

# Antegrade Use of Intra-Aortic Balloon Pump as Bridge to Transplantation

## *Empleo anterógrado del balón de contrapulsación como puente al trasplante*

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### ABSTRACT

**Introduction:** The possibility of prolonged circulatory assistance on the waiting list for heart transplantation has associated complications. Different from the conventional access, antegrade balloon pump implantation through the subclavian artery could avoid or, at least, limit the adverse effects of assistance.

**Objective:** The aim of this study was to consider circulatory support using intra-aortic balloon pump implantation through the left subclavian artery as bridge to transplantation.

**Methods:** Patients on the waiting list for heart transplantation with acute decompensation and expected prolonged assistance interval received antegrade balloon pump implantation through the left subclavian artery.

**Results:** Between August 2007 and July 2012, 38 patients underwent uneventful antegrade balloon pump implantation. Twenty-nine patients (76.3%) were transplanted under circulatory support and 9 patients required transition to more complex support techniques. Among these patients 5 (13.2%) were transplanted while the other 4 (10.5%) died. Average circulatory assistance with intra-aortic balloon pump was 24 days (5 to 68 days) during which the majority of patients were able to move and even ambulate.

Observed complications were low; 1 patient (2.6%) developed a big local hematoma, 1 (2.6%) presented catheter rupture and replacement, and 1 (2.6%) experienced distal pulse loss which was managed in a conservative way. Hemodynamic assessment before and after implantation showed improved systolic function (cardiac output and cardiac index) and reduced filling pressures.

**Conclusions:** Selected patients with decompensated end-stage heart failure could be stabilized and supported for a prolonged period of time using intra-aortic balloon pump implanted through the subclavian artery. This technique was associated with a low number of complications and, different from the conventional retrograde access, it allowed mobility in the majority of patients while awaiting transplantation.

**Key words:** Intra-aortic balloon pump – Heart Transplantation – Heart failure

### RESUMEN

**Introducción:** La perspectiva de un tiempo de asistencia circulatoria prolongada en lista de espera de trasplante cardíaco implica complicaciones asociadas. Con el implante anterógrado del balón de contrapulsación por vía subclavia, a diferencia del acceso convencional, podrían evitarse o al menos limitarse los efectos adversos de la asistencia.

**Objetivo:** Considerar la asistencia circulatoria con balón de contrapulsación implantado por subclavia izquierda como puente al trasplante.

**Material y métodos:** Se incluyeron pacientes en lista para trasplante cardíaco con descompensación hemodinámica y presunción de un tiempo prolongado de asistencia que recibieron el implante anterógrado del balón de contrapulsación a través de la arteria subclavia izquierda.

**Resultados:** Entre agosto de 2007 y julio de 2012, en 38 pacientes se efectuó el implante del balón de contrapulsación en forma anterógrada, sin complicaciones. En 29 (76,3%) pacientes se realizó el trasplante bajo dicho apoyo y en 9 pacientes se requirió la transición hacia una forma más compleja de asistencia. De estos, en 5 (13,2%) se realizó el trasplante y los 4 (10,5%) pacientes restantes fallecieron. El tiempo de asistencia con balón fue de 24 días (5-68 días); la mayoría de los pacientes lograron movilizarse, e incluso deambular, bajo esta asistencia.

El número de complicaciones apreciadas fue bajo: 1 (2,6%) paciente presentó hematoma mayor local, en 1 (2,6%) paciente se produjo rotura del catéter, que debió reemplazarse, y en 1 (2,6%) se evidenció pérdida del pulso distal, sin necesitar intervención alguna. Al comparar la evaluación hemodinámica previa y posterior al implante se observó mejoría, con incremento de los parámetros de la función ventricular (volumen minuto e índice cardíaco) y reducción de las presiones de llenado.

**Conclusiones:** Pacientes seleccionados con insuficiencia cardíaca avanzada descompensada pueden ser estabilizados y apoyados durante un período prolongado mediante el empleo del balón de contrapulsación por acceso subclavio. Esta técnica se asoció con un número bajo de complicaciones y permitió, a diferencia del acceso retrógrado, la movilización de la mayoría de los pacientes durante la espera del trasplante.

**Palabras clave:** Contrapulsador Intraaórtico- Trasplante - Insuficiencia Cardíaca.

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## Abbreviations

**IABP** Intra-aortic balloon pump

## INTRODUCTION

Intra-aortic balloon pump counterpulsation (IABP) is the most widely used ventricular assist device and is generally implanted through the femoral artery. (1, 2)

Use of this access implies a permanent bed-ridden patient with significant restricted mobility. This is associated with several adverse effects, which may be enhanced in case of prolonged support (and hence rest), as for example, in patients on the waiting list for heart transplantation. These situations could be avoided or at least limited using another access route.

The alternatives to retrograde femoral access are direct aortotomy, used in emergency situations in the operating room when conventional access is not possible, mainly due to peripheral vascular disease, and antegrade subclavian or axillary device implantation. (3-5)

The present work includes a series of patients on the waiting list for heart transplantation to assess prolonged IABP support through antegrade subclavian access as bridge to transplantation, considering:

- Number of IABP-assisted patients
- Support duration and outcomes
- Patient comfort using this access
- Associated complications due to the implantation procedure or permanence of this access route (hematomas, bleeding, infections, ischemia, etc).

## METHODS

### Population

Patients with end-stage heart failure (stage D) under optimal medical treatment, on the waiting list for heart transplantation, and hospitalized due to hemodynamic decompensation were included in the study. Patients whose characteristics suggested a prolonged support interval (blood type O, elevated panel reactive antibody, extreme body surface, etc) were implanted with a 7.5 Fr catheter connected to a Datascope CS 100 console (Maquet, NJ) through a subclavian vascular access.

### Surgical technique

The procedure was performed in the operating room under radioscopic control using general anesthesia, orotracheal intubation and hemodynamic monitoring with SwanGanz catheter and transesophageal echocardiography. Following standard antiseptic preparation, an oblique incision was performed in the anterior thoracic wall, 2 cm below the middle third of the left subclavian artery, separating the major pectoralis muscle fibers, going through the brachio-pectoral fascia and shifting the inferior subclavian vein. The homonymous artery was identified and exposed at the level of the axilo-subclavian junction and surrounded with a vascular loop. After heparin administration, the artery was proximally and distally clamped and arteriotomy was performed. At that level, a 4 cm Hemashield graft (Boston Scientific, Mass) was sutured with Prolene 5-0. The free end of the graft was shortened applying circular suture around it, also with Prolene 5-0.

A guide catheter was advanced through the Hemashield graft and positioned in the descending aorta under fluoroscopic assistance. After checking the position, the IABP was advanced up to the descending aorta and the distal end of the graft was tightly closed. IABP position was confirmed by transesophageal echocardiography. After careful deaeration, the distal end of the graft was tunneled inside the pocket and 1:1 counterpulsation was initiated.

Careful hemostasis was performed and the incision was closed in layers. The skin was approximated and the IABP was fixed to the patient's skin. Patients were transferred to the intensive care unit where early extubation was performed.

Hemodynamic assessment was done using a previously implanted SwanGanz catheter. Complete hemodynamic measurements were acquired and values before and 6 hours after IABP implantation were compared.

### Complications

The following associated complications were considered:

- a) Hemorrhagic: blood loss associated with the access site with unexplained hematocrit drop, requiring or not transfusion.
- b) Ischemic: temperature reduction, pallor, loss of pulses or decreased perfusion, manifested by pain or paresthesia in the left upper limb.
- c) Infectious: signs of local flogosis, bacteremia, or unexplained increase of white cell count with bacterial rescue.
- d) Others: Unexplained low platelet count, catheter mechanical complications (e.g. rupture), etc.

Duration of IABP therapy was considered until the occurrence of one of the following: heart transplantation, need of progressing to a more complex device, death or IABP discontinuation due to complications. The patient's comfort was analyzed assessing the possibility of sitting, standing or ambulating with the implanted device.

### Statistical analysis

Variables with Gaussian distribution were expressed as mean and standard deviation, and those with non-Gaussian distribution, as assistance duration, were expressed as median and range. Distribution normality was calculated with the K-S goodness of fit test. Continuous data were compared using Student's t test for variables with normal distribution or the Mann-Whitney test for non-normal distribution. Analysis of categorical data was performed using the chi-square test. A p value < 0.05 was considered as statistically significant. SPSS Statistics 17.0 software was used for statistical analyses.

## RESULTS

A total of 38 patients received subclavian IABP implantation between August 2007 and July 2012. Patient characteristics are shown in Table 1. The reason for expected prolonged support were blood type O in 13 patients (34.2%), elevated panel reactive antibody in 22 (57.9%), low body mass index in 6 (1.8%) and in contrast, increased body surface area in 10 (26.3%), with combined factors in various patients.

Duration of circulatory assistance ranged between

5 and 68 days, with a median value of 24 days. Twenty-nine patients (76.3%) were transplanted under IABP support, while the remaining 9 patients required transition to more complex assistance with a CentriMag continuous flow device in all cases. Among

these patients, 5 (13.2%) were transplanted, and the other 4 (10.5%) died. Complications during IABP support were local hematoma in 1 patient (2.6%), together with a 5 point drop in the hematocrit not requiring transfusion, catheter rupture in 1 patient (2.6%), evidenced by the presence of blood in the catheter leading to its replacement with rupture confirmation, and loss of radial pulse in 1 patient (2.6%) without decreased temperature, pain or paresthesia, which was managed expectantly with favourable outcome. No patient died during IABP support.

Thirty-two patients (84.2%) were able to sit on the bed, 30 (78.9%) could sit outside the bed, while 26 (68.4%) could ambulate in the unit carrying the device.

Figure 1 shows hemodynamic measurements before and after (6 hours) subclavian IABP implantation, in all cases used using 1:1 assistance.

**Table 1.** General population characteristics

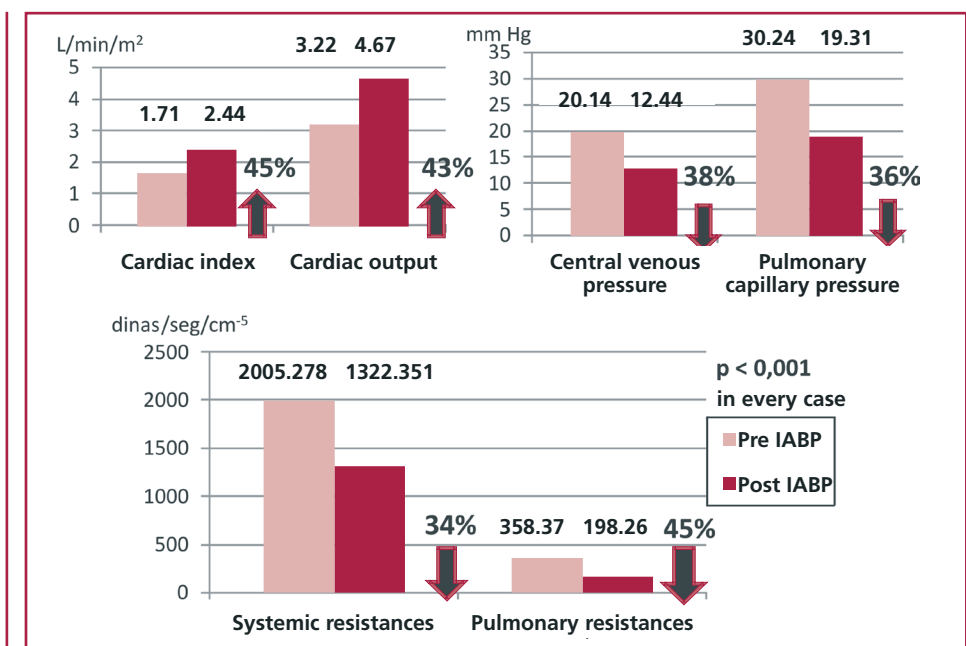
Characteristic	n = 38
Male gender, n (%)	32 (84.2%)
Age, years, median (range)	57.4 (20-65)
Body mass index > 25, n (%)	32 (84.2%)
Body mass index < 18, n (%)	6 (15.8%)
Blood type O, n (%)	13 (34.2%)
Elevated panel reactive antibody, n (%)	22 (57.9%)
Hypertension, n (%)	20 (52.6%)
Diabetes, n (%)	14 (36.8%)
Dyslipidemia, n (%)	13 (34.2%)
Ex-smoker, n (%)	16 (42.1%)
Previous surgery, n (%)	18 (47.4%)
Etiology of ischemic	
necrotic cardiomyopathy, n (%)	20 (52.6)
Idiopathic, n (%)	10 (26.3%)
Valvular, n (%)	5 (13.2%)
Viral, n (%)	2 (5.3%)
Peripartum, n (%)	1 (2.6%)
Functional class IV, n (%)	38 (100%)
Ejection fraction, % (range)	15 (5-30)
Inotropic therapy, n (%)	38 (100%)
Implantable cardioverter defibrillator, n (%)	32 (84.2 %)

**DISCUSSION**

The main findings of our study are that antegrade implantation of IABP support allowed 76.3% of patients to reach heart transplantation directly, stabilizing and supporting for a prolonged period of time initially unstable patients with decompensated heart failure, requiring in all cases inotropic therapy prior to device implantation. Furthermore, most patients with this type of assistance attained a significant level of comfort while awaiting transplantation, evidenced by the number of patients who could sit and even ambulate compared to the compulsory permanent bed confinement in those with retrograde or femoral device implantation.

The obligation of lying permanently in bed is particularly detrimental in patients with end-stage heart

**Fig. 1.** Hemodynamic determinations before and after intra-aortic balloon pump implantation



failure, worsening physical and muscular conditions and thrombotic risk. Moreover, it produces higher rate of infections associated with the femoral access of the catheter and increased possibility of ischemic events due to atherosclerotic disease of the lower limbs, which is exceptional in the upper limbs.

The subclavian access for IABP implantation was originally considered by Kantrowitz, who, in 1967, not long after the first IABP clinical reference, attempted antegrade implantation in a patient in cardiogenic shock with impossible IABP placement through the femoral access, which failed. (2)

Ten years had to elapse before Meyer reported, in 1977, the first successful implant through the subclavian artery, followed by Rubinstein et al in 1984. (4-6)

The possibility of providing support through the subclavian access while awaiting transplantation has been previously postulated. H'Doubler et al. in 2000, published a series of 13 patients assisted between 10 to 86 days, 10 (76.9%) of whom were transplanted, and Cochran et al. in 2002, presented 4 patients with left subclavian implantation, assisted between 12 and 70 days, without any complications and rapid ambulation. (7-8)

Nawar et al. reported the use of subclavian IABP implantation in 16 patients with decompensated heart failure under inotropic treatment and contraindications for left ventricular assist devices. All patients were able to ambulate within the first week of assistance, which lasted between 4 and 59 days. (9)

Estep et al evaluated 48 patients between 2009 and 2011 to compare axillary IABP access (25 cases) with the use of complex devices (23 cases) as bridge to transplantation. Assistance lasted 27 days in the former with a significant reduction of 50% in total direct costs (175,579 vs. 313,602 dollars). As in prior series, ambulation was possible in patients with IABP assistance. (10)

These last two references express certain advantages of IABP implantation as bridge to transplantation even at times when more complex circulatory assist devices are used. IABP avoids a complex surgical procedure with extracorporeal circulation and stereotomy prior to transplantation. The most frequent complications of complex device implantation are massive bleeding with the undesirable need of hemoderivatives, right ventricular dysfunction and vasoplegia, which are reduced in the case of IABP implantation. In addition, device management is simple, not requiring, as in the case of complex devices, a specialized medical team, which significantly reduces associated costs. (11, 12)

An expected prolonged circulatory assistance on the waiting list for heart transplantation implies accepting associated complications. The disproportion between the number of patients included annually in waiting list for heart transplantation, which in Europe and the United States exceeds 3000 cases/year, and the 2000 annual transplants actually performed,

implies prolonged delay. Stevenson has reported that in the period comprised between 2006 and 2011 this delay has doubled in certain stages, extending from less than 30 days to more than 2 months. (13)

The above refers to average values, but there are situations in which these numbers increase, as in the case of blood type O receptors, sensitized patients, certain geographical regions or patients with extreme physical contexture. (14-16)

Another outstanding aspect is the effectiveness demonstrated by IABP to optimize hemodynamic parameters.

Although it is classically accepted that IABP has low hemodynamic effect, with approximately 10 to 20% increase in systolic function parameters, we observed higher values whose explanation merits further analysis.

### Limitations

The present study is a retrospective assessment without randomized comparison with a control group. Neither were nutritional parameters evaluated which could have influenced the results.

### CONCLUSIONS

The results support the use of subclavian IABP as bridge to transplantation in selected patients. Assistance was prolonged, hemodynamic conditions were optimized and complications were scarce providing our population the possibility of sitting and even ambulating.

This could be interesting in settings such as ours that can hardly afford the forbidding costs of complex forms of assistance as bridge to transplantation.

### Conflicts of interest

None declared.

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