VasoScreen3000 with integrated ACM module) from postoperative patients who underwent open heart surgery in intensive care unit. 34 measurements were successfully taken, on 22 patients. We found high agreement in heart rate and acceptable agreement with strong correlation in CO/I and SV. The mean difference in cardiac output was -0.44 ± 1.06 L/min (-0.31± 0.63 L/min/$m^2$ for cardiac index), correlation after Pearson was $r_{CO}$ = 0.67 ($p < 0.001$). In our study, the appearance of mechanical ventilation affects the accuracy of impedance measurement. We concluded that impedance cardiography is a reliable and accurate method for determining cardiac performance, it is practical to use and without any discomfort to the patients.

**Keywords:** Impedance cardiography, thermodilution, validation study, agreement, critical care

## 1. Introduction

Cardiovascular disease is one of the leading causes of mortality in most of the developed countries [1]. Although invasive techniques, such as Thermodilution, Picco or Lidco, give satisfactory results on the estimation of cardiac output and stroke volume, they are not suitable for long-term or repeated measurements because of their invasive nature [2-6]. Nevertheless, the invasive hemodynamic assessment is often used after an acute cardiac episode, like coronary artery bypass graft or valve repair or replacement [7] in patients under critical care. If there was an accurate, reliable, non invasive method for determining cardiac output and other parameters available, surgical patients after open heart surgery would benefit [8]. Several methods are capable to determine those parameters in fundamental different ways, from non invasive to highly invasive. However, the gold standard is the thermodilution method (Swan Ganz), which, thus its questioned positive effect of its highly invasive nature in critical ill patients and its lack of clinical outcome benefits [9] is used routinely in clinics and hospitals to determine cardiac performance [10].

Impedance cardiography (ICG) is a non invasive method to determine hemodynamic parameters by changes of resistivity in the thorax, via four dual sensors applied on the neck and thorax, during the cardiac cycle. The signal shows the mechanical activity of the heart. During systole, the signal is mostly generated by volume changes taking place in the aorta. During diastole, blood volume changes in the large veins and the pulmonary aorta may also contribute to ICG waveforms, especially in case of pathological changes [11] [12]. In the past decade, impedance cardiography was improving its performance with the goal to replace highly invasive techniques in hemodynamic monitoring. In this context, a new module was introduced by the German company medis. GmbH, Ilmenau, Germany. In cases of arterial stiffness or reduced elasticity of the aorta, the left ventricular ejection time (LVET) is detected falsely caused by the changed appearance of impedance signal. The new technology, called ACM (arterial compliance modulation) module aims the reduction of error of false LVET detection with an additional ear clip or cuff for upper arm to take into account the effects of arterial stiffness. The aortic signal, in fact the end of the systolic cycle, is used to detect the time of aortic valve closure more exactly in patients with unusual impedance signal, to determine the left ventricular ejection time in cardiac patients more precise – and so improve the accuracy of further calculations (e.g. Stroke volume and cardiac output). The purpose of this study is the assessment of the new module in cardiac patients who underwent open heart surgery.

## 2. Methods

### 2.1 Setting and procedure

The comparison between the two methods for determining cardiac output was obtained by data collection from a set of readings from each patient by using thermodilution method and impedance cardiography with ACM module. This study is performed in intensive care unit at National Cardiovascular Centre Harapan Kita, Jakarta, Indonesia. The appropriate institutional review board approved this study (ethnic approval No.0.5.0.4.1.4/21/2013). A pulmonary artery catheter (Edwards, Swan Ganz pulmonary artery catheter) is

applied in patients who underwent open heart surgery, introduced in internal jugular on the right side of the neck, to manage the hemodynamic performance. Patients are calm and mostly sleeping. Thermodilution data was collected by trained, experienced nurses. For each session the nurse measured hemodynamic parameters by using 10 ml room temperature fluid bolus. A total of 3 or 4 thermodilution measurements (3 to 4 boluses injected) were obtained for each patient. Coincided with the routine measurement an impedance cardiography measurement was applied. The electrodes were placed as recommended by the manufacturer, on the neck and midaxillary line at the level of the xiphoid process. Since the application of the pulmonary artery catheter introduced on nearly the same place as the electrode on the right neck side, its position has been adjusted up to three centimetres dorsal. During measurement patients did not move, speak or turn their head. The ear clip had been applied to the ear lobe and the required parameters, taken from the patients history, were entered in the system. Height and weight values were transferred to determine body surface area. All patients gave consent to have leads for the impedance cardiography system applied, to be monitored for 10 to 15 minutes during the thermodilution treatment and have their hemodynamic data recorded for the purpose of comparing cardiac parameters obtained by the two methods. Patients admitted to intensive care unit were in different status of recovering during the testing period. The impedance cardiography system measured the beat to beat changes and determined the heart parameters continuously. With each injection a maker was set to compare the data at a particular time. Mean heart rate, cardiac output/index and stoke volume was determined by three thermodilution measurements and recorded manually.

26 patients were evaluated in 39 measurements, all in supine position with necessary treatment for their individual health status. No patients were excluded at the basis of structural or functional heart disease. Excluded are patients in unstable hemodynamic condition. Required sample size for a significance of 0.05 and power of 80% are 30 samples. All patients were Indonesian.

### 2.2 Analysis

Analysis was performed in SPSS (PAWS Statistics 18). The agreement between both methods for heart rate, cardiac output/index and stroke volume was assessed by mean bias, the SD and the 95% confidence limits (Bland Altman). The linear relationship between thermodilution and impedance cardiography was determined graphical and calculated with linear regression and the correlation by Pearson. A t- test was performed to identify the statistical similarity means. $\alpha$ was set as 5% and $H_0$ states that the means of both samples were equal. Outliers were classified.

## 3. Results

39 measurements out of 26 patients were recorded in this study. Five measurements had to be excluded because of detection problems of the device. Accordingly a total of 34 measurements recorded form 22 patients (15 male, 7 female) with an average age of 56.68 ± 11.7 years and a BMI of 23.7 ± 4.60 kg/m$^2$ are relevant. The demographic data is shown in table 1.

**Table 1:** The characteristics of the samples. BMI = body mass index, CABG=coronal artery bypass graft, MV=mitral valve, TV=tricuspid valve, AV=aortic valve, EF=ejection fraction.

| Patients | 22 |
|---|---|
| Male | 15 |
| Female | 7 |
| Age | 56.68 ± 11.70 years |
| BMI | 23.70 ± 4.60 kg/m$^2$ |
| >25 | 4 |
| >30 | 3 |
| >35 | 2 |
| Weight | 61.86 ± 10.96 kg |
| Height | 155.55 ± 7.47cm |
| Mean EF | 48.10 ± 18.04 % |
| Arterial fibrillation | 2 |
| Surgery/supporting | |
| CABG | 19 |
| MV surgery | 11 |
| TV surgery | 5 |
| AV surgery | 3 |
| Incubator | 16 |

### 3.1. Heart rate

The mean heart rate and standard deviation in thermodilution and impedance cardiography was 90.00 ± 14.60 1/min and 89.38 ± 12.76 1/min. Mean difference ± SD between the two devices therefore is 0.62 ± 4.19 1/min. The correlation coefficient after Pearson is $r_{HR}$ = 0.957 ($p < 0.001$). Limits of agreement are 8.36 and -7.59 1/min. T-test shows a result of $p_{HR}$ = 0.397. Linear regression is shown in figure 3.

### 3.2. Cardiac output/index

Cardiac output measurements determined by thermodilution were 4.44 ± 1.20 L/min in average, impedance cardiography was 4.88 ± 1.37L/min. Mean difference and standard deviation between the methods was -0.44 ± 1.06 L/min for cardiac output and -0.31± 0.63 L/min/m$^2$ for cardiac index. Pearson correlation coefficient was $r_{CO}$ = 0.67 ($p < 0.001$) for cardiac output and 0.61($p < 0.001$) for cardiac index. Bland Altman plot of cardiac output in figure 1 shows, that all collected data points cluster within the confidential lines of 1.56 and -2.51 L/min (bias±1.96×SD). The t-test shows values of $p_{CO}$= 0.023 and $p_{CI}$ = 0.009 for cardiac output and index. The linear regression is shown in figure 3.

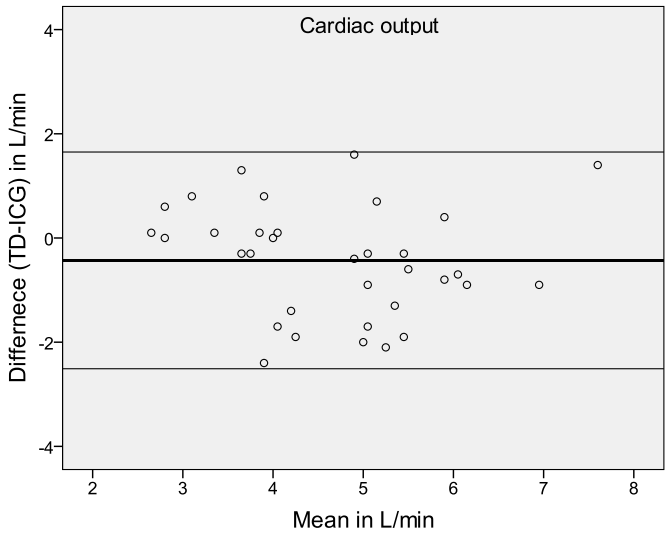


**Figure.1:** Bland Altman plot for Cardiac output obtained by thermodilution (TD) and impedance cardiography (ICG)

### 3.3. Stroke volume

The stroke volume determined by thermodilution is 49.71 ± 12.20 ml and 55.19 ± 16.67 ml obtained by impedance cardiography, mean difference is -5.48 ± 12.05 ml. The correlation after Pearson is $r_{SV}$ = 0.691 ($p<0.001$). Limits of agreement are 18.15 and -29.08 ml, the agreement is shown in figure 2. T-test shows a result of $p_{SV}$ = 0.012. Linear regression is shown in figure 3.

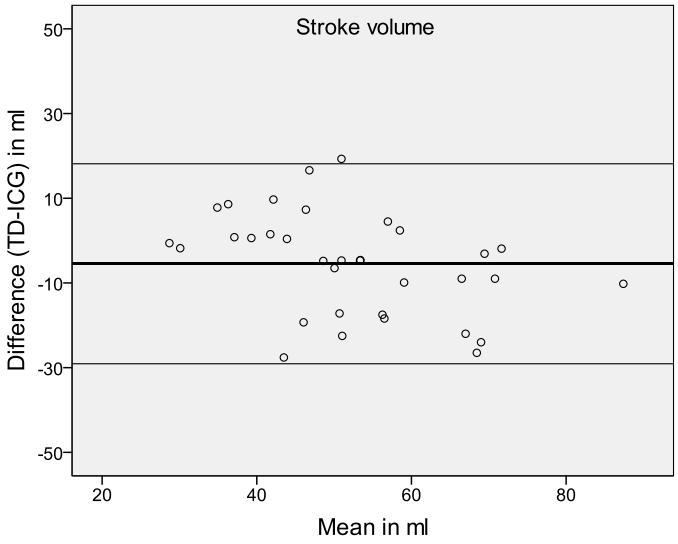


**Figure 2:** Agreement of methods shown in Bland Altman plot for stroke volume obtained by thermodilution and impedance cardiography

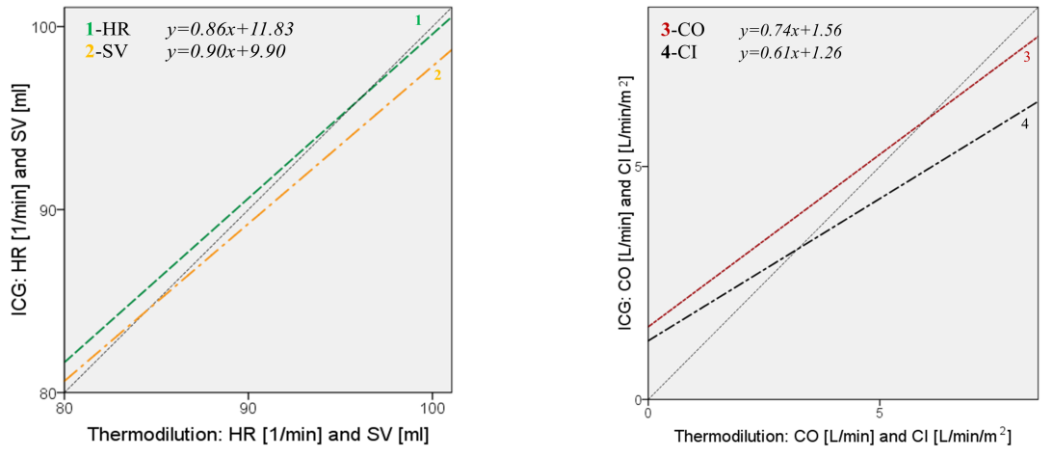


**Figure 3**: Linear regression of heart rate [1/min], cardiac output [L/min]/index [L/min/$^2$] and stroke volume [ml]

### 3.4. Influence of mechanical ventilation

Mechanical ventilation on patients does influence the accuracy of the measurement. Comparing the differences of cardiac output from both devices, people with ventilation (23 measurements) show a lower difference (-0,12L/min) than not ventilated patients (-1.17L/min) but a greater standard deviation (±1.08 for ventilated patients, ±0.58 for not ventilated) which means a higher spreading of values for single measurements. With the t test ($p = 0.022$ for cardiac output and $p = 0.009$ for cardiac index) is proven, that the means are not equal. In this study the mechanical ventilation effects the measurement and accuracy of impedance cardiography in cardiac output and index, but not the other parameters. Other influences has been tested (high BMI, arterial fibrillation and low ejection fraction (EF)), but didn't show a significant result on any parameter.

**Discussion**

Standard impedance cardiography is a noninvasive method that provides continuous beat to beat measurements of hemodynamic parameters, it is cheap and easy to use. Nevertheless, so far it is not the method of choice if exact measurements of cardiac output in postoperative patients are needed, because of the lack of correlation compared to the gold standard and highly invasive method of thermodilution. Recent developments aim to improve accuracy, which needs to be proved by studies like this, to ensure the reliability of new methods. Postoperative patients after open heart surgery in critical care are mostly provided with the pulmonary artery catheter, to obtain their hemodynamic performance with thermodilution method. These patients had been measured with both devices, thermodilution and impedance cardiography with new ACM module simultaneously, and showed acceptable accuracy and high correlation for the parameter cardiac output/index and stroke volume. The agreement and correlation of heart rate was very high.

The impact of mechanical ventilation in impedance measurements shows that impedance cardiography measurements can be influenced by other mechanical equipment in the treatment plan of the patient. The impact is not yet clear because of the number of measurements and need to be clarified in further studies.

Even though, the ACM module increase the accuracy of impedance cardiography, compared to usual impedance measurements [13], the principle of measurement set certain limitations in detecting right and left ventricular filling pressure [14] [15]. Moreover, impedance cardiography does not provide information about intra cardiac pressure like thermodilution, but about fluid trending and myocardial contractility [14]. Other known limitations are aortic valve regurgitation and septic shock [16].

Another study [9] questioned the accuracy of the gold standard method itself, in measuring cardiac output. Its been claimed that CO changes less than 30-40% are detected unreliable with pulmonary artery catheter and that other methods to determine cardiac output have smaller error to each other than to PAC in animals [9].

Our results show satisfying agreement in postoperative patients in determining cardiac output/index and stoke volume, but the results need to be treaded carefully. One study suggested, that the impedance parameter could alter a physicians plans of treatment [17]. Also the impact of mechanical ventilation is indicated, but need to be proven in further studies.

**Conclusion**

Impedance cardiography nowadays cannot be considered as accurate as the gold standard itself, but this, and other researches, show a high correlation and accuracy of the non invasive device. It is overall an easy to use, user independent, continuous beat to beat measurement, which has big advantages for patients and hospitals. Our study indicates that the measurements with impedance cardiography are adequately accurate and highly correlated with thermodilution measurements on postoperative patients. The method decreases the discomfort of patients, which are already highly injured after open heart surgery. Once, the electrodes are applied, impedance cardiography delivers continuously hemodynamic parameters without additional personnel effort. With respect of the limitations of this method, impedance cardiography could be used in clinical treatment in replacement of highly invasive methods. The impact of mechanical ventilation has to be considered in further studies.

*All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). Informed consent was obtained from all patients for being included in the study.*

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