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Treatment of Acute Lower Limb Ischemia Following the Use of the Duett Sealing Device: Report of Three Cases and Review of the Literature

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Abstract

Three cases of local thrombolysis in the treatment of acute lower limb ischemia complicating the utilization of the Duett sealing device are presented. Routine usage of several vascular closure devices after cardiac catheterization and percutaneous coronary intervention (PCI) has been adopted in our institution during the last 3 years (September 1999 to April 2003). The Duett closure device has been used in 420 patients (post-coronary angiography, 359; post-PCI, 61). Three patients (0.7%) demonstrated acute leg ischemia caused by inadvertent intravascular administration of the sealing material related to this device. All three were treated successfully by catheter-directed local thrombolysis (tissue plasminogen activator 5 mg bolus followed initially by 1 mg/hr and consequently by 0.5–1.0 mg/hr depending upon the development of significant hematoma and lasting for 24 hr). In conclusion, interventional treatment using local thrombolysis should be the first-line treatment in acute lower limb ischemia complicating the utilization of the Duett sealing device.

Key words: Duett—Closure devices—Acute limb ischemia—Local thrombolysis—Complications

Hemostasis following percutaneous vascular access has traditionally been accomplished by manual compression. However, the large number of percutaneous cardiac and peripheral procedures performed currently worldwide has led to an increased utilization of percutaneous vascular closure devices in order to shorten time to hemostasis, maximize patient comfort, and expedite time to ambulation and discharge [1]. These devices have been stated to be of particular use in patients who have been anticoagulated [2]. There has been a recent growth in the number and design of closure devices, without a consensus as to whether these devices should be used routinely or selectively and under which circumstances [3]. With increased usage of these devices reports of complications have also emerged [4]. One of the most important complications that has been reported is collagen embolization to the lower extremity arteries [5].

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Routine usage of several vascular closure devices after cardiac catheterization and percutaneous coronary intervention (PCI) has been adopted in our institution since 1999. One of the closure devices used is the Duett system (Vascular Solutions, Minneapolis, MN, USA), a sealing device comprised of a balloon delivery catheter and a flowable procoagulant consisting of thrombin and collagen.

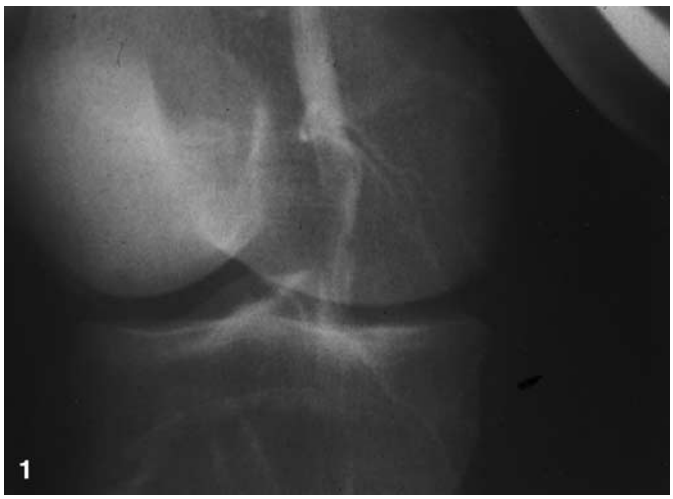
We present the experience of our center in acute leg ischemia caused by collagen embolization following the use of the Duett device. Of 420 patients in whom the device was used, three (0.7%) developed acute below-the-knee ischemia and were treated successfully by local thrombolysis. We also review the literature regarding the incidence and treatment of lower limb ischemia related to collagen embolization after the utilization of the Duett vascular sealing device.

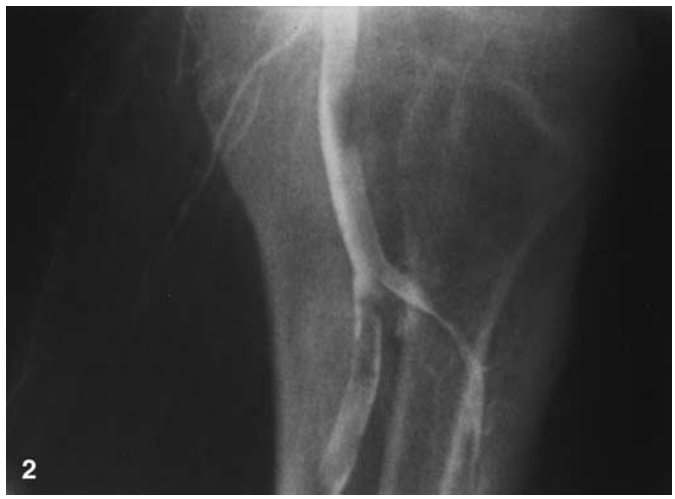
Case Reports

From September 1999 to April 2003, the Duett vascular sealing device was utilized in 420 patients who underwent percutaneous procedures via the femoral arteries (in 359 following diagnostic cardiac catheterization and in 61 following PCI).

The device delivers a mixture of bovine collagen and thrombin by the use of a balloon positioning catheter, which incorporates a moveable core wire. This mixture is delivered through a 3 Fr catheter system positioned inside the artery through the sheath. The balloon is then inflated within the artery and retracted initially against the sheath and subsequently the whole system against the vessel wall. An attempt at aspiration through sheath is made when the balloon reaches the site of the punctured arterial wall. As the sheath lies outside the artery and the inflated balloon tamponades the arterial puncture, blood should not be aspirated. At this point, injection of the pro-coagulant mixture takes place. If blood is aspirated through the sheath, then the balloon is deflated and the system repositioned deeper in the arterial lumen. Then the steps of balloon inflation and system retraction are repeated. The pro-coagulant mixture is injected through the sheath as this is removed, with the intention of covering only the external surface of the artery and sealing the whole track from the artery to the skin surface. After the end of the injection the balloon is deflated and removed through the sealed track, while the operator applies pressure to the puncture site.

The Duett device was utilized by three interventionists experienced in the usage of the device and the device was positioned according to the manufacturer's instructions. None of the patients had significant stenoses in the femoral and iliac arteries ipsilateral to the puncture site, as this is considered to be a contraindication to the use of the Duett system.





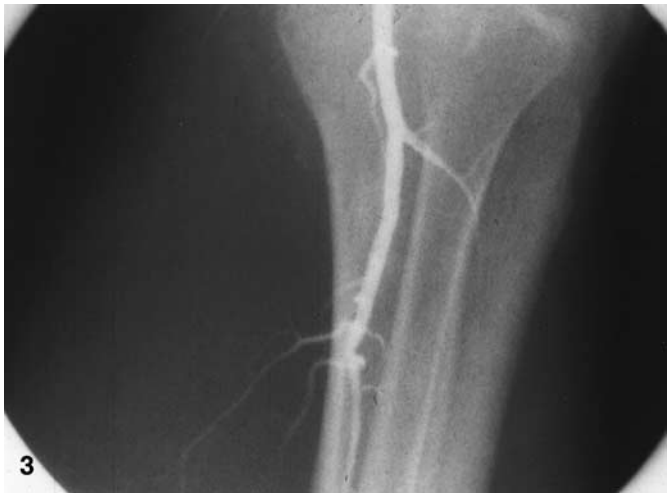


Fig. 1. Patient 1. The first angiogram showing a totally occluded popliteal artery proximal to the trifurcation with angiographic evidence of thrombus.
Fig. 2. Patient 1. Angiogram performed 6 hr after the initiation of thrombolysis, showing the remaining thrombus and partial restoration of flow in the popliteal artery.
Fig. 3. Patient 1. Angiogram 24 hr after the index event showing lysis of the thrombus and restoration of the peripheral circulation.

Lower limb ischemia related to collagen embolization following the usage of the device was reported in three patients who had undergone diagnostic cardiac catheterization through a 6 Fr introducer sheath via the right femoral artery. None of these patients had known peripheral vascular disease or suffered from claudication. On routine physical examination prior to the catheterization, femoral, popliteal, posterior tibial and dorsalis pedis arteries were palpable bilaterally in all three patients. Immediately after catheterization, the right femoral artery puncture site was sealed using the Duett device. Five to ten minutes later all three patients complained of pain in their right calf. Their lower limbs were pale and cold below the knee while previously palpable anterior tibial and posterior tibial arteries were absent. Pedal Doppler signals were also absent. The patients were immediately brought back to the catheterization laboratory and underwent diagnostic angiographies via their left femoral arteries. In all three cases these revealed normal right iliac and femoral arteries and totally occluded popliteal arteries proximal to the trifurcation with angiographic evidence of thrombus (Fig. 1). In each case local thrombolysis (tissue plasminogen activator 5 mg bolus, followed by 1 mg/hr for 24 hr) was initiated using a 5 Fr straight catheter with side-holes positioned within the occlusion. Within 6 hr, clinical improvement with relief of pain, partial restoration of temperature and color in the lower limb were observed and confirmed by a subsequent angiogram in all three patients (Fig. 2). Twenty-four hours following the index event, there was complete clinical recovery and a third angiogram showed that the thrombus had been fully dissolved (Fig. 3). Subsequently thrombolysis was terminated. Low-dose intravenous unfractionated heparin (500 IU/hr) was also administered in conjunction with thrombolysis and for an additional 24 hr after the discontinuation of the thrombolytic regime.

All three patients developed hematomas at the site sealed with the Duett system but only one required blood transfusion due to a significant drop in hematocrit. In this patient although thrombolysis lasted for 24 hr its rate was reduced to 0.5 mg/hr after the third hour when the hematoma started developing while firm pressure was applied at the site of the hematoma. This patient was discharged home at day 7 post-angiography and 15 days later he underwent PCI at his left anterior descending artery following an episode of unstable angina. At that time the hematoma had fully dissolved and the right groin was used again as the access site. All patients recovered without further complications. On clinical follow-up (2–30 months), none of the three patients developed any problems related to the event.

Discussion

Sealing of arterial access sites utilizing closure devices achieves more rapid ambulation compared with manual compression [6]. Deployment of these puncture closure devices is an additional procedure, with the attendant risk of higher complication rates [6, 7]. The most important concern relating to devices employing hemostatic agents, such as the Duett system, is the risk of inadvertent intravascular administration which could lead to extensive intra-arterial thrombosis with resultant limb ischemia or infarction.

The Duett device delivers outside the arterial lumen a mixture of bovine collagen and thrombin. The procoagulant is a suspension comprised of 250 mg of bovine microfibrillar collagen (Avitene, Davol, Woburn, MA, USA) and 10,000 units of bovine thrombin (Gentrac, Middleton, WI, USA) reconstituted in 5 ml of phosphate-

buffered water for optimal viscosity, osmolarity and pH. The mechanisms of the Duett sealing effect are based on platelet activation by collagen and conversion of fibrinogen directly to fibrin by thrombin.

The principal goal in the treatment of acute limb ischemia is rapid restoration of blood flow to the ischemic region before the occurrence of irreversible damages. Surgical treatment of acute limb ischemia, because of co-morbidity, has a high 30-day mortality and morbidity rate [7, 8]. Alternative, less invasive solutions are highly desirable. We reviewed the four published series referring to the usage of the Duett device which included a large number of patients (≥200). Silber et al. [10] reported four cases of arterial occlusion related to the use of the Duett in a total of 1,587 patients (0.25%). Three patients were successfully treated with thrombolysis, while surgical intervention was performed in one. The SEAL Trial Study Team [11], assessing the safety and efficacy of the Duett device in 392 patients, reported two cases (0.5%) of arterial occlusion following its use. Successful restoration of blood flow was achieved following intra-arterial administration of urokinase in one of these patients and surgical femoral-popliteal thrombectomy in the other. Heyer et al. [12] reported no incidence of lower limb ischemia after using the Duett device in their series of 200 patients. Our group has previously reported a 0.7% (2/281) incidence of acute lower limb ischemia related to the Duett device, all treated successfully by local thrombolysis [13].

In summary, according to the published data, the incidence of acute lower limb ischemia due to collagen embolization following the use of the Duett device ranges from 0.25% to 0.7% and a total of nine cases have been reported (0.35%). Seven of these nine patients were treated with thrombolysis and two with surgical intervention. No criteria on which the choice of treatment (intra-arterial thrombolysis vs surgical intervention) should be based have been proposed in the literature. In the two patients managed surgically, it is not known whether surgical treatment was used as a first-line treatment or after failure of a thrombolytic regime. In the published studies reviewed, the site of the occlusion following use of the Duett device is not clearly stated. According to our experience, the occlusion occurs at the popliteal artery before the trifurcation. This is possibly due to the type of the procoagulant used in conjunction with this device (fluid, as opposed to the plug used in the other commercially available device). The site of the occlusion may not be attributed to pre-existing atherosclerosis in the popliteal artery. Significant peripheral vascular disease may be excluded by the patient's history and physical examination prior to the catheterization and the follow-up angiograms after thrombolysis. The three cases that we report, demonstrate that the procoagulant mixture used in the Duett device is relatively easily degraded by thrombolytics, such as tissue plasminogen activator, delivered intra-arterially at the site of the occlusion. Hematomas, however, develop at the site sealed with the system and transfusions may be needed.

In conclusion, the incidence of acute lower limb ischemia after the use of Duett sealing device is low, but significant (0.35%). The complication, which is due to an occlusion of the popliteal artery, secondary to collagen embolization, occurs very early (i.e., 5–10 min) after the procedure. The treatment of acute lower extremity ischemia caused by the thrombotic material related to the Duett vascular sealing device by local catheter-directed 24 hr infusion of a thrombolytic agent in conjunction with low-dose intravenous heparin is safe and effective and can be used as the initial treatment option.

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