

Pressure ulcer: an unreported complication of the Safeguard[®] hemostasis device. No need to crack under pressure

Claudio Moretti, Giorgio Quadri, Fiorenzo Gaita, Imad Sheiban

Interventional Cardiology, Division of Cardiology, University of Turin, Turin, Italy

Abstract

Diagnostic cardiac catheterizations are predominantly performed using the femoral artery access. Several devices have been developed to aid in the closure of femoral arteriotomy.

Safeguard[®] is a new pneumatic compression device that has been developed for compression of the femoral artery after brief manual compression. We hereby report the case of an elderly patient who underwent a percutaneous coronary intervention *via* the femoral artery in whom a Safeguard[™] device, left overnight because of persistent oozing, provoked an extensive pressure ulcer. Knowledge of this potential complication is important to minimize its occurrence and provide appropriate treatment.

Correspondence: Claudio Moretti, Division of Cardiology, University of Turin, San Giovanni Battista "Molinette" Hospital, Corso Bramante 88-90, 10126 Turin, Italy.
Tel. +39.011.6334195 – Fax: +39.011.6967053.
E-mail: drclamore@yahoo.it

Key words: cardiac catheterization, closure vascular access, femoral closure device, vascular access complication.

Contributions: CM, GQ, FG, IS, manuscript conception and design, data acquisition, analysis and interpretation, manuscript revision and final approval.

Conflict of interest: the authors report no conflicts of interest.

Received for publication: 7 May 2011.

Revision received: 28 May 2011.

Accepted for publication: 30 May 2011.

This work is licensed under a Creative Commons Attribution NonCommercial 3.0 License (CC BY-NC 3.0).

©Copyright C. Moretti et al., 2011
Licensee PAGEPress, Italy
Heart International 2011; 6:e3
doi:10.4081/hi.2011.e3

Introduction

The femoral approach is still the most commonly used route for diagnostic cardiac catheterizations and percutaneous coronary interventions. At the end of the procedure the femoral artery is usually compressed manually to control bleeding until hemostasis is achieved. Local vascular complications such as bleeding and hematoma are not uncommon, ranging from less than 1% to 12%.^{1,2}

Many devices have been developed to aid in the closure of the femoral arteriotomy, including the VasoSeal[®] (Datascope Inc., Montvale, NJ, USA), AngioSeal[®] (St. Jude Medical Devices, Minneapolis, MN, USA), the Starclose[®] clip closure system (Abbott Vascular, Redwood City, CA, USA), and the Perclose[®] (Perclose, Redwood City, CA, USA) suture-mediated closure system. In two recent meta-analyses^{3,4} these devices have proven their efficacy in significantly reducing time to hemostasis while simultaneously improving patient comfort.

Vascular closure devices should be avoided or used with caution with non-common femoral artery sheath location, small femoral artery size, bleeding diathesis, morbid obesity, inflammatory disease, uncontrolled hypertension and in the presence of significant peripheral vascular disease, especially with calcification.

In an attempt to reduce local complications, inflatable compression devices such as the FemoStop[®] (RADI Medical System AB, Uppsala, Sweden) and the Safeguard[®] (Datascope Corp., Fairfield, NJ, USA) (Figure 1) have thus been developed for compression of the femoral artery and are now in use in some centers because they are well accepted by the nursing staff.

We hereby report a clinical experience describing a significant complication occurring after Safeguard[®] use for femoral hemostasis. In this case, an extensive pressure ulcer developed in the groin of a very elderly patient in whom a Safeguard[®] had been applied overnight because of persistent oozing after diagnostic coronary angiography.

Case Report

A 95-year old diabetic female was referred to our catheterization laboratory for workup of percutaneous aortic valve replacement because of a severe calcified aortic stenosis and pronounced dyspnea on effort. The diagnostic angiogram was performed *via* the right femoral artery. The patient was anesthetized locally with 2% lidocaine and the femoral artery cannulation and placement of a 6 Fr introducer sheath (Cordis, Miami, FL, USA) were performed by the usual technique without complications. Angiography disclosed a significant stenosis of the mid tract of the right coronary artery which was treated with a 3.5×18 mm bare metal stent dilated at up to 20 ATM, achieving a good final angiographic and clinical result.

Three hours after the procedure, when a check of the activating clotting time showed a value of 150 sec, the sheath was removed and manual compression was performed. After achieving hemostasis, a 24 cm Safeguard[®] pressure assisted device was positioned in the point of maximum femoral pulse and inflated with 40 ml of air, as recommended in the device package insert. No bleeding or oozing was found after manual compression or shortly after positioning the Safeguard[®].

Two hours later the Safeguard[®] bulb was deflated but a persistent oozing was observed. It was, therefore, reinflated with 20 mL. Similarly, 4 h after positioning the Safeguard[®] another deflation attempt was performed, but oozing was still present and the device was again inflated with 20 mL of air, and kept overnight. Since the volume of inflated air was significantly lower than recommended, the nurse did not deflate the bulb every 2 h as suggested by the Safeguard instructions. In the early morning of the following day, the device could be removed without any evidence of oozing or bleeding. Nonetheless, a circular area of non-blanchable erythema was observed which developed into a pressure ulceration two days after (Figure 2), with partial-thickness loss of dermis. The lesion was treated with frequent irrigations of saline solution, gentle manual debridement and hydrocolloid-based dressings

(3M TegaSorb®, Minneapolis, MN, USA) and resolved without any need for systemic antibiotics in a week, leaving, however, a minor scar.

Discussion

The 24 cm Safeguard® pressure-assisted device is a disposable device with a clear polyurethane bladder and a pressure sensitive self-adhesive peel backing. A luer valve enables a syringe to be connected to the device in order to inflate the central bladder with air to provide pressure to the puncture site. Adverse effects reported by the manufacturer that may result from the use of this device include hematoma, local bleeding, pseudoaneurysm and arterio-venous fistula; all complications associated with bleeding.

To date, only a single prospective, non-randomized, multicenter study⁵ has been conducted in 101 low-risk patients to evaluate the safety and effectiveness of the Safeguard® space. The device proved to be effective in reducing active compression time without increasing risk in patients undergoing diag-

nostic and interventional procedures.

The case report described here highlights how such a device, despite its inherently favorable features including user friendliness for staff, may seriously harm a patient if the instructions for use are not meticulously followed.

Given its inherent mechanical pressure properties, it is absolutely mandatory to deflate the bulb of the device every 2 hours to allow for capillary refill in accordance with the device instructions. Even if long-term harm to the patient could be avoided, thus leading to an acceptable final cosmetic result, greater harm could have been caused, possibly with potentially dire medico-legal implications (e.g. in the case of groin skin damage in a younger woman).

Conclusion

Vascular access complications are amongst the most common adverse events associated with coronary angiography and intervention. A number of devices are available to aid in

achieving post-procedure homeostasis. Information on vascular complications from access of the femoral artery, the methods of arterial closure, and post-procedural care instructions (including avoidance of lengthy mechanical pressure with pneumatic devices) can help physicians and nurses to provide safe and effective care to patients after cardiac catheterization.

References

1. Applegate RJ, Sacrinty M, Kutcher MA, et al. Propensity score analysis of vascular complications after diagnostic cardiac catheterization and percutaneous coronary intervention 1998-2003. *Catheter Cardiovasc Interv* 2006;67:556-62.
2. Piper WD, Malenka DJ, Ryan TJ Jr, et al. Predicting vascular complications in percutaneous coronary interventions. *Am Heart J* 2003;145:1022-9.
3. Koreny M, Riedmuller E, Nikfardiam M, et al. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization systematic review and meta-analysis. *JAMA* 2004; 291:350-7.
4. Nikolsky E, Mehran R, Halkin A, et al. Vascular complications associated with arteriotomy closure devices in patients undergoing percutaneous coronary procedures: A meta-analysis. *J Am Coll Cardiol* 2004;44:1200-9.
5. Roberts A, Collins J, Harlamert E, et al. Safeguard manual assist technique: the SMAT Study. *Cath Lab Digest* - June 2008. Available from: <http://www.cathlabdigest.com/article/8818>



Figure 1. The Safeguard® 24 cm pressure assisted dressing.



Figure 2. Right groin's extensive (12x9 cm) pressure ulcer with loss of epidermis and dermis.