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ORIGINAL ARTICLE

# Favorable Single-Operator Experience with *VasoSeal*, a Vascular Closure Device with Extravascular Collagen in a Large High-Risk Cohort of Patients Undergoing Percutaneous Coronary Interventions

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**KEY WORDS:** *cardiac catheterization; coronary angiography; transfemoral technique; vascular closure device; VasoSeal; percutaneous coronary intervention*

**Abbreviations**
PCI = percutaneous coronary intervention
VCD = vascular closure device
ACS = acute coronary syndrome(s)

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**ABSTRACT**

**BACKGROUND:** Prolonged duration of manual or mechanical compression at the site of femoral artery access after sheath removal upon completion of coronary procedures followed by extended period of bed rest has significant logistical and practical problems for both patients and hospital staff. The availability of vascular closure devices (VCDs) has ushered in a new era in the routine clinical practice in the catheterization laboratory.

**AIM:** The aim of this prospective study was to assess the effectiveness and safety of the use of the VCD VasoSeal, a collagen plug, in patients undergoing cardiac catheterization and/or percutaneous coronary intervention (PCI).

**PATIENTS AND METHODS:** VasoSeal was employed over 2.5 years in 388 consecutive patients mostly presenting with acute coronary syndromes and subjected mainly to PCI procedures performed via transfemoral arterial access. All the patients who underwent PCI were given 7,000 IU of heparin intravenously during the procedure and had been receiving or were acutely loaded with dual antiplatelet therapy (aspirin and clopidogrel). The majority (90.7%) of patients also received a platelet glycoprotein IIb/IIIa inhibitor during and for 12-14 hours after the procedure. The sheaths were removed at the end of the procedure and hemostasis achieved with VasoSeal.

**RESULTS:** Deployment of the VCD was successful in 99.2%. Complete hemostasis without bleeding or hematoma was obtained in 95.4% of cases (370/388). In 3 patients VasoSeal could not be or was partially deployed. The mean time required for the placement of VasoSeal was 1 min. The mean time-to-hemostasis was 3 min. The mean time-to-mobilization was 3 hours. Only one patient developed a pseudoaneurysm of the right common femoral artery; the lesion was treated with ultrasonography -guided compression. In addition, 16 small local hematomas and 2 large inguinal hematomas (one requiring blood transfusion) were recorded. In 2 cases retroperitoneal bleeding occurred, requiring blood transfusion in one of them. Local infection (cellulitis) responding to antibiotic treatment was observed in 2 patients. No patient required local surgical intervention.

Conflict of Interest: none declared

**CONCLUSION:** VasoSeal was a safe collagen closure device characterized by a high success rate of deployment and highly successful hemostasis with few manageable complications in a very high-risk patient cohort undergoing PCI under heavy anticoagulation and antiplatelet drug therapy. In these patients this vascular closure device reduced the time-to-hemostasis and time-to-mobilization and the incidence of complications.

## INTRODUCTION

Vascular closure devices (VCDs) play an increasingly important role in the catheterization laboratory during percutaneous coronary interventional (PCI) procedures as an alternative to manual or mechanical compression.[1,2] Their use aims at combined expedience, safety, patient convenience and early mobilization, and reduced hospital resources and costs. Initial experience in our laboratory with such a device involved use of the extravascular VCD, VasoSeal (Datascope Corporation, Mahwah, NJ, USA) for femoral artery puncture site closure and hemostasis. VasoSeal is an extravascular VCD that achieves hemostasis via collagen-mediated thrombotic closure at the puncture site.[3] No material is left within the artery and delivery is quite expedient. It accommodates various vessel sizes, and the presence of existing peripheral vascular disease does not preclude its use. Fluoroscopy is not required to confirm or guide access site location. Several studies have documented both its effectiveness and safety,[3-7] albeit some have suggested a relatively higher risk of local complications in the setting of PCI.[1,8-11]

## PATIENTS AND METHODS

Over 2.5 years, 388 consecutive patients, mostly with an acute coronary syndrome (ACS), were submitted to cardiac catheterization via a transfemoral approach by a single operator in order to perform coronary angiography and PCI. This was the group that was catheterized during the period when a vascular closure device became available in our catheterization laboratory to use for obtaining local hemostasis. Patients were excluded when transfemoral access was deemed problematic or impossible due to peripheral vascular disease, requiring a radial or brachial approach. The study was ended when a newer VCD became available and local hemostasis was continued with use of the new device. Procedures were performed 12 years ago at two institutions with (n=25) or without (n = 363) cardiac surgery backup. Vascular surgery back-up was available at both institutions. An informed written consent was obtained from each patient before the procedure.

Arterial access was routinely obtained via the right femoral artery and occasionally via the left femoral artery in cases where vascular access problem was anticipated or encountered from the right femoral artery or when repeat access was required at a short period after a right inguinal puncture. Selection of the entry site was guided by a combination of anatomical landmarks. Usually, the artery was entered 2 to 3 cm below the midpoint of the inguinal skin crease or at the midpoint between the anterior superior iliac spine and pubic tubercle, guided by palpation of the maximal arterial pulse. A modified Seldinger technique was used for arterial access and sheath insertion.

A 6 French femoral sheath was routinely used except when a demanding PCI procedure was planned, in which case a 7 French sheath was employed. After arterial access was secured, 2,500 U of intravenous unfractionated heparin was given. When after completion of coronary angiography a decision was made to proceed with adhoc PCI, an additional 7,000 U of heparin were administered. When feasible, activated clotting time (ACT) was monitored during the PCI procedure and maintained at ≥300 sec with adjusted heparin doses or additional 2,000 U of heparin were administered every 1 hour during prolonged procedures. All patients had received dual antiplatelet therapy with aspirin and clopidogrel prior to catheterization usually with a loading dose (500 mg and 300 mg, respectively) provided upon admission for those with ACS. As the majority of patients presented with ACS, they also received a glycoprotein IIb/IIIa inhibitor during the PCI procedure. All three IIb/IIIa agents were available for use. Abciximab was given at a loading dose of 0.25 mg/kg IV followed by maintenance dose of 0.125 mcg/kg/min IV infusion for 12 hours; eptifibatide was given at one loading dose of 180 mcg/kg, followed by maintenance dosing at 2 mcg/kg/min for 24 hours; tirofiban infusion was given at an initial dose of 0.4 mcg/kg/min for 30 minutes, then reduced to 0.1 mcg/kg/min which was continued for 24 hours.

When the procedure was completed, reversal of the effect of heparin was not performed. For manual compression, the sheath was removed when the ACT was <200 sec. However, when the vascular closure device was used, the sheath was removed immediately without checking the ACT.

### VASCULAR CLOSURE DEVICE

The VasoSeal (Datascope Corporation, Mahwah, NJ, USA) vascular closure device is totally extravascular, delivering purified bovine collagen into the tissue tract created by the removal of the femoral sheath (Figure 1). It achieves hemostasis via collagen-mediated thrombotic closure at the puncture site. Fluoroscopy is not required to guide its deployment. A sterile dressing is applied afterwards at the entry site and pressure is applied for ~5 minutes.

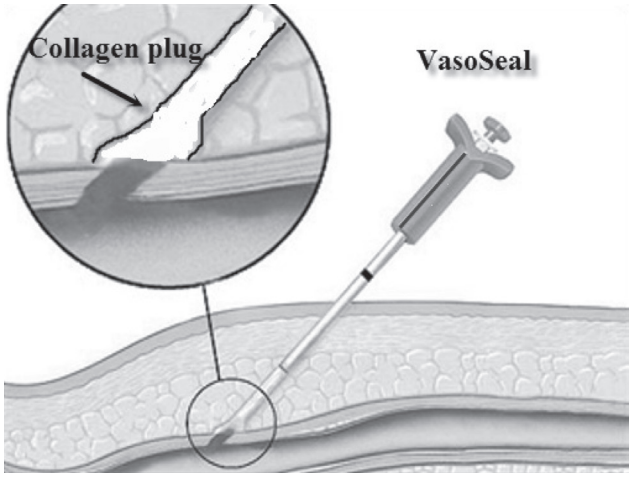


**FIGURE 1.** VasoSeal was an extravascular collagen plug delivered to the entry site. First the dilator and the sheath ensemble were advanced over the guidewire to prior demarcated depth at the outer border of the femoral artery at the entry site; then the dilator was removed and the collagen plug was injected through the sheath into the skin tract while simultaneously withdrawing the delivery apparatus thus sealing the arteriotomy site with resultant hemostasis. The device was suitable for use with 5-8 French sheath sizes.

An attempt was made to record the time to hemostasis and to ambulation after the deployment of the VCD. Complications were recorded in every patient when it occurred. All data were collected prospectively. All patients were followed closely until discharge.

The occurrence of a pseudoaneurysm, arterio-venous fistula, arterial thrombosis, need for vascular surgery, retroperitoneal bleed, local abscess, bleeding or large hematoma at the puncture site requiring transfusion, or in-hospital death were considered as major complications. Routine duplex ultrasound was not performed to check the puncture site unless there was a clinical suspicion of a pseudoaneurysm or a fistula. A minor complication was defined as a localized allergic reaction or cellulitis or a hematoma not requiring transfusion. Failure to deliver the collagen to the puncture site was recorded as VCD deployment failure.

### STATISTICS

Data are presented as descriptive statistics with use of mean ± standard deviation and/or percentages.

## RESULTS

A total of 388 consecutive patients (63 women) receiving a VCD were included in the study, with a mean age of 59.8±10.8 years (range 33-87 years) (Table 1). Diabetes mellitus was present in 92 (24%) patients. The majority (n=354, 91.2%) were patients admitted with an ACS. A total of 381 (98.2%) patients underwent a PCI procedure, which was performed adhoc (during the same session as coronary angiography) in 267 (70%) patients. PCI was performed on a mean number vessels of 1.22±0.45 with a mean of 1.8±0.96 lesions dilated and/or stented. Stents were used in 356 (93%) patients; bare metal stents in 195 (54%) patients, endothelial progenitor cell capture stents in 145 (41%) patients; and drug-eluting stents in 16 (5%) patients. The mean left ventricular ejection fraction was 52.5±8.9% (range, 20-80%). A platelet glycoprotein IIb/IIIa inhibitor was administered in 352 (90.7%) patients.

The right femoral artery was accessed in 382 patients and the left femoral artery in 6 patients. Successful VCD deployment was achieved in 385 (99.2%) patients. In one patient insertion of the device failed completely, while in the other two there was incomplete deployment and in all three cases, manual compression was applied.

The mean time required for the placement of VasoSeal was 1 min. The mean time-to-hemostasis was 3 min. The mean time-to-mobilization was 3 hours.

**TABLE 1.** Characteristics of Patients Receiving the Vascular Closure Device (VasoSeal)

| | |
|---|---|
| Patients | 388 |
| Female | 63 |
| Age (years) | 59.8±10.8 |
| Acute coronary syndrome | 354 (91.2%) |
| Left ventricular ejection fraction (%) | 52.5±8.9 |
| Access | |
| RFA | 382 |
| LFA | 6 |
| Procedure | |
| PCI | 381 |
| CATH | 7 |
| Adhoc PCI | 267 (70%) |
| PCI | |
| Number of vessels | 1.22±0.45 |
| Number of lesions | 1.80±0.96 |
| Stent procedures | 356 (93.4%) |
| Diabetics | 92 (24%) |
| IIb/IIIa agents | 352 (91%) |

CATH = (cardiac) catheterization (coronary angiography); LFA = left femoral artery; PCI = percutaneous coronary intervention; RFA = right femoral artery

### COMPLICATIONS

No patient had an arterio-venous fistula. One patient developed a pseudoaneurysm of the right common femoral artery; the lesion was treated with ultrasonography -guided compression. In addition, 16 small local hematomas and 1 large inguinal hematomas were recorded (Table 2). One additional large hematoma occurred which required blood transfusion. In 2 cases retroperitoneal bleeding occurred, requiring blood transfusion in one of them. Local infection (cellulitis) responding to antibiotic treatment was observed in 2 patients. No cases of arterial thrombosis occurred and no patient required local surgical intervention.

**TABLE 2.** Procedural Characteristics of 388 Patients Receiving VasoSeal

| | |
|---|---|
| Successful deployment | 385 (99.2%) |
| Failed deployment | 3 |
| Complications | 23 (5.9%) |
| Groin hematomas | 16 |
| Large groin hematomas | 2* |
| Retroperitoneal bleeding | 2* |
| Cellulitis | 2 |
| Pseudoaneurysm | 1** |
| Arteriovenous fistula | 0 |
| Local vascular surgery | 0 |

*1 patient required blood transfusion; **managed with Doppler-guided local compression

## DISCUSSION

Historically, femoral arterial access for cardiac catheterization procedures has necessitated prolonged (≥20-30 minutes) manual compression and extended (≥6-12 hours) bed rest following sheath removal.[2,12,13] Over the last almost 20 years, vascular closure devices (VCDs) have become available to improve upon achieving quicker hemostasis, but it is mostly with the availability of newer generation products over the last decade that VCDs have become more widely utilized in clinical practice to allow for early ambulation and to shorten patients' hospital stay.[1,2] In the setting of percutaneous coronary intervention (PCI), VCDs have emerged as a practical alternative to manual or mechanical compression in an attempt to achieve faster hemostasis at the puncture site of the femoral artery and earlier patient mobilization. VCDs are categorized mainly based on the mechanism of hemostasis they provide, which includes biodegradable collagen or other plug, staples, or sutures.[14] VCDs do offer advantages over mechanical compression which relate to patient convenience from shorter time to achieve hemostasis and earlier patient ambulation, and to greater cost-effectiveness.[15] However, complications at the site of femoral artery access still occur.[8,10]

Manual compression can take 20-30 minutes or even more to accomplish hemostasis.[2] However oftentimes, especially if a patient has been administered antithrombotic and anticoagulant drugs prior to the percutaneous procedure, sheath removal is deferred for later, occasionally for several hours,[15] for the anticoagulant effect to dissipate (e.g. until the measured ACT drops below 180-200 sec) and reduce the risk of bleeding before manual compression can be successfully applied on the puncture site. Reversal of the coagulant effect may be used when the procedure is limited to diagnostic coronary angiography, albeit many operators may skip the use of heparin in diagnostic procedures, but when PCI is performed, whereby heavy anticoagulation is routinely employed, reversal is avoided due to risk of coronary vessel occlusion and/or stent thrombosis.

Several trials have evaluated efficacy and safety of VCDs,[1,2,4,8,11,16] but there is still a paucity of strong data from randomized clinical trials establishing the superiority of VCDs over manual or mechanical compression.[17] In diagnostic procedures where no or minimal anticoagulation is used, VCDs are effective and more practical over manual compression. However, when heavy anticoagulation and/or antiplatelet therapy is employed, like during PCI procedures, safety is sought in addition to efficacy, since these demanding procedures are associated with lower success and higher complication rates for both methods of hemostasis (manual compression or VCDs).

Among the drawbacks of VCDs, deployment failure is a major issue,[18] but more important are the local complications that may ensue, which may lead to leg ischemia and/or need for vascular surgery with its attendant risks. Data from various meta-analyses have demonstrated that complications and success rates may not be significantly different between mechanical compression and VCDs.[8,9,11] It appears that this may finally be operator dependent despite that the learning curve appears to be relatively short. Integration of clinical data, having performed the arterial puncture at the correct site and familiarizing oneself with a particular VCD seem to play a key role in successfully deploying the device and achieving complete hemostasis and avoiding disastrous local complications. Deployment of older generation VCDs was cumbersome and benefits were not that apparent compared with manual compression, particularly with regards to safety.[11,16,18,19] However, newer generation devices have overcome such limitations and have contributed to reduced local complication rate.[17]

In the present study, we have demonstrated a high (99%) success rate of initial deployment of the VCD with also a high (95%) rate of successful final hemostasis in a large cohort of high-risk patients with acute coronary syndromes undergoing PCI procedures via a transfemoral approach. A heavy use of anticoagulation and/or strong antiplatelet therapy with IIb/IIIa inhibitors on top of dual antiplatelet therapy did not lead, as

it might have been expected, to inordinate local complication rate. In contrast, only 2 patients sustained major bleeding (inguinal or retroperitoneal) requiring blood transfusion, and only one additional patient developed a local pseudoaneurysm treated conservatively with ultrasound-guided compression. It is important to note that our study results regarding success and complication rates are consistent with other previously published data concerning patients who underwent vascular radiological intervention procedures.[5]

### STUDY LIMITATIONS

Although this is a prospective study, it lacks randomization with a control group of patients having manual compression during the same time period. This is because the VCD was employed systematically in all consecutive patients undergoing cardiac catheterization during the study period, except for patients having peripheral vascular disease who had the procedure done via a radial or brachial approach, and thus there was no group having concurrent manual compression to compare with. The lack of 30-day follow-up in this cohort may be considered another limitation of the present study, but it has been demonstrated by other studies that most of the events (95.5%) occur during hospitalization.[17]

## CONCLUSION

VasoSeal was a safe collagen vascular closure device characterized by a high (99%) success rate of deployment and highly successful hemostasis with few manageable (1% major and 4.9% minor) complications in a very high-risk patient cohort undergoing PCI under anticoagulation and antiplatelet therapy. In these patients this vascular closure device reduced the time-to-hemostasis and time-to-mobilization and the incidence of complications. Newer generation devices, to which we have switched to at the end of the present study, appear more promising in terms of efficacy and safety,[17] and even cost-effectiveness,[15] while increasing adoption of the radial approach as an alternative access for cardiac catheterization may further reduce access site complications.[20]

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