Initial experience of intra-aortic balloon pump removal using Angio-Seal

Jan Rychter[1, 2], Krystian Jakimowicz[2], Tomasz Jaźwiec[2], Roch Pakuła[1, 2], Ali Aidibi[2], Witold Bratkowski[1, 2], Jerzy Pacholewicz[3], Tomasz Hrapkowicz[1, 2]

[1]Department of Cardiac, Vascular and Endovascular Surgery and Transplantology, Faculty of Medical Science in Zabrze, Medical University of Silesia, Katowice, Poland
[2]Department of Cardiac Surgery, Heart and Lung Transplantation and Mechanical Circulatory Support, Silesian Centre for Heart Diseases, Zabrze, Poland
[3]Department of Cardiac Surgery, Pomeranian Medical University, Independent Public Clinical Hospital No. 2, Szczecin, Poland

Correspondence to:
Jan Rychter, MD,
Department of Cardiac, Vascular and Endovascular Surgery and Transplantology, Faculty of Medical Science in Zabrze,
Medical University of Silesia in Katowice,
Marii Skłodowskiej-Curie 9,
41–800 Zabrze, Poland,
phone: +48 600 169 529,
e-mail: janrychter@gmail.com

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INTRODUCTION

The Angio-Seal™ vascular closure device (VCD) (Terumo, Tokyo, Japan) uses a biodegradable anchor and a resorbable collagen plug to achieve local hemostasis after cardiac catheterization with arterial sheaths (Figure 1). It can be used as a standalone device in small arterial punctures — up to 8 French (Fr) — or in combination with other VCDs, such as Perclose Proglide, for large arterial punctures. The intra-aortic balloon pump (IABP) is still one of the most commonly used circulatory assist devices in critically ill patients with compromised cardiac function. Manual compression (approximately 15–30 minutes) of the femoral artery is a conventional method for achieving hemostasis after IABP removal. We have limited data on whether the Angio-Seal is effective in removing an IABP [1]. We investigated whether the Angio-Seal could be used safely and achieve hemostasis when removing an IABP.

METHODS

The study was approved by the Local Ethics Committee and was in compliance with the Declaration of Helsinki. We had the following inclusion criteria: patients over 18 years of age, patients with IABP inserted before, during, or after cardiac surgery, and written consent to participate in the study. The exclusion criteria were pregnant women, active IABP site insertion infection or sepsis, IABP therapy duration above 7 days, and patients' inability to make decisions for themselves. Data were collected from a prospective internal registry of patients who had an 8-Fr IABP (Maquet, Rastatt, Germany) placed under ultrasound guidance in the femoral artery position and included 34 consecutive patients treated from January 2018 to December 2021 in the Cardiac Surgery Intensive Care Unit. Most of these devices were placed for acute heart failure deemed to require mechanical circulatory support based on hemodynamic indices and used as a bridge to cardiac surgery (Coronary Artery Bypass Grafting, Orthotopic Heart Transplantation, etc.) or recovery after cardiac surgery procedures (Low Cardiac Output Syndrome). Following device insertion, the patients were most frequently supported initially with 1:1 counterpulsation and anticoagulated with a weight-based bolus of heparin and subsequently started on a weight-based drip to maintain an activated partial thromboplastin time of 50–80 seconds for the duration of device of implantation. Before device removal, all patients were assessed for their ability to tolerate weaning of IABP with trials of 1:2 and 1:3 augmentation. If weaning was tolerated, 1:1 augmentation was resumed, and anticoagulation was discontinued 2 hours before device removal.

All patients were treated at the bedside by properly trained cardiac surgeons. First,

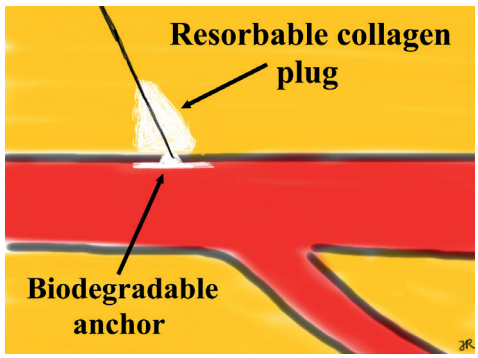

Figure 1. Angio-Seal device components

the IABP console was placed on the "standby" mode to fully extract helium from the catheter. Next, the skin site of entry was sterilely scrubbed with caution, and the sutures holding the IABP catheter were cut and removed, then the IABP was removed leaving a dedicated 8-Fr IABP sheath. The sheath was replaced with an Angio-Seal dedicated sheath with a guide wire (0.038 inches). The Angio-Seal sheath was inserted into a suitable position. After determining the correct position of the sheath, the insertion system was introduced through the sheath, and an anchor was placed against the inner arterial wall. By retracting the entire device, the anchor and collagen sponge were drawn together, sandwiching the arteriotomy, and the collagen sponge was then tamped further down onto the outer arterial wall by a plastic tube. Controlled tension on the collagen was taken for the time needed to stop the oozing of blood. If needed, additional 5-minute manual compression was applied. Finally, a sterile wound dressing was applied to the puncture site, and the patient was required to remain in bed for 2 hours. In the case of device failure, a 15-minute manual compression was applied, followed by 6 hours of immobilization. An ultrasound scan of the groin was performed one day after the procedure to assess the effectiveness of closure and the presence of any complications. If the IABP did not want to go through the IABP sheath (due to insufficient deflation of the balloon), a proper guidewire was placed and the IABP with its dedicated sheath was removed as one. Then an Angio-Seal dedicated sheath was inserted as described above.

The primary safety endpoint was the composite incidence of major vascular injuries requiring surgical or interventional repair (acute access site bleeding, hematoma >5 cm, pseudoaneurysm, arteriovenous fistula, arterial/venous thrombosis or stenosis, and new lower extremity ischemia), access site bleeding requiring transfusion, access site nerve injury requiring intervention and access site infection requiring intravenous antibiotics or a prolonged hospital stay. The secondary safety endpoint was the composite incidence of minor vascular injuries including arteriovenous fistula, hematoma <5 cm, access site bleeding (oozing) without the need for surgical intervention, transient lower extremity ischemia, and ipsilateral deep venous thrombosis. The primary efficacy endpoint was device success, which was defined as successful hemostasis by using the Angio-Seal device alone or after <5 min of adjunctive compression and freedom from major vascular complications, as listed above. The secondary efficacy endpoint was the procedural success on discharge, which was defined as attainment of final hemostasis by using any method and freedom from major vascular complications.

Statistical analysis

Normally distributed continuous variables were presented as means, standard deviations, medians, first quartiles (Q1) and third quartiles (Q3). Categorical variables were expressed as numbers (n) and percentages (%). Statistical analyses were performed using IBM SPSS Statistics version 29 for Windows (IBM, Armonk, NY, US).

Table 1. Device safety and efficacy

IABP indications, n (%)	
Myocardial infraction/cardiogenic shock	16 (47.1%)
Hemodynamic instability/cardiogenic shock	14 (41.1%)
Low cardiac output syndrome/cardiogenic shock	4 (11.8%)
IABP timing, n (%)	
Preoperative implantation	14 (41.1%)
Intraoperative implantation	16 (47.1%)
Postoperative implantation	4 (11.8%)
IABP support (days), mean (SD)	4.29 (1.14)
Device success, n (%)	32 (94.1%)
Time to achieve hemostasis after Angio-Seal deployment (minutes), median (Q1, Q3)	2 Q 1 — 1 Q 3 — 3
Procedural success, n (%)	34 (100%)
Device-related deaths, n (%)	0 (0%)
Major vascular complications, n (%)	0 (0%)
Acute access site bleeding	0 (0%)
Pseudoaneurysm	0 (0%)
Hematoma >10 cm	0 (0%)
Arteriovenous fistula	0 (0%)
New lower extremity ischemia	0 (0%)
Access site bleeding requiring transfusion	0 (0%)
Access site infection	0 (0%)
Access site nerve injury	0 (0%)
Minor vascular complications, n (%)	3 (8.8%)
Transient lower extremity ischemia	0 (0%)
Deep venous thrombosis	0 (0%)
Arteriovenous fistula	0 (0%)
Access site bleeding (oozing)	2 (5.9%)
Small hematoma <5 cm	1 (2.9%)

Continuous data were presented as means (standard deviations [SD]) and medians (first quartiles [Q1], third quartiles [Q3]); categorical data were given as n (%)

Abbreviation: IABP, intra-aortic balloon pump

RESULTS AND DISCUSSION

There were no procedure-related deaths or major vascular complications during the study. Minor vascular complications occurred in 3 (8.8%) patients including blood oozing (2 patients) treated by manual compression for 15 and 20 min and small hematoma <5 cm (1 patient). No arteriovenous fistulas, transient lower extremity ischemia, or ipsilateral deep venous thrombosis were observed (Table 1). Device failure occurred in 2 cases, so the overall success rate was 94.1% (32/34). In both cases, after primary Angio-Seal closure, there was blood oozing from the groin, which was successfully treated with conventional manual compression (in the first 2 patients, 10 minutes and 15 minutes). Both patients were male with hypertension, diabetes, overweight, and IABP support for 5 days. One of these patients developed a small 3 cm hematoma that was treated conservatively. Therefore, the procedure success rate (including hemostasis by any means without occurrence of major complications) in the 34 patients was 100%.

As far as we know, this is the first report of IABP removal using the Angio-Seal device in a series involving more than 30 patients. Kato et al. described in 2006 the usefulness of the 8 Fr Angio-Seal in the removal of an 8 Fr IABP in 11 patients and 7 Fr in 5 patients. The IABP counterpulsation was continued for 1–5 days (mean 2.7 days). The time-to-hemostasis was 2–5 min (mean 3.3 min), and no patient developed any major bleeding, vessel occlusion, or required vascular surgery. The results of our study are comparable [1]. We achieved a device success rate of 94.1% and a procedure success rate of 100% for hemostasis using the Angio-Seal device. In addition, there were no major and only a few minor complications, and all of them did not require surgical or endovascular treatment. We also found the time to achieve hemostasis to be shorter compared to the previous study [1].

In many studies, the Angio-Seal device allowed for shortening time-to-hemostasis and ambulation compared to conventional manual compression techniques after cardiac catheterization. Vascular complication rates are similar for Angio-Seal and manual compression [2]. So far, no randomized trials have compared VCD and manual compression for removing IABP. Some authors demonstrated that vascular closure with the Angio-Seal device following high-risk percutaneous coronary intervention with intra-aortic balloon hemodynamic support was safe and feasible [3]. Similarly, our results confirm the safety and efficacy of the Angio-Seal device in patients with 8 Fr introducer sheaths during the femoral catheterization procedure. However, our study differed from that earlier study [3]. We used the Angio-Seal device in patients who received IABP support, but had not yet been systematically examined. Moreover, the closure procedure was not performed at the catheterization theatre but at the bedside, and not immediately after the procedure but 2–7 days later.

The limitation of our study is a relatively small group of patients, and despite the prospective nature, the study was not randomized. In addition, the indication for manual compression or Angio-Seal deployment was not standardized and the decision was individually undertaken by the operator so the success rate of this procedure may partly depend on the operator's skill. Further studies are necessary to elucidate the safety and full benefits of utilizing the Angio-Seal device in this patient population and to recommend its routine use in the removal of an IABP. The Angio-Seal VCD is effective for hemostasis after IABP procedures using 8-Fr femoral sheaths. However, randomized controlled trials are needed to be able to compare manual compression and Angio-Seal VCD in these clinical settings.

Article information

Conflict of interest: None declared.

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