

# Evaluating the Efficacy of Intra-Aortic Balloon Pump Timing Using the Auto-Timing Mode of Operation With the Datascope CS100

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**Abstract:** The intra-aortic balloon pump (IABP) was first introduced by Mouloupoulos et al. in 1962 and was described clinically by Kantrowitz et al. in 1968. The subsequent development of the IABP has resulted in its widespread application, resulting in >70,000 applications per year, making it the most common cardiac assist device after pharmacologic intervention. The correct timing of the inflation and deflation of this device is critical to it being clinically advantageous to the patient. The purpose of this study was primarily to examine the Datascope CS100 automated timing of inflation and deflation, and secondarily, to create an awareness of the risks of solely relying on technology for patient treatment decisions in lieu of clinical evaluative skills. Timing data were collected from 165 IABP patients from January 1, 2003 to March 31, 2005 using the Datascope series System 97, System 98, and CS100 IABP consoles. Timing criteria used in the evaluation of the IABP in this study included proper inflation, defined as inflation at the dicrotic notch of arterial pressure waveform, and proper deflation, resulting in a presystolic decrease of dias-

tolic pressure by 5-10 mmHg. These parameters were evaluated by examining a printed strip from the IABP console after timing selection stabilization. Before implementation of the CS100, 78.6% of inflations and 53.6% of deflations were correct when using the criteria listed above. After implementation of the CS100, 83.3% of inflations were correct and 44.4% of deflations were correct. Although improvement in consistency of IABP inflation quality was observed, a net decrease in the quality of IABP deflations was also observed. Total reliance on the auto-timing operation mode of the CS100 may not be warranted, and imposing clinical judgment in therapeutic application is necessary to avoid dangerous timing errors. An awareness of the dangers of solely relying on technology for patient treatment decisions vs. the use of technology combined with clinical evaluative skills for assessing therapeutic intervention to improve patient care is discussed. **Keywords:** intra-aortic balloon pump, balloon pump timing, counterpulsation, preload, afterload. *JECT 2007; 39:87-90*

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The intra-aortic balloon pump (IABP) is at present the simplest and most frequently used circulatory assist device (1). It was first introduced by Mouloupoulos et al. in 1962 and was described clinically by Kantrowitz et al. in 1968 (1). Therapy with the IABP is indicated in patients with unstable angina, acute myocardial infarction, cardiogenic shock, mechanical complications after myocardial infarction, adjunct to percutaneous transluminal coronary an-

gioplasty and cardiac catheterization, bridge to cardiac transplant, and perioperative support, among others (2). IABP consoles have become quite technologically sophisticated, including a progression toward increased user-friendliness. It seems it has become possible for the operator to develop a reliance on the machine to establish proper timing. The primary purpose of this study was to evaluate the effectiveness of automatic timing using the Datascope CS100 Intra-Aortic Balloon Pump (Datascope Corp., Fairfield, NJ). The secondary intention of this study was to develop an awareness of the need for absolute understanding of IABP therapy and the evaluative skills necessary for assessing and establishing proper balloon pump timing to improve patient care, as well as exploring the reliance on technology to make health care treatment decisions.

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Inflation and deflation of the CS100 balloon in the auto-timing operation mode is triggered automatically using the electrocardiogram (ECG) or aortic pressure waveform, both of which are automatically and dynamically adjusted by the system to compensate for variations in trigger signal amplitude (3). In the auto-timing operation mode, the balloon catheter inflates during diastole (counterpulsation), propelling blood to the coronary arteries and the periphery because of the displacement of volume, and resultant pressure increase. This increase in diastolic pressure during the diastolic period leads to increased coronary perfusion (4). Deflation should be timed to be just before the onset of systole and remaining deflated throughout the cycle. When deflation occurs, there is a sudden decrease of pressure because of the volume displacement loss within the aorta, yielding a decreased aortic end diastolic pressure. This decreased end diastolic pressure provides a decrease in the imposed afterload to the heart (4). The effects of decreased afterload may and often does yield a decrease in myocardial work, decreased oxygen consumption, and an increase in cardiac output (5). Use of a properly timed IABP system improves cardiac function by augmenting cardiac output by ~10% or 500–800 mL/min (1).

The correct timing of the inflation and deflation of the IABP is critical to it being clinically advantageous to the patient. Incorrect timing can cause further harm and distress. The actual application of correct timing is often of clinical debate among practicing clinicians, and the absolute determination of ideal inflation and deflation points is usually left to individuals or institutions. It is generally accepted that intra-aortic balloon inflation should occur at the dicrotic notch. This indicator of closure of the aortic valve is a reasonably clear indicator of natural separation from myocardial blood volume contribution to the systemic circulation. Early inflation will cause a premature closure of the aortic valve, which in turn will cause increased left ventricular end diastolic volume and pressure, increased preload, and increased myocardial oxygen demand, and consumption caused by the resultant increase in myocardial wall stress and distension from the increased volume load (6). Late deflation of the IABP catheter occurs after the dicrotic notch and is generally regarded as relatively harmless. The late inflation usually diminishes clinical therapeutic effect for augmentation support.

It is recognized that late deflation of the intra-aortic balloon will result in physical obstruction within the aorta to which the left ventricle must compete to open the aortic valve for systolic volume emptying (6). Deflation should be set to occur near the end of diastole during isovolumetric contraction immediately before systole (4). Such determination of proper deflation timing is done by evaluating the assisted aortic end diastolic pressure to ensure that it is less than the unassisted aortic end diastolic pressure. The consequences of late deflation are not only the

absence of a reduction in afterload, but an increase in afterload caused by cardiac ejection against the increased greater resistance caused by the inflated balloon (6). Early deflation of the intra-aortic balloon is defined as deflation before isovolumetric contraction, may result in suboptimal coronary perfusion, the potential for retrograde coronary and carotid blood flow, angina, suboptimal afterload reduction, and an increase in myocardial oxygen demand (6).

## MATERIALS AND METHODS

The effectiveness of proper IABP timing was evaluated in 64 sequential patients between April 1, 2004 and March 31, 2005. The patient device selection was made by device availability. Four patients were excluded from the evaluation because of improper documentation of device selection. Thirty-six of the patients were treated with the Datascope CS100, and 28 were treated with other Datascope consoles. Once timing was established in the auto-timing operation mode, three parameters were checked to evaluate the proper timing of inflation and deflation of the balloon catheter. The guidelines for proper timing in this evaluation included the following: (a) augmentation setting to just below maximum, (one bar less than the maximum setting), (b) inflation at the dicrotic notch of the central aortic pressure waveform, and (c) deflation resulting in a presystolic decrease of central aortic pressure between 5 and 10 mmHg. These parameters were evaluated by examining a print strip containing both the ECG and arterial pressure waveform after timing was established and the patient was stabilized. Fisher exact test was used to compare the timing (early, correct, or late) of the inflation and deflation of the balloon between the CS100 and devices other than the CS100. The value of  $p \leq .05$  was considered statistically significant.

## RESULTS

Before implementation of the CS100, 78.6% of inflations and 53.6% of deflations were correct when using the three criteria listed above. Inflation occurred early in 3.6% of the cases and late in 10.7% of the cases, whereas deflations occurred early in 3.6% of the cases and late in 28.6% of the cases (Figure 1). After implementation of the CS100, 83.3% of inflations were correct and 44.4% of deflations were correct. Inflation occurred early in 2.8% of the cases and late in 13.9% of the cases, whereas deflations occurred early in 27.8% of the cases and late in 22.2% of the cases (Figure 2). Table 1 shows the association of inflation and deflation timing. There were no differences between the timing of the CS100 compared with the other devices for inflation ( $p = 1.0$ ). There was a statistically significant difference between the CS100 and other de-

CS100 IABP Timing Results

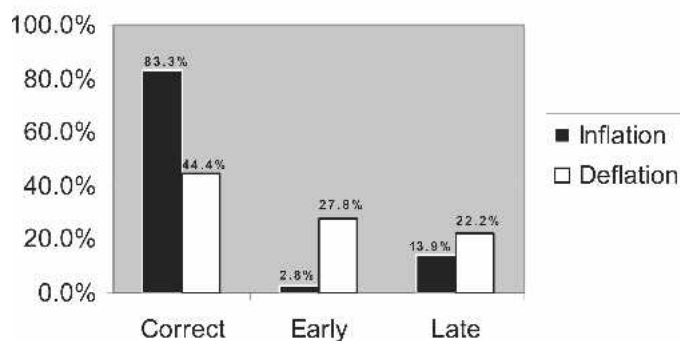


Figure 1. Results of timing evaluations using the Datascope CS100 IABP.

Non-CS100 IABP Timing Results

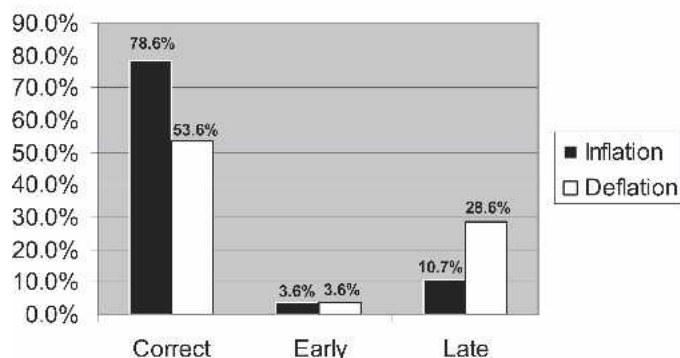


Figure 2. Results of timing evaluations using non-Datascope CS100 IABP.

Table 1. Association of inflation and deflation timing.

	Early	Correct	Late	p Value
Inflation				
CS100 (n = 36)	1 (3%)	30 (83%)	5 (14%)	1.0
Other (n = 26)	1 (4%)	22 (85%)	3 (12%)	
Deflation				
CS100 (n = 34)	10 (29%)	16 (47%)	8 (24%)	0.05
Other (n = 24)	1 (4%)	15 (63%)	8 (33%)	

vices when comparing the deflation timing ( $p = .05$ ; Figure 3). The CS100 had a higher percentage of early deflation compared with the non-CS100 group (Table 1). Table 2 shows the association between timing and devices when timing is classified as correct vs. incorrect (early or late). When timing was classified in this manner, there were no significant differences between the CS100 vs. the non-CS100 group (Table 2).

DISCUSSION

The primary purpose of this study was to evaluate the effectiveness of automatic timing using the Datascope

Results Comparison

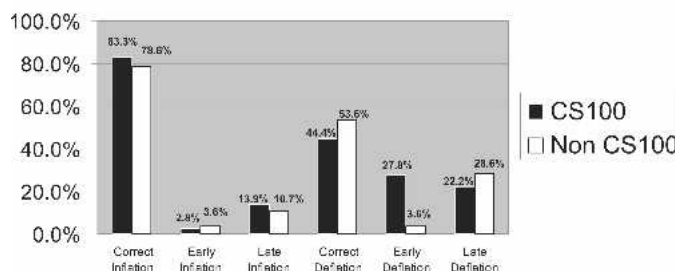


Figure 3. Results comparison of CS100 and non-CS100 IABPs.

Table 2. Association between timing and devices when timing is classified as either correct or incorrect (incorrect meaning early or late).

	Correct	Incorrect	p Value
Inflation			
CS100 (n = 36)	30 (83%)	6 (17%)	1.0
Other (n = 26)	22 (85%)	4 (15%)	
Deflation			
CS100 (n = 34)	16 (47%)	18 (53%)	0.30
Other (n = 24)	15 (63%)	9 (37%)	

CS100 Intra-Aortic Balloon Pump. The intra-aortic balloon pump is at present the simplest and most frequently used circulatory assist device after pharmacologic treatment, and the correct timing of the inflation and deflation of this device is critical to it being clinically advantageous to the patient (1). Improper timing of an IABP may cause a reduced benefit to the patient and also has the potential to inflict harm. The consequences of improper timing are noteworthy. Late inflation occurs after the closure of the aortic valve. This results in suboptimal coronary perfusion. Early deflation results in suboptimal coronary perfusion, as well as the potential for retrograde coronary and carotid blood flow. Early deflation also has the potential to cause an increase in myocardial oxygen demand and a less than optimal reduction in afterload. Early inflation occurs before the aortic valve and will force premature closure of the aortic valve increasing ventricular wall stress, myocardial oxygen demand from the increased left ventricular end diastolic volume, and left ventricular end diastolic pressure. The consequences of late deflation of the IABP are an absent reduction in afterload, and impedance on left ventricular ejection, which will likely increase the afterload. An increase in myocardial oxygen consumption is the result of the left ventricle ejecting against a greater resistance caused by the inflated balloon. A prolonged isovolumetric contraction phase in the cardiac cycle may also arise with late balloon deflation.

The secondary intention of this study was to develop an awareness of the need for absolute understanding of IABP therapy and the evaluative skills necessary for assessing and establishing proper balloon pump timing to

improve patient care. The technology of the IABP has become sophisticated, although there has been a progression toward increased user friendliness. With this ease of use, it has become possible for the operator to develop a reliance on the machine to establish proper timing. It is not the intention of this author to discredit Datascope in any way, and in fact the company is to be commended for developing such ingenious software to help guide the busy clinician through the myriad of responsibilities they face. In personal communication with Datascope engineers by the author of this paper, they stressed the company's position of the importance of using clinical judgment in conjunction with the available technology to best establish IABP timing to best serve the patient. It is the position of Datascope that the deflation algorithm is one that needs end-user confirmation of proper technique.

Advancements in technology for devices used in health care may have increased ease of use and decreased the time needed to obtain results, but without user training and judgment, these advancements may not necessarily result in increased accuracy in patient treatment. A study by Latman et al. (7) evaluated the accuracy of digital oral and tympanic thermometers vs. the traditional mercury-filled glass thermometers. The digital thermometers' displays are easier to read, the need to shake down the mercury is eliminated, thus increasing safety, and results are obtained in 1–2 seconds rather than 4–5 minutes. The comparison of Latman et al. of traditional mercury-filled thermometers vs. digital and tympanic thermometers revealed that, although there was an increase in ease of use, speed of results, and safety, the accuracy of these devices was less than optimal (7). An article published in the *British Journal of Sports Medicine* examined the reliability of commercial heart rate monitors. When bench testing was performed, the electronic equipment rarely exhibited errors exceeding 2–3 beats/min when used in a range of 30–240 beats/min. When these same devices were tested on humans walking or jogging on a treadmill, 20%–70% of the machines had errors of >20 beats/min, and in some cases, >50% of the readings were >50 beats/min different than the actual heart rate (8). Similar findings were reported in *Biomedical Instrumentation and Technology* concerning the accuracy of blood glucose monitors (9) and in *Regional Anesthesia and Pain Medicine* in regard to the accuracy of portable infusion pumps used for patients for pain management (10). Advances in technology can also result in an increase in convenience without compromising

accuracy, as found by Gardner (11) in evaluating the accuracy and reliability of disposable pressure transducers. All of the disposable transducers tested by Gardner were more accurate than the standards established by the American National Standards Institute (ANSI), and even the worst case transducers were more than twice as accurate as the ANSI requirements.

Advances in technology have benefited medical care practices; however, technology cannot and should not replace sound clinical judgment. It is only with the combination of technology and clinical training that health care service can be optimized for the best possible patient outcomes. The trend toward an easier, faster diagnosis and treatment may come at a cost of less reliable results of which practitioners must be aware. Health care providers must make treatment decisions based on all available information, trusting their judgment and clinical skills if a device's information seems inaccurate. Technology has positively affected health care but can only do so with human involvement.

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