

Efficacy and safety of a new hemostatic wound dressing following diagnostic heart catheterization

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Abstract

Inadequate hemostasis and bleeding are frequent complications after surgical procedures and medical interventions (for example, after a percutaneous heart catheterization). To stop bleeding during coronary interventions, in addition to mechanical arteriotomy closure devices, many products are used that aid manual compression and/or activate the coagulation cascade.

The goal of this study was to clinically prove the efficacy and safety of a new wound dressing. We treated 100 patients after their coronary angiogram using the Hematrix® Active Patch on the arterial puncture site (femoral artery).

The results show that applying the patch to the wound for five minutes resulted in hemostasis in 93% of the patients and leads to comparatively quicker mobilization. No vascular complications were observed in any of the patients.

Keywords: Coronary heart disease - coronary angiogram - hemostasis - control of bleeding - external wound dressing

Introduction

Inadequate hemostasis and bleeding after surgical procedures and medical interventions (for example, after a percutaneous heart catheterization) are potential risks. In addition to electrocauterization and closure of the source of the bleeding using sutures, a range of topical hemostatic materials are used to stop heavy bleeding mechanically within the body or by activating coagulation [2, 5, 6, 8, 17]. The most commonly used materials are gelatin sponges, oxidized cellulose or microfiber collagens [4, 7, 11]. However, the hemostatic efficacy of most of these products has not been proven in clinical studies or under controlled bleeding conditions. They are also often not suited for external use, such as for example after a percutaneous angiogram or on open wounds.

The most frequent bleeding complication after a percutaneous coronary intervention involves the arterial puncture site [11]. The method of choice is still manual compression on the puncture site after removing the catheter, followed by several hours of compression with a compression dressing, aided by a sandbag. In the meantime

numerous arteriotomy closure devices that are supposed to reduce the vascular complication rate have been introduced into clinical use. Meta-analyses show that none of these products have a clear advantage over the standard method with regard to the complication rate after a percutaneous coronary angiogram [10, 16].

The objective of this study was to demonstrate the efficacy and safety of the Hematrix® Active Patch (Hematrix Wound Care GmbH, Neubiberg) in use after a percutaneous coronary angiogram to achieve quick and reliable hemostasis.

Method

The study was designed as an open, monocentric cohort study without a control group. One hundred patients who were admitted to our hospital for a diagnostic heart catheterization were enrolled in the study in the order in which they were admitted. All of the patients were treated using the hospital's conventional methods both during the coronary angiogram as well as after removal of the catheter. Instead of a control group, we used the historic data of our patients as a comparison.



Fig. 1: Wound over the arterial puncture channel after removal of the wound dressing

standard contrast medium and heparin (approx. 100 I.E.) was administered. At the end of the examination, the wound dressing was pressed on the bleeding insertion site immediately after the catheter was removed; the staff ensured that the wound dressing had briefly had contact with the streaming blood. After compressing the dressing on the

discharged (approximately 24 hours after the surgical procedure) and an adhesive strip was applied over the wound.

Results

100 patients (average age: 65 ± 10.7 years, height: 172 ± 9.06 cm, weight: 81.1 ± 16 kg) were enrolled in the study. The artery was punctured and angiographed in all of the patients in the same manner. Sixty eight patients were given acetylsalicylic acid before the procedure, seven patients received heparin, thirteen patients were given ADP (adenosine diphosphate) antagonists and one patient received GP (glycoprotein) IIb/IIIa antagonists.

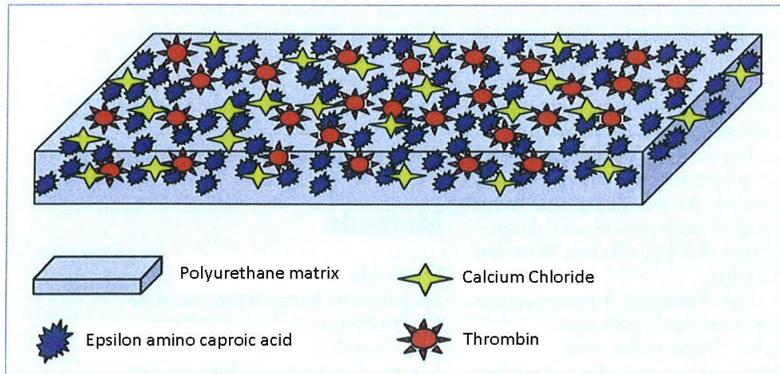


Fig. 2: Schematic diagram of the wound dressing

The study was conducted in accordance with the 2000 and 2002 versions of the Declaration of Helsinki and was approved by the Ethics Committee of the Bavarian State Medical Association. Each patient signed an informed consent form that had been reviewed by the Ethics Committee and was enrolled in the study after verification of the applicable inclusion and exclusion criteria. The exclusion criteria were the patient's refusal to participate in other studies, an International Normalized Ratio (INR) of over 1.8, patients receiving anticoagulation (e.g., Marcumar) and a known allergy to one or more components of the wound dressing.

In all of the patients, the femoral artery was punctured using a 6F catheter with a

wound for five minutes the wound was inspected for hemorrhaging or the diffuse flow of blood without removing the dressing by lifting the edges. After determining that hemostasis had been achieved, a compression dressing was placed over the wound dressing. The patients were treated, as usual, with a sandbag placed over the puncture site, which was removed again after two hours. The wound was inspected again at this time (in the same manner as before) and the clotting status around the wound was documented and a bandage was applied over the dressing at the puncture site. The patients were allowed to sit up in bed again and even stand up briefly. This process was repeated after 6 and 24 hours, respectively. The wound dressing was removed (Fig. 1) before the patient was

The compression time was exactly five minutes for all of the patients. Hemostasis was reached within five minutes in 93 out of the 100 patients; an additional five minutes of compression was needed to reach hemostasis in six patients, resulting in a confidence interval of 94.55 to 99.98%. No satisfactory clotting could be reached in one patient, who was viewed as a non-responder. None of the other patients had any complications such as subsequent bleeding, hematoma, pseudoaneurysm, arteriovenous fistula, a decrease in hematocrit levels or blood transfusion. No serious adverse events were observed. One patient complained of itching that was traced back to the wound dressing. No other adverse events were reported. Investigator satisfaction, which is measured using the visual analog scale (VAS), with the tested wound dressing was high.

Discussion

In this study we were able to show the efficacy and safety of the wound dressing during use in hemostasis after an arterial puncture during a diagnostic heart catheterization. The product achieved rapid hemostasis after removal of the catheter with no vascular complications and enabled early mobilization of the patients.

The arterial puncture and the resulting complications are the main causes for morbidity after diagnostic and interventional heart catheterizations. The complication rate is between 2 and 17% [10, 11, 15]. Arteriotomy closure devices are available as an alternative to traditional manual compression after a percutaneous coronary intervention with the objective of facilitating quick patient mobilization and discharge with a low complication rate [11]. There is a controversial discussion in the literature about whether the introduction of these closure devices actually lower the vascular complication rates. Nikolsky et al. [12] conducted a meta-analysis of 30 randomized, controlled studies as well as cohort studies and compared the complication rates after using three different arteriotomy closure devices (AngioSeal®, Perclose®, VasoSeal®) with the results from manual compression. The study did not find that the vascular closure devices were superior to manual compression. In fact, it showed an increased risk in complication rates for VasoSeal®. In addition, the comparatively higher costs of the arteriotomy closure devices should be taken into

consideration [1, 3]. Silber et al. came to the same and/or similar conclusions [15, 16].

With this study, we present an easy to use, non-invasive wound dressing that, in addition to 27 mg of epsilon amino caproic acid/cm², contains 0.9 mg of calcium chloride/cm² and 8 I.E. of thrombin/cm² and results in safe closure of the arterial puncture site and earlier mobilization of the patient by producing rapid and sustained hemostasis (Figures 1 and 2).

The thrombin in the wound dressing initiates and activates the body's own coagulation cascade in which fibrinogen is converted into fibrin, which in turn activates coagulation factors VII, V and XII and leads directly to stimulation of the platelets and their aggregation. The only requirement is that blood streams into the wound dressing for a split second. This activates the coagulation cascade, which continues from the dressing up to the insertion site on the arterial wall. There is no risk of the substances from the dressing penetrating the vascular system. Immediate hemostasis is achieved through the high speed of coagulation as well as the increased platelet aggregation time by more than 55% in the first 30 seconds of contact.

Even if the absence of a direct control group limit the results of our study, we assume that our large patient collective, which is always treated using manual compression followed by a pressure dressing, can serve as a comparative group for successful coagulation after 24 hours. The primary endpoint of

the study was proving the patch's efficacy and safety in patients with compromised coagulation systems due to coagulation-altering drugs. Early mobilization of the patients was one of the secondary endpoints of the study.

In summary, we were able to demonstrate that using the Hematrix Patch after a diagnostic heart catheterization with an arteriofemoral access site led to immediate hemostasis at and around the arterial puncture site as well as early mobilization of the patient without an increase in the vascular complication rate.