How should I wean my next intra-aortic balloon pump? Differences between progressive volume weaning and rate weaning

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Objective: Although the intra-aortic balloon pump is the most used ventricular assist device, no study has ever evaluated the best weaning method. We compared 2 different intra-aortic balloon pump weaning methods.

Methods: Thirty consecutive patients needing an intra-aortic balloon pump because of perioperative low-output cardiac syndrome were randomized to be weaned by ratio (4 consecutive hours of a 1:2 assisting ratio followed by 1 hour of a 1:3 ratio; group R) or by progressive volume deflation (10% of total volume every hour for 5 consecutive hours; 15 patients, group V). A duration of 5 hours was set a priori as the weaning duration. The weaning protocol was started when the cardiac index was greater than 2.5 L/min/m^2, the central venous pressure was 12 mm Hg or less, the blood lactate was less than 2.5 mmol/L, the mean arterial pressure was greater than 65 mm Hg, and the preserved urine output ($\geq$1 mL/kg/hr) lasted for at least 5 consecutive hours before weaning. The cardiac index, indexed systemic vascular resistance, cardiac cycle efficiency, and central venous pressure were registered at 9 points (T0, start; T1 to T5, the first 5 weaning hours; T6, 2 hours after withdrawal; T7, 12 hours after withdrawal; and T8, at intensive care unit discharge) using the pressure recording analytical method. The interval from intra-aortic balloon pump withdrawal to intensive care unit discharge, weaning failure, perioperative troponin I, and lactate (same points) were compared.

Results: All patients, except for 1 belonging to group R ($P = 1.0$), were successfully weaned. Group V had better preserved cardiac index, indexed systemic vascular resistance, cardiac cycle efficiency, and central venous pressure (group*time $P = .0001$). Group R had worse cardiac index from T5 to T8 ($P \leq .0001$), indexed systemic vascular resistance from T2 to T8 ($P \leq .004$), cardiac cycle efficiency from T3 to T8 ($P \leq .001$), central venous pressure from T4 to T8 ($P \leq .0001$), and a longer interval from intra-aortic balloon pump withdrawal to intensive care unit discharge ($P = .0001$). The lactate level was lower in group V from T5 to T8 ($P \leq .027$; group*time $P = .001$).

Conclusions: Intra-aortic balloon pump weaning by volume deflation allowed better hemodynamic and metabolic parameters. (J Thorac Cardiovasc Surg 2013;145:1214-21)

Since the demonstration in previous decades of the efficacy of intra-aortic balloon counterpulsation (IABP) in different conditions of cardiac failure,[1-3] its use has widened to include hemodynamic support in high-risk procedures, refractory unstable angina, acute myocardial infarction and its complications, low cardiac output syndrome (LCOS), difficulties in weaning from cardiopulmonary bypass, intractable ventricular arrhythmias, and so forth.[3,4] Because of the progressive referral of sicker patients for interventional and surgical procedures, IABP indications have recently widened further to consider include this therapy as a prophylactic tool in high-risk procedures.[5] Although the exact prevalence of IABP is still far from assessed, a recent survey estimated its use in 52,000 patients per year in the United States.[6] In 2001, the Benchmark Registry reported the results of IABP use on more than 16,000 patients, with LCOS the most prevalent indication.[3]

Although IABP currently represents the first-line left ventricular assist device in patients with LCOS, no study has assessed which is the best method to wean a patient from the IABP of the 2 available methods: volume deflation or rate reduction. Therefore, it was the aim of the present pilot study to investigate, for the first time in humans, the hemodynamic response and leakage of biochemical markers of myocardial and peripheral ischemia (troponin I and lactate) using these 2 weaning methods for IABP discontinuation.

METHODS

Patients

From January 2009 to October 2011, of 4390 patients undergoing cardiac surgery with cardiopulmonary bypass at our institution, 33

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Abbreviations and Acronyms

AMI = acute myocardial infarction
CCE = cardiac cycle efficiency
CI = cardiac index
CVP = central venous pressure
IABP = intra-aortic balloon pump
ICU = intensive care unit
ISVR = indexed systemic vascular resistance
LCOS = low cardiac output syndrome

consecutive patients (0.75%) requiring an intra- or postoperative IABP because of LCOS refractory to inotropic or volume support were preliminary scheduled for enrollment in the present pilot study. Three patients who also required extracorporeal circulation and membrane oxygenation for progressive heart failure were eventually excluded. Thus, 30 patients able to start a weaning trial were finally enrolled.

LCOS was diagnosed in the presence of an inadequate cardiac index (CI, $\leq$2.2 L/min/m^2 for >30 minutes); reduced urine output (<1 mL/kg/hr); metabolic acidosis (elevated serum lactate [>4 mmol/L]) despite inotropic support and adequate correction of preload, afterload, electrolytes, blood gas abnormalities, and glycemic control; and without evidence of cardiac tamponade.[7]

The IABP catheter was always inserted percutaneously, always using the sheathless technique (8F, 34 or 40 mL according to the patient's body surface area; Datascope, Fairfield, NJ) and connected to a Datascope pump (Datascope). The correct positioning was always assessed by transesophageal echocardiography and confirmed by chest radiography. The preoperative/intraoperative data, timing, and indications for IABP are reported in Table 1.

Weaning Trial

The duration of the weaning trial was established a priori to last for 5 consecutive hours, according to our traditional institutional policy. The weaning trial was started when the CI was greater than 2.5 L/min/m^2, the central venous pressure (CVP) was 12 mm Hg or less, the blood lactate level was less than 2.5 mmol/L, the mean arterial pressure was greater than 65 mm Hg, and the preserved urine output ($\geq$1 mL/kg/hr) lasted for at least 5 consecutive hours. Patients were randomized by lottery to the intensive care unit (ICU) with 2 different weaning strategies. Fifteen patients (group R) were randomized to be weaned using the rate-reduction weaning protocol, consisting of switching IABP from a 1:1 to a 1:2 electrocardiographic-coupled assisting ratio for the first 4 consecutive hours and from a 1:2 to a 1:3 ratio for the last (fifth) hour of the weaning trial, followed by IABP withdrawal. The other 15 patients (group V) were allocated to the volume-deflation weaning protocol, consisting of progressive volume deflation (10% of the full volume of inflation every hour for 5 consecutive hours to reach 50% of the total volume of inflation at the end of the trial), followed by IABP withdrawal.

The weaning trial was stopped and IABP therapy prolonged beyond the fifth hour in the case of acute hemodynamic instability with signs of renewed LCOS. These patients were immediately switched to full IABP assistance (1:1 ratio with full-volume inflation) and considered to have weaning failure and were withdrawn from the trial.

Hemodynamic Monitoring and Collected Data

The pressure recording analytical method was used for hemodynamic monitoring and consisted of a beat-by-beat evaluation of the CI, indexed systemic vascular resistance (ISVR), and cardiac cycle efficiency (CCE), derived from the arterial-pressure waveform.[8,9] The degree of CI changes during the weaning trial was considered as the primary endpoint of the study (see the section "Statistical Analysis"). The pressure recording analytical method is based on the mathematical analysis of the arterial pressure profile changes and has been recently validated for patients with LCOS and unstable patients undergoing IABP and/or receiving high-dose inotropic support after cardiac surgery.[8] It has been also recognized as the only less-invasive method able to correlate with the thermodilution calculations obtained using the Swan-Ganz catheter during IABP and to compare with the hemodynamic parameters calculated by direct oxygen Fick method or with transesophageal echocardiography in different hemodynamic conditions.[8] From the continuous recording of the arterial-pressure waveform, the algorithm of the machine computes the CCE, which provides information about left ventricular wall stress and the heart's effort to maintain adequate blood flow and oxygen delivery to the tissues.[9] CCE is a nondimensional number ranging from +1 to negative values. Positive CCE values represent a better coupling between cardiac function and energy expenditure (ie, lower left ventricular wall stress). Negative CCE values represent greater energy expenditure and left ventricular wall stress.[9] Hemodynamic indexes were collected using the pressure recording analytical method at 9 different points (T0, start of the weaning trial; T1 to T5, the first 5 weaning hours; T6, 2 hours after withdrawal; T7, 12 hours after withdrawal; and T8, ICU discharge). The CVP was recorded at the same points and expressed as millimeters of mercury.

Serum troponin I (monoclonal antibodies; Siemens Medical Solutions Diagnostics, Terrytown, NY) and lactate (RapidLab1265 AutomaticQC Cartridge; Siemens Healthcare Italia, Milan, Italy) were measured at the same 9 points, just as for the hemodynamic indexes. Venous blood for the detection of troponin I and lactate was always sampled from the distal line of the central venous catheter.[7] The changes in the other hemodynamic variables and modifications of troponin I and lactate values during the weaning trial were considered the secondary endpoints of the study.

The prospectively recorded data also included the interval from IABP withdrawal to ICU discharge, inotropic support or the need for increment inotropic support after withdrawal, LCOS after withdrawal, the need for reinstitution of IABP after withdrawal, acute myocardial infarction (AMI) after withdrawal, paroxysmal/persistent atrial fibrillation after withdrawal, ICU stay, hospital stay, and hospital mortality. Inotropic support was categorized as none, low (dopamine $\leq$5 μg/kg/min), medium (dopamine >5 μg/kg/min and $\leq$10 μg/kg/min or dobutamine <5 μg/kg/min), and high (dopamine >10 μg/kg/min with or without dobutamine >5 μg/kg/min with or without epinephrine at any dose), according to institutional policy.[7] Postwithdrawal LCOS was defined as a CI of $\leq$2.2 L/min/m^2 for more than 30 minutes with reduced urine output (<1 mL/kg/hr), metabolic acidosis with elevated serum lactate (>4 mmol/L), despite adequate glycemic control, without any evidence of cardiac tamponade and despite inotropic support and adequate correction of preload, afterload, electrolyte, and blood gas abnormalities.[7] Postwithdrawal inotropic support was increased after IABP discontinuation in the presence of signs of LCOS and titrated on the hemodynamic indexes. Postwithdrawal LCOS refractory to inotropic support mandated reinstitution of IABP therapy and was also considered a weaning failure. Postwithdrawal AMI was defined according to the European Society of Cardiology/American College of Cardiology Foundation/American Heart Association/World Heart Federation expert consensus document on the definition of AMI.[10] Paroxysmal or persistent atrial fibrillation was defined according to the Heart Rhythm Society/European Heart Rhythm Association/European Cardiac Arrhythmia Society Expert Consensus Statement, as already reported.[11] The ICU stay was the days spent in the ICU. A eupnoeic, extubated patient, with the absence of IABP support and with stable hemodynamic status (as confirmed by a CI >2.5 L/min/m^2, a CVP of $\leq$12 mm Hg, a blood lactate level <2.5 mmol/L, a mean arterial pressure >65 mm Hg, and preserved diuresis of $\geq$1 mL/kg/hr) fulfilled the indication for an ICU discharge. The hospital stay was the days spent in the hospital after discharge from the ICU.