



**RESEARCH ARTICLE**

**A KAOLIN-BASED HEMOSTATIC GAUZE AS AN ADJUNCTIVE TOOL FOR BLEEDING CONTROL AFTER VASCULAR CLOSURE DEVICES USE IN TAVI PATIENTS**

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Hemostasis; Kaolin-based gauze; Vascular closure Device; TAVI

**ABSTRACT**

**Objectives:** To assess effectiveness of minor bleeding control with a kaolin-based hemostatic gauze after vascular closure devices (VCDs) use in patients undergoing transcatheter aortic valve implantation (TAVI).

**Background:** Large arterial sheath size use in TAVI pts may lead to major vascular complications and bleeding. New hemostatic dressings have been developed and there is a growing interest in their potential applications.

**Study Design:** Prospective, single center study. Methods: Forty-five patients (56% men, mean age 82.7±5) underwent TAVI by femoral approach with a mean sheath size of 18.3±1.3 F (18/19 F=89%; 22/24 F=11%). Patients were on aspirin (90%), aspirin + clopidogrel (7.5%) or LMWH (2.5%).

**Results:** Mean ACT value was 180±24 seconds. Femoral hemostasis was achieved with a double suture-based VCD deployment in 30 (67%) patients or a double VCD with cross-over balloon inflation in the remaining 15 (33%) patients. Bleeding after VCDs occurred in 15 (33%) pts. The kaolin-based dressing, activates the intrinsic blood coagulation pathway thus allowing for a short manual hemostasis period. The gauze was applied for 3 minutes above the puncture site obtaining complete and fast bleeding control.

**Conclusions:** The kaolin-gauze demonstrated to be effective in minor bleeding control after large arterial sheath removal with a VCD.

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**INTRODUCTION**

Vascular closure starts with a correct arterial access. Access site complications are the single greatest cause of morbidity after percutaneous femoral procedures.

In a recent review by de Jaegere *et al* [1], a full evaluation of predictors and implications of access site complications after transfemoral transcatheter aortic valve implantation (TAVI) was performed. Transfemoral TAVI resulted in a >10% incidence of major vascular-related complications. A considerable number of these events was related to arteriotomy closure failure [2]. Preclosure of the arterial access site [3], crossover balloon occlusion [4] and modified crossover technique [5] which enables the passage of a balloon through left radial access and inflation in the proximal iliac artery to allow percutaneous closure in a clean field, have also been described. In recent years, new hemostatic dressings have been developed to control heavy bleeding [6-7]. **Aim** of our clinical

evaluation was to assess the positive effect of an adjunctive external haemostatic tool such as QuikClot™ Interventional gauze (Z-Medica, Wallingford, CT) at the femoral arterial percutaneous site after single Vascular Closure Device (VCD)/preclosure technique with two suture-mediated VCDs helping to decrease bleeding and net adverse clinical events (NACE) in patients undergoing TAVI.

**Device description**

QuikClot™ Interventional Hemostatic Bandage is a non-woven coated gauze. Each dressing is a multiple-ply 1.5 in. × 1.5 in. × 0.5 in. rayon/polyester construction coated with kaolin. Kaolin is an aluminum silicate, a very potent coagulation initiator that acts as a surface activator.

Its inert characteristics allow for no skin allergies at the site of application. The gauze is stable after opening the external aluminum envelop. It is absorbent and has good clotting ability.

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This advanced clotting gauze is a Food and Drug Administration (FDA) and CE cleared device.

### Technical specifications

The method for QuikClot™ use after TAVI arterial femoral access management is as follows: 1) preclosure technique utilizing two Proglide devices (Perclose, Abbott Vascular, Redwood, California, USA); 2) additional cross-over balloon technique applicable; 3) apply a firm manual compression on the femoral artery with the QuikClot™ Interventional Bandage above the entry site 2) maintain a firm compression for 3 minutes; 3) leave the QuikClot™ over the access site and cover it with a non-compressive dressing; 4) check the groin at 15 min, 1, 4 and 12 h.

### Safety and effectiveness report

The first Italian safety study for oozing and bleeding control after percutaneous transfemoral aortic valve replacement (TAVI) was performed at the Centro Cardiologico Monzino in Milan, Italy, between January and December 2012. Forty-five consecutive patients (56% male, mean age  $82.7 \pm 5$  years) underwent TAVI (Edwards-Sapien XT =31; Medtronic CoreValve=14) by femoral approach with a mean arterial sheath size insertion of  $18.3 \pm 1.3$  F (18/19 F=89%; 22/24 F=11%). Patients were on aspirin (90%), LMWH (2.5%) or aspirin + clopidogrel (7.5%). Access site hemostasis was achieved with a suture-based technique using a double Proglide deployment in 30 (67%) patients or a double Proglide technique associated with cross-over balloon inflation to obtain a superior bleeding control in the remaining 15 (33%) pts. Bleeding after suture-based hemostasis occurred in 15 (33%) pts (minor bleedings: 12; major bleedings: 3, according to the Bleeding Academic Research Consortium (BARC) classification [8]. QuikClot™ interventional gauze was firmly applied over the access site in all the 12 cases of minor bleeding after Proglide implantation, obtaining complete and fast bleeding control (mean compression time  $2.3 \pm 1.8$  min).

### DISCUSSION

Transcatheter aortic valve implantation (TAVI) has given hope to aortic stenosis patients who were previously deemed inoperable. However, despite advancement in technology, large arterial sheath size use may lead to major vascular complications and bleeding requiring blood transfusion. Major bleeding leading to transfusion translate into longer overall in-hospital stay, as well as increased rates of recurrent ischemia and death. However, there is a paucity of outcome data in the literature with regard to major adverse events and bleeding with use of VCDs in elderly patients with aortic stenosis undergoing TAVI. A full evaluation of predictors and implications of access site complications after transfemoral transcatheter aortic valve implantation has been performed [1]. In the patient cohort with a completely percutaneous access strategy, major vascular complications and life-threatening/disabling bleedings were related to closure device failure in 64% and 29%, respectively. Transfemoral TAVI resulted in a >10% incidence of major vascular-related complications. A considerable number of these events was related to arteriotomy closure failure. Female gender and use of >19Fr system were independent predictors for major vascular

complications. Female gender (odds ratio 2.04, 95% confidence interval 1.31 to 3.17), use of >19Fr system (1.86, 1.02 to 3.38), peripheral arterial disease (2.14, 1.27 to 3.61), learning effect (0.45, 0.27 to 0.73), and percutaneous access strategy (2.39, 1.16 to 4.89) were independently associated with life-threatening/disabling bleedings. More encouraging data were presented by O'Neill *et al* [9] in a recent retrospective observational study to compare the effects of hemostasis with VCDs versus manual compression after TAVI. In this analysis vascular closure was associated with a significant reduction in NACE (24.5% vs 10%,  $p < 0.001$ ). However, occurrence of bleeding after suture-based femoral artery closure has been observed in a range of 18-24% of cases, thus requiring additional manual compression for several minutes. Earlier preliminary clinical evaluation in the interventional cardiology field showed QuikClot Interventional Hemostatic Bandage to be an easy to use and effective device that assists in achieving a short-term passive hemostasis [10]. This availability of an alternative technique to standard manual or mechanical compression, with an advanced clotting time, allows for a shorter and painless hemostasis procedure and for an additional tool in bleeding control when large size sheaths are removed.

### CONCLUSIONS

Suture-based devices deployment for large arterial sheath removal may be associated with prolonged cutaneous or minor bleeding, especially in anticoagulated pts. QuikClot Interventional Hemostatic Bandage tested after transfemoral Aortic valve replacement demonstrated to be safe and effective in reducing compression time and preventing oozing or bleeding after large sheath removal with a suture vascular device.

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