
Evaluation of a New Femoral Hemostatic Occlusive Device Following Cardiac Catheterization and Angiographic Procedures

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Introduction

Over the past thirty years cardiac catheterization has developed from a physiologic research tool into one of the more commonly employed cardiac diagnostic procedures. In the United States alone, it has been estimated that 400,000 to 1 million catheterizations are performed each year.

1. Although mortality and major morbidity has been rendered extremely rare, complications related to the percutaneous introduction of catheters via the femoral arterial route still occur. The incidence of post-catheterization hematomas has been reported to be approximately four percent.
2. Despite the frequency of post-catheterization hematomas, standard procedure following catheter removal in most laboratories, is the application of direct manual compression of the artery followed by the application of an elastic-adhesive dressing and/or sandbag for longer term pressure application.

In the following report, pressures generated by the standard catheterization laboratory procedure are contrasted to those achieved by the application of a new device specifically designed to achieve hemostasis via longer term application of increased pressure to the area of femoral puncture.

Methods

The device (HOLD, Pressure Products, Inc., San Pedro, CA) was designed to apply pressure to the femoral area via an elasticized groin strap (Figure 1). After initial hemostasis has been obtained with direct manual compression, the waist band was positioned just above the point of the patient's hips. A sterile dressing was applied to the femoral puncture area and the waist band adjusted so that the pelvic apron was centrally positioned. A foam compression hemisphere was positioned directly above the femoral arterial puncture site.

The groin strap was used to apply pressure to the site. This second elastic band, or groin strap, was affixed directly above the puncture site, then wrapped around the patient's thigh. The strap was tightened, and secured at its other end again directly above the femoral puncture site with a Velcro closure. The design of the HOLD device, with a groin strap beginning and terminating directly above the compression hemisphere, results in the downward direction of pressure applied maximally to the femoral puncture site.

The device requires no adhesive tape—remaining securely in place due to the geometric arrangement of the elasticized waist and groin straps (Figure 1).

In order to compare the amount of pressure exerted by a standard elastic-adhesive tape bandage with or without the use of a 5 lb. sandbag, with the pressure generated by the investigational device, a 25cc flat saline bag was attached to a standard



Figure 1 HOLD Device

pressure transducer. The saline bag was placed over the sterile dressing but beneath the pressure device applied to the groin. Pressure was measured only after the HOLD device or dressing was applied and no conscious attempt was made to exert any specific amount of pressure during application.

In twelve patients, after informed consent had been obtained, an elastic-adhesive dressing was applied to the area of femoral percutaneous puncture. Following pressure measurement, a five pound sandbag was placed over the dressing and pressure measurement repeated. The end results were contrasted with the pressure exerted by application of the hemostatic occlusive leverage device to the same area in 22 patients.

Results

Pressure measurements obtained in 32 patients are shown in Figure 2. The application of a standard elastic-adhesive dressing resulted in average pressures of 17.5 mmHg. By placing a 5 lb. sandbag over the site, pressure could be increased to 33 mmHg. In contrast, the application of the specialized pressure occlusive device resulted in pressures which were higher than

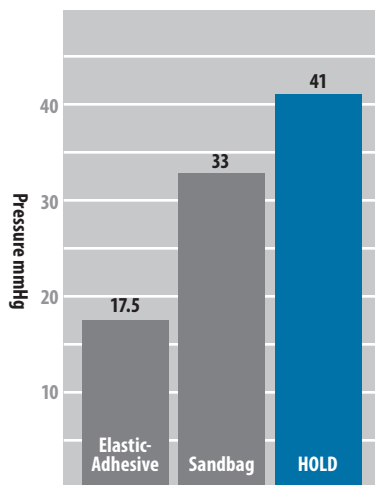


Figure 2 Femoral Pressure Device Comparison

either of the above methods. The HOLD device exerted average pressures of 41 mmHg; a value well above that exerted by standard pressure dressings yet still significantly below diastolic arterial pressure.

There were no complaints of pain associated with application of the HOLD device, and no untoward side effects noted. With this small a patient population, no attempt was made to assess the hemostatic efficacy of any of the methods used however, in none of the patients was post-catheterization bleeding or hematoma formation noted.

Discussion

Percutaneous femoral arterial puncture has become routine in cardiac catheterization and angiographic procedures throughout the United State. Although uncommon, post-catheterization bleeding and hematoma formation continues to occur with a frequency of approximately 4% and to be one of the more common complications of these procedures. Particularly in view of the recent increase in PTCA, and out-patient catheterization and angiographic procedures, post-operative hemostasis has been achieved by the initial manual application of direct pressure to the arterial puncture site, followed by the application of a "pressure dressing." This dressing consisting of elastic-adhesive tape with or without an additional 5 lb. sandbag, has been the standard in catheterization laboratories for years. The efficacy of this procedure has never been subjected to scientific analysis; and further, pressures actually generated by these dressings and or weights have never actually been measured.

Elastic-adhesive dressings are bulky, cumbersome and not without patient discomfort. Large areas of skin must be prepared and shaved, so that erythema, skin abrasion and allergic tape reactions are common. Sandbags applied to these dressings rarely remain in place, shifting in their application of pressure to areas other than that of the femoral puncture, if not sliding off the groin altogether.

The hemostatic occlusive leverage device (HOLD) described in this report suffers none of these problems. Easily applied, there is no need for a larger than usual area of skin preparation. The device's lack of adhesive avoids complications such as tape allergy and skin abrasion. The geometry of the two elastic straps does not allow the device to shift in the application of pressure directly to the area of femoral arterial puncture.

In comparing the application of pressure as exerted by standard dressings to that which results from application of this hemostatic occlusive leverage device, the difference is apparent. Pressure of 41 mmHg can be maintained using this device for periods as long as that deemed necessary by the physician responsible for patient care. Although variable pressure was exerted, in no patient did the device exert pressure in excess of arterial diastolic pressure, and no arterial complications were encountered.

Conclusion

A new device, HOLD, is presented wherein longer term compression of the site of femoral arterial puncture may be maintained. The device is easily applied and does not use adhesive to remain in position. Significantly higher direct pressures can be exerted using this device than can be accomplished with either adhesive-elastic dressings or those dressings in combination with application of a sandbag. Extensive usage will be required to determine the degree to which this type of device will decrease the incidence of post-catheterization bleeding or hematoma formation. However, even the present limited study shows its increased ability to exert direct femoral pressure while at the same time avoiding the patient discomfort associated with standard elastic-adhesive "pressure" dressings.

References

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