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Sheath Pulling Immediately After PTCA: Comparison of Two Different Deployment Techniques for the Hemostatic Puncture Closure Device: A Prospective, Randomized Study

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Sheath pulling immediately after percutaneous transluminal coronary angioplasty (PTCA) increases patients' comfort, decreases burden for the medical staff, and may reduce hospital costs by shortening the length of stay. Immediate sheath pulling in anticoagulated patients with a low risk of bleeding complications is feasible using hemostatic devices. For the hemostatic puncture closing device (HPCD), published data regarding sheath pulling in patients immediately after PTCA is limited. Furthermore, no study addressed the question whether the recommended deployment time (DT) of 30 min can be reduced to a few minutes. We, therefore, performed a prospective study, randomizing 140 patients to a DT of 5 and 30 min, respectively. There were no statistical differences in gender, age, height, weight, or cardiovascular risk factors between the two groups. Blood pressures measured invasively immediately before sheath removal were comparable. Activated coagulation time just prior to sheath removal was 227 ± 52 sec in the DT-5 group and 223 ± 37 sec in the DT-30 group. After deployment, 74% of the DT-5 patients and 71% of the DT-30 patients showed immediate and complete hemostasis. The remaining patients showed only little oozing with complete hemostasis at the time of the final device removal. Hematoma size after 24 hr was 6.2 ± 4.4 cm^2 for DT-5 and 6.8 ± 8.2 cm^2 for DT-30 patients. There was no statistical difference between both groups. No severe bleeding or major complications were observed in either group. Thus, the use of a collagen system with an intra-arterial anchor (HPCD) is effective and safe when sheaths are pulled immediately after PTCA. The reduction of deployment time from 30 to 5 min is not related to an increased risk of bleeding or other vascular complications; patients can be transferred much faster to the ward, therefore reducing the burden on the personnel in the catheterization laboratory and increasing patients' comfort by allowing them to return to their rooms without a sheath. ***Cathet. Cardiovasc. Diagn. 41:378–383, 1997.***

Key words: coronary artery disease; interventional cardiology; collagen; patient comfort

INTRODUCTION

Sheath pulling immediately after PTCA increases patients' comfort, decreases burden for the medical staff, and may reduce hospital costs by shortening the length of stay. With the development of new sealing devices for closing femoral arterial puncture sites, immediate sheath pulling in anticoagulated patients with a low risk of bleeding complications became reality [1-8]. Whereas the administration of the vascular hemostatic device (VHD) on the surface of the arterial puncture site [9] as well as the application of a suture-mediated closure device [10] are straightforward (using deployment techniques with standardized application protocols), the use of the hemostatic puncture closing device (HPCD) [11] allows several possibilities regarding its deployment time (DT): the recommended DT of 30 minutes [11] leads to a prolonged stay in the catheterization laboratory facilities, slowing down the transfer of the patients to the intermediate care unit. Because only scarce data exist regarding sheath removal immediately after PTCA using HPCD and no study addressed the question whether the DT can be reduced to a few minutes, we performed a prospective study, randomizing 140 patients to a DT of 5 and 30 min, respectively.

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PATIENTS AND METHODS

The inclusion criteria related to the puncture technique were quite stringent: the puncture of the right femoral artery using a single wall needle should avoid penetration of the posterior artery wall. If the puncture needle penetrated the artery, the patient was not enrolled. In addition, only a single puncture of the artery was allowed for enrollment. Each individual puncture was documented and classified as either arterial puncture or as (inadvertent) venous or "empty" puncture (connective tissue). PTCA was performed using 8 Fr sheaths. All patients received 10,000 units of heparin as a standard dose. A reversal of the effect of heparin was not performed. Patients with prolonged duration of the PTCA procedure and therefore requiring an additional bolus of heparin as well as patients with need for overnight heparin infusion or patients with stent implantations were excluded. Further exclusion criteria were as follows: previous application of collagen sealing of the femoral access site, known allergy to collagen, clinical signs of or known peripheral artery disease, patients with acute myocardial infarction, status post thrombolytic therapy, known coagulation defects or known platelet dysfunction, severe and uncontrolled arterial hypertension (systolic <220 mm Hg or diastolic <120 mm Hg), preexisting hematoma or hematoma developed during the procedure, or patients with a venous femoral sheath. Marked obesity or age were not exclusion criteria, because they do not seem to be related to the rate of vascular complications or the success of collagen application [3,12].

After informed consent was obtained, 140 patients were enrolled. Just prior to sheath removal, blood pressure was determined by invasive measurement through the sheath. Activated coagulation times (ACTs) were also measured just prior to device deployment, but sheaths were removed independent of this result. Sheaths were pulled immediately after the PTCA on the catheterization table.

The HPCD (Angio-Seal originally developed by the Kensey Nash Corporation, Exton, PA, distributed by Quinton Instruments and Sherwood Davis & Geck, St. Louis, MO) provides a mechanical block of the arterial puncture site with an anchor from inside the artery, guiding and holding the collagen in the tract. All components deployed into the patient (anchor, suture, and collagen) are completely resorbable. After the carrier device is introduced into the 8 Fr sheath, the device is deployed and a tamper is pushed downward to compress the collagen against the outer arterial wall ("sandwich technique"). Finally, a spring is attached between the tamper and a metal tag fixed to the positioning suture, thus applying continuous pressure on the tamper. The technique of deployment has been described in detail elsewhere [8,11]. It usually takes less than 60 sec to deploy the HPCD.

According to the randomization code, patients were assigned to either a DT of 5 min of spring application or a DT of 30 min with leaving the spring in place for 30 min. Patients with a DT of 5 min remained on the catheterization table, whereas patients randomized to a DT of 30 min were moved to the observational area within the catheterization laboratory facilities with careful observation of the sterile conditions of the groin. After 5 or 30 min, the visible portion of the suture was cut slightly below skin level and a light sterile covering was applied.

Definition of Bleeding and Peripheral Complications

Immediately after deployment, at 5 or 30 min respectively, the bleedings were described according to the following classification: (A) no bleeding; (B) minor bleeding, i.e., slight oozing (probably originating from the connective tissue between the arterial puncture site and the skin incision and hence not related to the artery); (C) brisk ooze (probably related to insufficient sealing of the artery); (D) severe, pulsatile bleeding (device was ineffective). The size of hematoma/ecchymosis was measured before ambulation by planimetry and expressed in cm^2.

Peripheral complications were classified as major or minor according to the following criteria [9]: A major complication was thrombosis or loss of distal pulses, large pseudoaneurysm, or arteriovenous-fistula, bleeding with need for transfusion or any vascular surgery. Bleeding from the puncture site not needing transfusion and/or vascular surgery were classified as a minor complication.

Patients were asked the next morning to characterize the local symptoms as comfortable, slightly uncomfortable, uncomfortable, or very uncomfortable. Hematoma size was measured just prior to ambulation. Two weeks after PTCA, patients received a telephone call with questions about possible late bleeding or other complications after hospital discharge.

Statistics

Continuous data with normal distribution were analyzed using the two-tailed Student's t-test. Continuous variables not normally distributed were analyzed using the unpaired Mann-Whitney U test. Comparisons of discrete variables were done using the chi-squared test. Results are presented as mean value $\pm$ SD; $P = 0.05$ was considered significant.

RESULTS

One hundred forty patients were enrolled. Seventy were assigned to the deployment time of 5 min (DT-5), another 70 patients to the deployment time of 30 min (DT-30). The baseline characteristics are listed in Table I. There were no statistical differences in gender, age, height, weight, or cardiovascular risk factors, blood pressures, or ACTs just prior to sheath removal between the two groups. In all patients, the device could be successfully deployed.

Immediately after deployment, 52 of the 70 (74%) patients assigned to DT-5 had bleeding classification A as did 71% of patients (50 of 70) assigned to DT-30 (Table II). Eighteen patients (26%) in the DT-5 group and 20 patients (29%) in the DT-30 group showed bleeding classification B (Table II). There was no statistical difference between both groups. At the end of deployment (spring removal), there was complete hemostasis in all patients. No bleeding classification C or D was observed in either group.

The answers to the inquiries the next morning regarding the patients' classification of their groin discomfort are also delineated in Table II. There was no statistical difference between both groups. Hematoma size was identical (Table II).

Time to mobilization was 23.2 ± 4.2 hr in the DT-5 group and 23.7 ± 3.9 hr in the DT-30 patients. The mean duration of hospital stay was 4.0 ± 3.1 days in the DT-5 group and 3.6 ± 2.7 days in the DT-30 group (not significant).

Follow-up after 2 weeks could be obtained in 96% of the patients and revealed no further bleeding or any major complications.

TABLE I. Baseline Characteristics of Enrolled Patients*

	DT = 5 Minutes	DT = 30 Minutes
Patients	n = 70	n = 70
Female (%)	16	19
Age (years)	59.6 ± 9.5 (43–70)	61.2 ± 8.8 (44–76)
Mean height (cm)	172.2 ± 8.5 (155–186)	169.9 ± 8.1 (155–182)
Mean weight (kg)	82.1 ± 13.9 (57–113)	81.4 ± 12.2 (53–105)
LV-EF[a] (%)	64.8 ± 11.6	65.3 ± 12.5
Risk factors		
Smoking	40%	35%
Hypertension	47%	49%
High cholesterol	52%	59%
Diabetes	19%	22%
Number of punctures		
Arterial punctures	1.0 ± 0.0	1.0 ± 0.0
Venous punctures	0.2 ± 0.6	0.3 ± 0.5
Connective tissue punctures	0.7 ± 0.7	0.6 ± 0.7
At sheath removal		
Systolic BP (mm Hg)	134.5 ± 18.6	138.5 ± 19.3
Diastolic BP (mm Hg)	82.8 ± 8.3	79.7 ± 11.2
ACT(s)[b]	227 ± 52 (166–321)	223 ± 37 (174–303)

*There was no statistical difference in demographic characteristics as well as in blood pressure or ACT at time of sheath removal between those patients randomized to a deployment time (DT) of 5 min or a DT of 30 min. The number of inadvertent venous or connective tissue punctures was identical; patients with more than one arterial puncture were excluded.
[a]LV-EF, left ventricular ejection fraction.
[b]ACT, activated coagulation time.

TABLE II. Bleeding Classification Immediately After the Deployment of HPCD, Hematoma Size Before Ambulation, and Patients' Own Characterization of the Local Symptoms the Next Morning*

	DT = 5 Minutes	DT = 30 Minutes
Bleeding after deployment		
No bleeding	74%	71%
Little oozing	26%	29%
Brisk ooze	0%	0%
Severe pulsatile bleeding	0%	0%
Ecchymosis size after 24 hours (cm^2)	6.2 ± 4.4	6.8 ± 8.2
Patients' own characterization		
Comfortable	41%	57%
Slightly uncomfortable	52%	43%
Uncomfortable	7%	0%
Very uncomfortable	0%	0%

*There was no statistical difference between those patients randomized to a deployment time (DT) of 5 min or a DT of 30 min.

DISCUSSION

PTCA is usually performed by the femoral approach with the brachial approach continuously showing a declining trend (from 4% in 1990 to 1% in 1994 [13]). Patients undergoing PTCA by the femoral approach are usually immobilized overnight, which may result in significant discomfort with increased back pain and need for analgesics [14,15]. Noncompliance of the patient regarding strict bedrest after the procedure (at a 30 degree angle for 8 hr) has been reported to be a substantial factor for femoral complications after PTCA, increasing the risk of hematoma formation by a factor of 14 and the risk of rebleeding by a factor of 2.5 [12,16]. Reducing the sheath size and/or the revival of the transradial approach was presumed to result in fewer vascular complications and increased patient comfort after PTCA [17-25]; however, bleeding complications were not related to the sheath sizes [13,26,27].

Biodegradable collagen induces platelet activation and aggregation, releasing coagulation factors and resulting in the formation of fibrin and the subsequent generation of a thrombus [28]. Collagen is ultimately degraded and resorbed by granulocytes and macrophages. Antigenicity of purified collagen is considerably reduced and, although allergies to collagen are described [29], allergic

reactions to collagen used for hemostasis have not been a clinical problem [1,2,9]. Today, besides the suture-mediated closure of arterial puncture sites [30], two different collagen devices are predominantly available: the VHD (VasoSeal®, Datascope Corp., Montvale, NJ) and the HPCD.

Hemostasis With Collagen Devices Immediately After PTCA

VHD was investigated in several randomized studies in which sheaths were pulled immediately after PTCA, showing a highly significant reduction in time to hemostasis compared with manual compression (with delayed sheath removal, of course): time to hemostasis for VHD ranged between 5 and 7 min [9,31,32]. These measurements for time to hemostasis were in good agreement with earlier VHD-studies, which were either nonrandomized or reported only the total results for diagnostic and interventional procedures [1-5]. Although it is assumed that the hemostasis induced by VHD is independent of the level of anticoagulation [1,33], it seems that time to hemostasis of 5 to 7 min is longer in patients on full anticoagulation than in patients after PTCA with delayed sheath removal (7.6 ± 11.6 min on heparin, 4.3 ± 3.7 min off heparin [9] or 5 hr after PTCA with 3 ± 3 min [34]). In the setting of aggressive anticoagulation, bleeding complications are particularly likely to occur [35]. Therefore, the hypothesis of collagen-induced hemostasis being independent of the presence or the level of anticoagulation may be questioned.

For HPCD, the data are sparse regarding hemostasis when sheaths are pulled immediately after PTCA: De Swart et al. reported 16 patients with immediate sheath pulling after PTCA [8]; time to hemostasis, however, was mixed with patients undergoing diagnostic catheterization. In the US multicenter trial, sheaths were pulled after approximately 8 hr (465 ± 523 min) in the 46 patients assigned to HPCD at an ACT of 213 ± 89 sec [11]. HPCD proved to be safe and effective with a significant reduction in time to hemostasis from 19.6 ± 12.6 to 3.5 ± 8.5 min [11]. These data were consistent with earlier findings from nonrandomized or general reports on patients after diagnostic and interventional procedures [8,36,37].

In our opinion, it is difficult to compare the results for time to hemostasis reported for VHD and for HPCD, because different methods for measurement were used: for VHD, time to hemostasis is defined as the time elapsed from initial compression at removal of the sheath until the completion of compression. The time interval between each check is not standardized and is reported to be in the range between 1 [9] and 5 [2] min. These choices, however, have a considerable impact on the results: too short intervals may not be sufficient to give enough time for thrombus formation and increase—particularly in the manual control groups—the time to hemostasis. For HPCD, the method suggested to determine time to hemostasis is different: inherent to the anchor concept ("sandwich technique"), hemostasis is usually immediate and no compression is required. In the US multicenter trial, no initial compression was applied to the puncture site, and time to hemostasis was measured as the time from device deployment to an absence of bleeding. In our study, we therefore decided not to determine the time to hemostasis but to more carefully describe the—albeit little—bleedings.

As our results show, sheaths can be safely pulled immediately after PTCA with the HPCD device. Immediate hemostasis was obtained in 102 of the 140 enrolled patients (73%). Our results are in good agreement with the immediate hemostasis rate of 76% reported by the US multicenter trial in the 46 PTCA patients [11]. HPCD obviously offers several advantages: it is deployed through an arterial sheath, not requiring an additional tissue dilation; no occlusive pressure must be applied above the deployment site; the entire device is absorbable, and it appears to leave no sequelae after 30–60 days [8,37].

Limitations of This Study

In this study, a rigorous patient selection was applied, and the results cannot be extrapolated to patients excluded. Furthermore, our study was not primarily designed to evaluate the important issue of cost reduction by hemostatic devices due to early ambulation and decreased length of hospital stay [38-40]. The decision when to ambulate and discharge patients was left to the physicians on the wards. Therefore, it is not surprising that the patients were not walked at night but rather after approximately 24 hr. To our knowledge, no study using a hemostatic device in PTCA patients defined early ambulation as an endpoint [3,40,41].

CONCLUSIONS

The use of a collagen system with an intra-arterial anchor (HPCD) is effective and safe when sheaths are pulled immediately after PTCA. The reduction of deployment time from 30 min to 5 min is not related to an increased risk of bleeding or other vascular complications. This finding makes handling of the HPCD easier, because the suture may be cut while the patient is still on the table in the catheterization laboratory. Furthermore, patients can be transferred much faster to the intermediate care unit, thereby reducing the burden on the personnel in the catheterization laboratory. The transfer of PTCA patients to the floor already without a sheath is welcomed

by the staff of the intermediate care units. Obviously, if patients are hemodynamically unstable and require arterial pressure monitoring, it may not be appropriate to use a hemostatic device to remove the sheath early. Cost/effectiveness analysis has yet to prove savings that may be generated by decreased duration of hospital stay by discharge within 24 hr [42] or even the same day on an outpatient basis in carefully selected PTCA patients [43].

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