Single Center Experience Of Removal Intra Aortic Balloon Pump With Angioseal

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Aim of study and methods

Due to great experience with the Angio-Seal device in our centre to close femoral puncture during transcatheter aortic valve implantation we investigated whether the Angio-Seal could be used safely and could achieve haemostasis rapidly when removing an intra-aortic balloon pumps (IABP) in patients after cardiac surgery.



Description of the Angio-Seal device
Introduction of a dedicated wire in the artery, followed by the insertion of a percutaneous closure device with an arteriotomy locator. The device creates a mechanical seal by sandwiching the arteriotomy between a bioabsorbable anchor and collagen sponge, which dissolve within 60 to 90 days.

Aim of study and methods

- We prospectively studied 32 consecutive patients in whom the Angio-Seal 8 Fr device was planned to be used to achieve vascular haemostasis after removal of an 8 Fr IABP from January 2018 until December 2020 in the cardiac surgery intensive care unit.
- In first step we remove IABP, then a guidewire was inserted through the sheath and were removed.
- The Angio-Seal sheath was inserted through the attached guidewire and was deployed with the usual steps.
- Finally, we maintained controlled tension of the collagen seal for approximately 20 seconds, and it was taken off in the absence of oozing of blood.

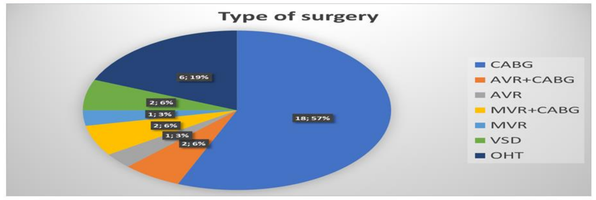
Aim of study and methods

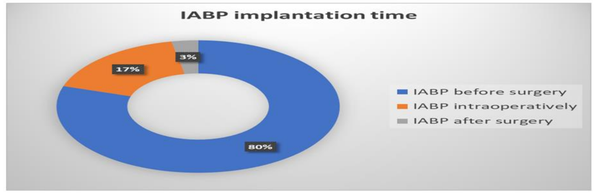
- The primary endpoint was a composite of any type of major and minor vascular complications.
- We defined major vascular complications as:
  - retroperitoneal bleeding, vessel occlusion, loss of distal pulse, massive bleeding, vascular surgery and device related death.
- We defined minor vascular complications as:
  - hematoma, AV fistula or pseudoaneurysm.
- The secondary endpoint were successful technical deployment of the device and immediate hemostasis without the need for additional treatment by manual compression.
- Technical success was defined as successful deployment of the device with immediate hemostasis achieved by the absence of bleeding immediately after the application of the closure device.

Baseline clinical characteristics of study cohort

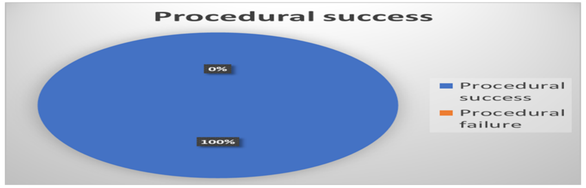
Variable	Angio-Seal IABP removal patient cohort (n=32)
Age [years]	58±7.0
Gender [male]	65.6%
Ejection fraction [%]	35±20.5
EuroSCORE II	6.7±2.64
Glomerular filtration rate (GFR) [mL/min]	57.07±18.58
Heart failure	30%
Unstable angina	70%
Acute myocardial infraction	56,2%
Diabetes mellitus	65,6%
Hypertension	71,8%
Hyperlipidemia	48%
Smoking	61,1%

Baseline clinical characteristics of study cohort





Procedural characteristics



Variable	Angio-Seal IABP removal patient cohort (n=32)
Procedural time [minutes]	3,5±2.2
IABP therapy [days]	4±3
Aspirin 75mg	78,1% (n=25)
Clopidogrelum 75mg	78,1% (n=25)
Unfractionated heparyn iv	100% (n=32)
APTT at the moment of IABP removal	50±7,9
Manual compression after IABP removal	0%

In-hospital outcomes

Variable	Angio-Seal IABP removal patient cohort (n=32)
Major vascular complications:	
Retroperitoneal bleeding	0%
Vessel occlusion	0%
Massive bleeding	0%
Vascular surgery	0%
Device related death	0%

Variable	Angio-Seal IABP removal patient cohort (n=32)
Minor vascular complications:	
Hematoma	6,25% (n=2)
Arteriovenous fistula	0%
Pseudoaneurysm	0%

Conclusions

- Removal of IABP with the Angio-Seal 8 Fr device is a fast, effective, and safe procedure that could improve the haemostasias and the comfort of patients compared with manual compression or other compression devices.
- We need further studies comparing Angio-Seal with conventional methods of compression to recommend routine use.