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The Safety and Efficacy of Angioseal in Therapeutic Endovascular Interventions

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Objective. *The aim of this study was to evaluate the safety and efficacy of the closure device Angioseal.*
Material and methods. *All consecutive patients, who underwent a therapeutic radiological intervention using the femoral artery approach from January 2001 to January 2005 in the Service of Vascular Surgery, Henri Mondor Hospital, Creteil, France, were prospectively included in the study. The efficacy of Angioseal was defined by the ability of the device to cover the puncture site and stop bleeding. The safety was defined by the rate of complications.*
Results. *A total of 79 Angioseal devices were employed on 77 patients. There were 62 (78.5%) males and 17 (21.5%) females. The mean age of the patients was 65.2 ± 11.6 years (mean ± SD). All Angioseal devices were deployed successfully. There were 62 (78.4%) 6F and 17 (21.6%) 8F sheaths employed during the procedures. There were two minor (2.5%) hematomas, one (1.2%) major hematoma and one (1.2%) pseudoaneurysm after the procedure. The mean time of discharge from the hospital was 2.1 ± 1.8 (mean ± SD) days. The patients were followed up for a mean of 9.0 ± 9.3 (1–60 months) months.*
Conclusions. *Angioseal provides a safe and effective way of closing the femoral artery puncture site with acceptable morbidity rates.*

Keywords: Closure devices; Angioseal; Vascular surgery; Radiology.

Introduction

The traditional method of hemostasis following an interventional vascular procedure is manual compression. Puncture site complications include bleeding, hematoma, vessel occlusion and pseudoaneurysm formation. The prolonged duration of manual compression and a prolonged bed rest leads to patient discomfort.[1,2]

A number of vascular closure devices are available.[3,4] Angioseal, which was introduced as a vascular closure device in Europe in 1994 operate by compressing the puncture site between an anchor and a collagen plug.[5]

This study aimed to evaluate the efficacy and safety of Angioseal in interventional radiological therapeutic interventions of the peripheral arterial system.

Material and Methods

All consecutive patients, who had undergone a therapeutic radiological intervention using the femoral artery approach from January 2001 to 2005 in the Service of Vascular and Endocrine Surgery, Henri Mondor Hospital, Creteil, France, were prospectively included in the study. The data regarding patient age, sex, demographics, and the use of anticoagulants and antiplatelet agents were recorded. The data concerning the procedural details such as the size of the vascular sheath employed, type of procedure performed, and indication for arteriography was noted.

A positive history of hypertension was defined as need for antihypertensive drugs or systolic blood pressure 160 mm Hg or greater or diastolic blood pressure 95 mm Hg or greater. A positive history of hypercholesterolemia was defined as need for cholesterol-lowering medication or serum cholesterol concentration 5.0 mmol/L or greater. A positive history of diabetes mellitus was defined as need for glucose-lowering medication or (non-fasting) serum glucose concentration of 11.0 mmol/L or greater. Currents smokers and former smokers in the last 10 years were categorized as smokers. A positive history of angina pectoris or previous cardiac intervention, ischemia on ECG and the need for a cardiac treatment were categorized as cardiac disease.

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Patients underwent percutaneous approach using the standard Seldinger technique. The procedures were performed in the operating theatre or in the interventional radiology suite. Patients were prepped with betadine before the intervention. Heparin (0.5 IU/kg) was administered intravenously before balloon dilatation or stent placement. The size of the Angioseal devices was decided according to the vascular sheath that was used. The puncture site was closed with 6-French Angioseal after the use of 5F and 6F sheaths whilst 8F Angioseal device was used for 7F sheaths. Patients were placed at bed rest for at least 30 min after use of the 6F device and 90 min following use of the 8F device according to the product representative recommendations.

The efficacy of Angioseal was defined by the ability of the device to cover the puncture site and stop bleeding. The safety was defined by the rate of complications. Bleeding was defined by a hematoma greater than 6 cm and a decrease in hemoglobin of more than 1 g, as well as those requiring transfusion or operation.

Results

A total of 79 Angioseal devices were employed on 77 patients during the study period. There were 62 (78.5%) males and 17 (21.5%) females. The mean age of the patients was 65.2±11.6 years (mean±SD). Of 79 patients, 9 (11.4%) had diabetes, 39 (49.3%) had hypertension, 17 (21.5%) had hyperlipidemia, 16 (20.2%) had coronary heart disease, and 22 (27.8%) were current smokers. There were 2 (2.5%) patients with bladder cancer, one patient (1.2%) with prostate cancer, one patient (1.2%) with Hodgkin's disease, one patient (1.2%) with larynx cancer, and another patient (1.2%) with cirrhosis Table 1. All patients were receiving antiplatelet treatment at the time of the intervention, whilst 2 (2.5%) of the patients were receiving anticoagulant treatment. Thirty-five (44.3%) patients were hospitalized for lower limb ischemia, whilst 27 (34.2%) and 17 (21.5%) patients were hospitalized for carotid stenosis and other causes, respectively.

The procedures included iliac and lower limb revascularization in 36 (45.5%) patients, cerebrovascular procedures in 28 (35.4%), and renal angioplasty and stenting in 10 (12.6%) patients. Two (2.5%) of the patients underwent two separate interventions during the procedure. The patients, who had undergone a procedure for lower limb revascularization, included 3 (3.7%) patients that received fibrinolysis for an occluded femoro-popliteal bypass. The details of the procedures are shown in Table 2.

Table 1. Patients' characteristics and risk factors

Hypertension	39 (49.3%)
Current smokers	22 (27.8%)
Hyperlipidemia	17 (21.5%)
Coronary heart disease	16 (20.2%)
Diabetes mellitus	9 (11.4%)
Bladder cancer	2 (2.5%)
Prostate cancer	1 (1.2%)
Hodgkin's disease	1 (1.2%)
Larynx cancer	1 (1.2%)
Cirrhosis	1 (1.2%)

All Angioseal devices were deployed successfully. There were 62 (78.4%) 6F and 17 (21.6%) 8F sheaths employed during the procedures. There were two minor (2.5%) hematomas and one (1.2%) major hematoma after the procedure. The patient, who had a major hematoma required two units of blood transfusion but no surgical intervention. He also had a pseudoaneurysm of 5 mm, which was demonstrated by computerized tomography scanning. The pseudoaneurysm resolved at 1 month. Two patients suffered from temporary renal insufficiency, which resolved with hydration. The mean time of discharge from the hospital was 2.1±1.8 (mean±SD) days (Table 2).

The patients were followed up for a mean of 9.0±9.3 (1–60 months) months. One patient, who had chronic renal insufficiency and a lower extremity ulcer died as a result of a septic shock 2 months after the intervention. There were no local complications during the follow-up period.

Discussion

Endovascular interventions have become a commonly accepted method of treatment in certain vascular diseases. Access site complications may lead to prolonged hospital stay and increased costs.[1,6] Hemostasis at the femoral artery access site is usually achieved by manual compression following

Table 2. The details of the procedures, which have been performed during the study period, are shown

Procedure	Frequency	Percent
Carotid and iliac artery	1	1.27
Iliac+superficial femoral artery	1	1.27
Iliac artery	21	26.58
Lower limb revascularisation	16	20.25
Renal artery	10	12.66
Subclavian artery	2	2.53
Superior mesenteric artery	1	1.27
Vertebral artery	1	1.27
Total	79	100

angiographic and interventional cardiovascular procedures. Although manual compression is effective in achieving hemostasis in most cases, it requires a 15–20 min sustained compression over the puncture site followed by prolonged rest.[7] When manual compression is used, a number of standard protocols require a minimum of 4 h of bed rest following diagnostic studies performed with 5F sheaths and a minimum of 6 h of bed rest when larger sheaths are used for therapeutic interventions.[7] Upper extremity fatigue and human resource considerations are other disadvantages of the method.

The drawbacks of manual compression have led to a search for a more comfortable methods of puncture site hemostasis for both the physician and the patient. The initial attempt was to reduce the sizes of catheters and guidewires. This led to an decreased rate of groin complications but the latest procedures in endovascular surgery required larger sheaths.[8,9] The frequent use of antiplatelet or anticoagulant agents created a tendency to bleeding in patients and an increase rate of access site complications.[10,–12] The first generation of vascular closure devices was not very welcome since these 'unsophisticated' devices were plagued with significant complication rates.[13] The design has undergone some significant changes in order to achieve a safer and a more beneficial device. The Angioseal device consists of an anchor composed of a polylactide and polyglycolide polymer, a collagen plug, and suture contained within a special carrier system.[5] When inserted, it achieves hemostasis by compressing the arterial puncture site between the anchor and the collagen plug. The Angioseal can consistently be deployed within 1 min, and is completely bioabsorbable.

In our series, Angioseal was effective in achieving hemostasis in 98.7% of the patients. One patient developed a retroperitoneal hematoma, which required two units of blood transfusion and had a pseudoaneurysm of 5 mm at the puncture site on the computerized tomography scan. However, the hematoma did not require further treatment than transfusion and the pseudoaneurysm resolved spontaneously at 1 month. The results of previous studies are in accordance to ours, revealing Angioseal as an effective and a safe method of femoral puncture site closure device following interventional vascular procedures. An efficacy of 95–100% exists in different reports.[14] In a recent report, which included 188 patients and 144 procedures, all but three of Angioseal devices were deployed successfully.[2] These results are satisfying because manual compression was effective in achieving hemostasis without any further complications in patients with failure of deployment. As well as its efficacy, its safety is promoted by these reports as complications such as infection, hemorrhage, and vessel occlusion have been uncommon, ranging from 0 to 1.9%.[15–17] In the series of Abando *et al.*,[2] which included 76 therapeutic interventions, there were no significant bleeding complications or infections.

Angioseal allowed early ambulation, rapid recovery time, and decreased discomfort in our patients. Hence, the patients may be more satisfied with safe and effective closure devices. The mean time of discharge of our patients was 2.1 days but this group also included patients with diabetic foot ulcers. Therefore, it included patients, who needed prolonged hospitalization for local treatment. However, in 1-day procedures, closure devices are supportive since patients can be ambulated 1 h after the placement of a 6F device, and within 3 h after placement of an 8F device.[2]

In conclusion, we believe that Angioseal provides a safe and effective way of closing the puncture site at the femoral artery following an interventional therapeutic vascular approach.

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