Comparison of Different Methods for Achieving Hemostasis After Arterial Sheath Removal

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Background and Research Objective: Randomized studies are limited on whether the use of procoagulant pads improve outcomes after arterial sheath removal in interventional cardiology patients. The purpose of this study was to determine if the use of a procoagulant pad in combination with manual compression would decrease time to hemostasis compared with our institution's manual compression alone procedure after arterial sheath removal associated with a percutaneous coronary intervention (PCI). Participants and Methods: A convenience sample of PCI patients were randomly assigned to 3 methods for achieving hemostasis at the femoral artery site after sheath removal (manual compression alone, SyvekPatch NT plus manual compression, and D-Stat Dry plus manual compression). Outcome variables included time to hemostasis, number of pressure applications, and development of complications. Analysis of variance and χ² analysis were used to test differences among the 3 groups, with P < .05 considered significant. Results and Conclusions: A total of 80 PCI patients were studied (n = 26 manual compression only; n = 26 SyvekPatch NT; n = 28 D-Stat Dry). Significant differences were found among the 3 methods for time to hemostasis (F2,77 = 4.12, P = .020), with the manual compression alone method significantly longer than either of the 2 procoagulant pad groups. Complications were rare and were not significantly different with the 3 methods. KEY WORDS: manual compression, procoagulant pads, randomized controlled trial, SyvekPatch NT/D-Stat Dry

Cardiac catheterization is a common invasive procedure for diagnostic evaluation and therapeutic intervention in the treatment of patients with coronary artery disease. Percutaneous coronary intervention (PCI) may include balloon catheter angioplasty or percutaneous transluminal coronary angioplasty (PTCA), which pushes the plaque to the sides of the artery with or without placement of a hollow mesh tube or stent in the artery to keep it open after balloon angioplasty. Management of bleeding at the femoral artery insertion site after removal of the arterial sheath is an important step after the procedure.

A variety of methods are available to achieve hemostasis after arterial sheath removal, including external compression at the site (manual or with mechanical devices), internal vascular closure devices, and/or procoagulant drug pads applied to the skin over the puncture site before application of manual compression.

Although a large number of studies have compared manual compression with internal vascular closure devices, reports of complications associated with vascular closure devices have limited their clinical use. Complications reported included retroperitoneal bleeding,
pseudoaneurysm, large hematoma, site infection, and device failure.1–4

Despite increasing use of procoagulant pads in conjunction with manual compression for achieving hemostasis after arterial sheath removal and several nonexperimental studies finding them safe,5–9 limited randomized controlled trials (RCTs) have evaluated their impact on times to hemostasis.10–13 Using pads impregnated with several different procoagulants, times to hemostasis were found to be significantly shorter (average of 2–6 minutes) when procoagulant pads plus manual compression were used in patients with interventional catheterizations,11–13 but not for diagnostic catheterizations.10,11 Vascular complication rates were similar to those for manual compression alone and procoagulant pads plus manual compression groups.

Additional RCTs are needed to validate the findings of prior studies, particularly with arterial sheath removal after interventional procedures. The purpose of this study was to determine if the use of procoagulant pads in combination with manual compression would decrease time to hemostasis compared with our institution’s manual compression alone procedure after arterial sheath removal associated with PCI. Two different procoagulant pads were evaluated: pads impregnated with poly-n-acetyl glucosamine (SyvekPatch NT; Marine Polymer Technologies, Inc, Danvers, Massachusetts) and pads impregnated with thrombin (D-Stat Dry; Vascular Solutions, Inc, Maple Grove, Minnesota).

Materials and Methods

This study was conducted in a 394-bed community-based hospital in the Southeastern region of the United States. Approval was obtained from the institution’s investigational review board before data collection.

Study Design

Using an RCT design, different methods were compared for achieving hemostasis after arterial sheath removal. After PCI, patients were randomized to 1 of 3 methods for achieving hemostasis after arterial sheath removal: manual compression alone or a noninvasive vascular procoagulant pad (SyvekPatch NT or D-Stat Dry) with manual compression. Randomization to treatment groups was performed by a computer-generated, random number sequence.

Sample Selection

Participants for this study were a convenience sample of adult patients after a PTCA procedure with stent placement. Inclusion criteria included the presence of a 6-French femoral arterial catheter. Exclusion criteria included emergent coronary artery bypass graft surgery, medical management requiring hemodialysis, systolic blood pressure greater than 180 mm Hg and/or diastolic blood pressure greater than 95 mm Hg immediately before sheath removal, and/or allergy to latex. Minimum sample size (N = 75 total) was determined a priori with power analysis.14–16 Power was set at 0.80, a level at .05, and effect size at 0.37.

Intervention

Three different methods for achieving hemostasis at the femoral insertion site were evaluated:

- The manual compression alone group had manual pressure applied immediately after the removal of the arterial sheath with direct occlusive pressure (absence of distal pulse for 1 minute) above the skin puncture site and then nonocclusive pressure for a total of 20 minutes. This treatment arm represented the institution’s usual practice of care after a PCI.
- The noninvasive vascular procoagulant pad with manual compression groups (SyvekPatch NT or D-Stat Dry) had a sterile, chemically impregnated, external pad placed at the vascular access site and manual pressure was applied immediately after the removal of the arterial catheter with direct occlusive pressure (absence of distal pulse for 1 minute) above the skin puncture site and then nonocclusive pressure for a total of 13 minutes for SyvekPatch NT and 10 minutes for the D-Stat Dry pads. This method represented the recommendations for product use directed by the manufacturer of each procoagulant pad.

In all 3 groups, the site was observed for 5 minutes after the initial release of manual pressure. Pressure was reapplied for 10 minutes at the site if there was any evidence of oozing of blood at the puncture site. This process was repeated 1 more time, and if hemostasis still was not present, a mechanical compression device (Femostop; Medtronic, Minneapolis, Minnesota) was used according to manufacturer’s directions until no oozing of blood was observed at the puncture site.

Outcome Measures

The primary outcome measure was the time required to achieve hemostasis after arterial sheath removal. Hemostasis was defined as the time interval from sheath removal to the time when bleeding or oozing at the puncture site ended. Secondary outcome measures included the number of times that manual pressure was reapplied after the initial pressure application and development of complications (hematoma formation, pseudoaneurysm, or retroperitoneal bleeding). Hematoma formation was quantified by measuring the size (in centimeters) of any skin discoloration,
and/or manually palpated fluid, at the arterial sheath puncture site.

**Study Procedure**

Consenting participants were randomly assigned by a computer-generated number sequencer to 1 of 3 methods for achieving hemostasis after sheath removal: manual compression alone, SyvekPatch NT procoagulant pad with manual compression, or D-Stat Dry procoagulant pad with manual compression. Per usual hospital standards, the arterial sheath was removed when the activated clotting time was below 180 seconds, and then the randomly assigned method for achieving hemostasis was applied according to manufacturers’ directions (procoagulant pad groups) or standard hospital procedures (manual compression alone group) as previously described. Time to hemostasis, number of times that manual pressure was reapplied after the initial pressure application, and development of complications were recorded for each participant.

Manual compression was applied by hospital personnel who routinely provided this care for patients after arterial sheath removal. Investigators were blinded to group assignment until after study consent was obtained and just before arterial sheath removal.

**Data Analysis**

Data were summarized using descriptive statistics. Analysis of variance was used for comparison of time to hemostasis for the 3 treatment groups. The Bonferroni multiple comparison test was used to identify group differences. \( \chi^2 \) analysis was used for nominal variables (number of second or third applications of manual pressure at the femoral site; number of complications). The level of significance for all statistical tests was \( P < .05 \).

**Results**

A total of 80 patients (manual, \( n = 26 \); SyvekPatch NT, \( n = 26 \); D-Stat Dry, \( n = 28 \)) were enrolled and completed study participation from April 2008 to June 2010. Participant characteristics and demographic data are summarized in Table 1, with no significant differences found between groups for any of these variables.

The mean (SE) total time of manual pressure application to achieve hemostasis was 22.3 (1.2) minutes for manual compression only, 17.8 (1.3) minutes for SyvekPatch NT, and 17.5 (1.4) minutes for D-Stat Dry (Table 2). Statistically significant differences were found among the 3 methods for time to hemostasis (\( F_{2,77} = 4.77, P = .020 \)), with the manual compression only method significantly longer than the SyvekPatch NT (\( P = .008 \)) and D-Stat Dry (\( P = .010 \)) methods.

After release of the initial manual pressure application, 21 participants required a second pressure application (\( n = 3 \) for manual compression only, \( n = 9 \) for SyvekPatch NT, and \( n = 9 \) for D-Stat Dry). Five of those participants (\( n = 2 \) for SyvekPatch NT and \( n = 3 \) for D-Stat Dry) required a third pressure application. No differences were found between the groups for number of participants requiring second and third pressure applications (\( P > .05 \)) (Table 2).

Of the 80 patients, 6 required the use of the Femostop device when the third application of pressure did not achieve hemostasis (manual, \( n = 3 \); SyvekPatch NT, \( n = 1 \); and D-Stat Dry, \( n = 2 \)). These differences were not found to be significant (\( P > .05 \)).

Two patients developed a hematoma at the arterial puncture site, both of which were in the manual compression only group (Table 2) and neither of

| TABLE 1 | Demographic Variables for 80 Patients Receiving 1 of 3 Methods for Hemostasis After Cardiac Catheterization |
|----------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Age\(^a\) \( \text{in years} \) & 65.2 ± 1.2 & 65.7 ± 2.1 & 63.4 ± 2.1 & 66.4 ± 2.2 |
| BSA\(^a\) \( \text{in m}^2 \) & 1.99 ± 0.02 & 1.94 ± 0.04 & 2.0 ± 0.04 & 2.0 ± 0.05 |
| Gender \( \text{in participants} \) & | | | |
| Male & 58 & 16 & 19 & 23 |
| Female & 22 & 10 & 7 & 5 |
| Antiplatelet treatment \( \text{in participants} \) & | | | |
| Angiomax & 51 & 15 & 17 & 19 |
| Epitifibatide & 24 & 11 & 5 & 8 |
| Activated coagulation time, s\(^a\) & 156.9 ± 2.1 & 155.8 ± 3.0 & 158.6 ± 3.1 & 156.7 ± 4.8 |

Abbreviation: BSA, body surface area.
\(^a\)Mean ± SE.
which required medical intervention. Sizes of the 2 hematomas were 2 × 2 cm and 14 × 10 cm. Hematoma formation at the puncture site was not found to be significantly different among the 3 methods (P > .05).

### Discussion

In a study of 80 patients after PCI with stent placement, the time to achieve hemostasis with manual compression alone was found to average almost 5 minutes longer than with either of the 2 other methods (SyvekPatch NT + manual compression and D-Stat Dry + manual compression) (see Summary and Implications). No differences were found in time to hemostasis between the 2 procoagulant pad groups. Hematomas at the arterial puncture site were small, rare, and limited to the manual compression group.

This is only the fourth RCT of procoagulant pads impregnated with either poly- n-acetyl glucosamine or thrombin.11 In a small study (N = 33) of diagnostic PTCA patients, Najjar et al10 found that use of poly-n-acetyl glucosamine procoagulant pads in combination with mechanical compression decreased time to hemostasis by an average of 6 minutes compared with mechanical compression alone. Nguyen et al12 found that poly-n-acetyl glucosamine procoagulant pads of 2 different manufacturers each decreased time to hemostasis by an average of 3 minutes compared with manual compression alone in 184 PCI patients. In the only RCT to date of thrombin impregnated procoagulant pads with in combination with mechanical compression, Applegate et al11 found no difference in time to hemostasis from mechanical compression alone in patients after a diagnostic catheterization (N = 2464) but an average decrease of 6 minutes in patients after PCI (n = 1,000). Our study results in PCI patients, a decrease of 5 minutes with the use of a poly-n-acetyl glucosamine pad and the thrombin pad, are similar to those of the 2 RCT studies of PCI patients.

Theoretically, shorter compression times could be clinically beneficial in terms of patient comfort and staff time. The reduction in compression times after PCI found in this and prior studies, although may not be enough of a time reduction to justify the additional cost of procoagulant pads (approximately $43–$50/patient).

Limitations in the design of this study include the lack of investigator and participant blinding to intervention groups, as well as the evaluation of a manual compression technique only. Whether similar results would occur with compression applied with a mechanical device is not known, and future studies should evaluate this compression technique as well. Another limitation is that this study evaluated only 1 manufacturer’s product for 2 different types (poly-n-acetyl glucosamine and thrombin) of procoagulant pads. Additional RCTs are needed for pads impregnated with other types of procoagulant substances.

In summary, this study found a statistically significant reduction in time to hemostasis in the procoagulant pad plus manual compression groups compared with manual compression alone. Complications were rare and were not significantly different with the 3 methods.

### Summary and Implications

An RCT of 3 different methods for achieving hemostasis after interventional percutaneous cardiac catheterization found the following:

- In PCI patients, time to hemostasis averaged almost 5 minutes shorter for patients receiving procoagulant pads.
pads combined with manual pressure than for patients receiving manual pressure alone. Individual institutions will need to consider whether this reduction in manual compression times offsets the additional costs associated with procoagulant pads.

A third of patients with procoagulant pads had oozing at the site of the manufacturer’s recommended initial period of pressure, requiring a second or third application of pressure to achieve hemostasis. Clinicians should not assume that the 10- or 13-minute manufacturers’ recommended compression times for the procoagulant pads will be adequate in all PCI patients.

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REFERENCES