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Suture-mediated Percutaneous Closure of Antegrade Femoral Arterial Access Sites in Patients Who Have Received Full Anticoagulation Therapy[1]

PURPOSE: To assess the feasibility and clinical usefulness of suture-mediated closure of femoral arterial access sites after antegrade puncture for peripheral arterial interventions.

MATERIALS AND METHODS: Eighty consecutive patients (49 men, 31 women; mean age ± SD, 65.4 years ± 12.3) who had undergone femoropopliteal angioplasty underwent suture-mediated percutaneous closure with 6-, 7-, or 8-F devices. Patients received heparin intravenously and aspirin orally and were immobilized for 1 hour after the intervention. All patients underwent a physical examination the day after the procedure. Color-coded duplex ultrasonography was performed in those patients (n = 27 [33%]) who were obese, were experiencing pain, and had suspicious clinical findings. After 3 months, an identical clinical examination was performed in every third patient.

RESULTS: Hemostasis was achieved in 77 (96%) patients; one of 80 patients required blood transfusions and surgery despite an initially successful closure. The closure devices could be deployed in 78 (98%) patients; two of 80 patients needed compression because of a steep angulation of the puncture track and suture entrapment. Adjunctive compression was necessary in two (3%) of the remaining 78 patients. Mean time to hemostasis in the 78 patients who had successful device deployment was 5.2 minutes (range, 3.0–21.0 minutes). Minor complications (ie, three small hematomas, a pseudoaneurysm, and a small lymphatic fistula) occurred in five (6%) patients.

CONCLUSION: Suture-mediated percutaneous closure of antegrade puncture sites in the groin is feasible. Problems may arise in antegrade punctures owing to steep device angulation.

Interventional radiologic procedures for revascularization of lower-limb arteries are usually performed through the common femoral artery. Hemostasis of the arterial entry site is normally achieved by using manual compression followed by a prolonged period of bed rest. Thus, patient treatment after transarterial procedures is time-consuming and affects the cost of hospitalization (1). To overcome these limitations, percutaneous vascular closure devices have been developed. The Vasoseal (Datascope, Montvale, NJ) and Angioseal (Kensey Nash, Exton, Pa) closure devices have collagen plugs that are intended to seal the arterial entry site by applying discrete pressure against the wall and forming a coagulum. The Angioseal device has an additional intravascular absorbable anchor to facilitate collagen plug apposition. The use of collagen plugs helps to reduce the time to hemostasis and has resulted in a decreased time to ambulation in several studies (2,3). However, other investigators (4,5) could not prove the superiority of collagen sealing compared with manual compression for achieving primary hemostasis or for substantially reducing arterial access site complications.

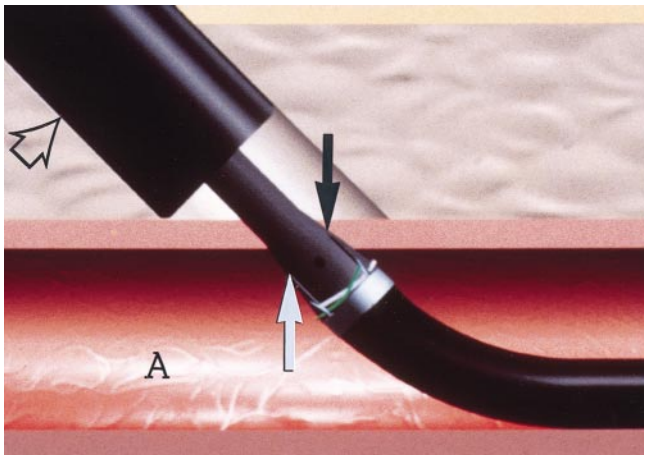

Figure 1. Schematic drawing of percutaneous vascular suturing device, which has a flexible sheath that encloses the suturing needles (straight arrows) and a barrel (open arrow) that receives the deployed needles. *A* = lumen of the common femoral artery.

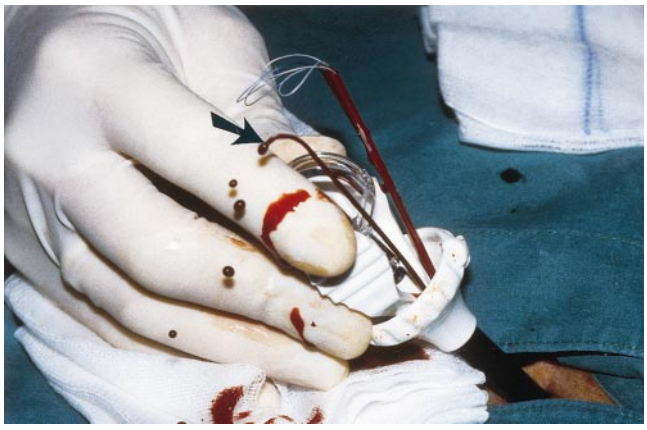

Figure 2. Photograph of pulsatile flow (arrow) exiting from the marker port, which indicates proper positioning of the device.

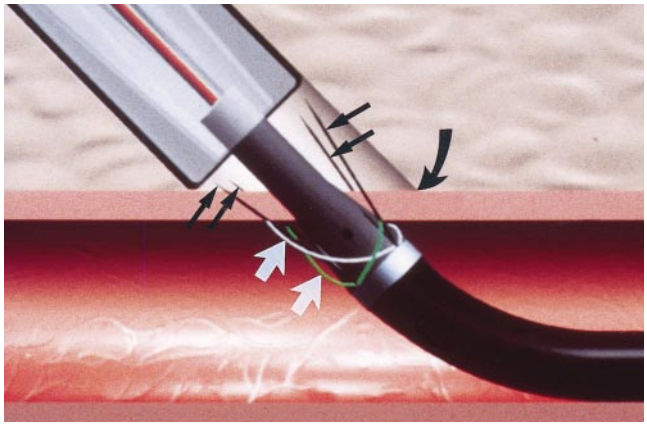

Figure 3. Schematic drawing of deployment of needles (straight black arrows) and sutures (white arrows) through the arterial wall (curved black arrow) around the puncture site.

A different approach has involved the development of a percutaneous vascular closure device that delivers needles and sutures through the arterial wall around the access site. A potential advantage of this device is the lack of delayed bleeding after the interventional procedure because there are no collagen plugs that could become resorbed or dislodged (4,6,7). The purpose of this study was to assess the feasibility and clinical usefulness of suture-mediated closure of femoral arterial access sites after antegrade puncture for peripheral arterial interventions in patients who have received full anticoagulation therapy.

MATERIALS AND METHODS

This was a prospective, single-center registry in which clinical and ultrasonographic (US) follow-up was used to assess the safety and usefulness of a percutaneous vascular closure device after antegrade puncture.

Subjects

Eighty consecutive patients (49 men, 31 women; mean age ± SD, 65.4 years ± 12.3) were enrolled from January to August 1997. No patients were eliminated from the study for any particular reason such as having undergone prior bypass grafting or previous punctures. All patients had undergone antegrade puncture of the common femoral artery. The procedures were performed in accordance with institutional guidelines. All subjects gave written informed consent. In 65 patients, 5-F sheaths (Cordis, Miami, Fla) were used for balloon angioplasty. In 10 patients, 7-F introducer sheaths were used for placement of Palmaz stents (Johnson & Johnson, Warren, NJ). In five patients, 8-F introducer sheaths were used for percutaneous suction of thrombi with aspiration catheters (Cordis). Two hours before the scheduled intervention, patients received 100 mg of aspirin (Bayer, Leverkusen, Germany) orally, and continued taking it for 6 months. Immediately after placement of the introducer sheaths, 5,000 IU of unfractionated heparin sodium (Medac, Hamburg, Germany) was administered intraarterially, followed by 20,000 IU of heparin sodium, which was administered intravenously for 24 hours. Antibiotics were not administered. All variables were expressed as means ± SDs or as numbers of patients and percentages.

Device Description

The Techstar and Prostar Plus devices (Perclose, Menlo Park, Calif) were designed to deliver 3-0 polyester sutures to close femoral arterial puncture sites. All of the systems used in this trial were second-generation devices. The Techstar device, which was available for use with 6- or 7-F sheaths, delivered one suture with two needles, whereas the Prostar Plus device, which could be used with 8-F sheaths, delivered two sutures with four needles. The devices consisted of a sheath that enclosed the sutures and needles, a guide for needle placement around the puncture site, and a barrel that received the deployed needles (Fig 1). The Techstar device was 11 inches long and had a straight tip. The Prostar Plus device was 15 inches long and had a J-shaped tip at the distal end. A marker lumen ensured proper device positioning. A pulsatile

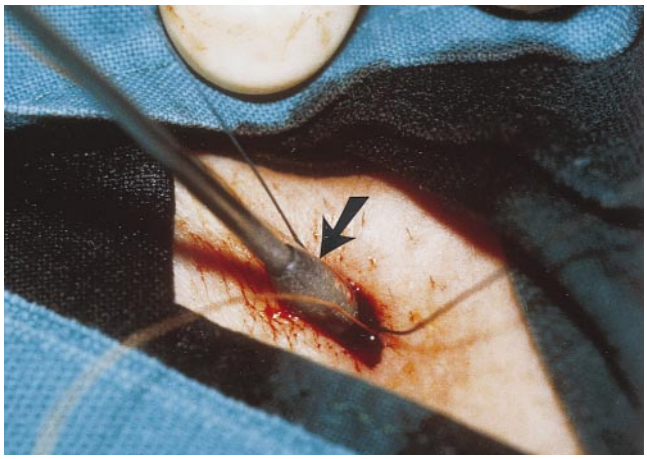

Figure 4. Photograph of knot pusher (arrow) sliding the square knot and two overhand throw knots down to the artery. The knot pusher tightens the arterial tissue and brings the tissue layers into apposition.

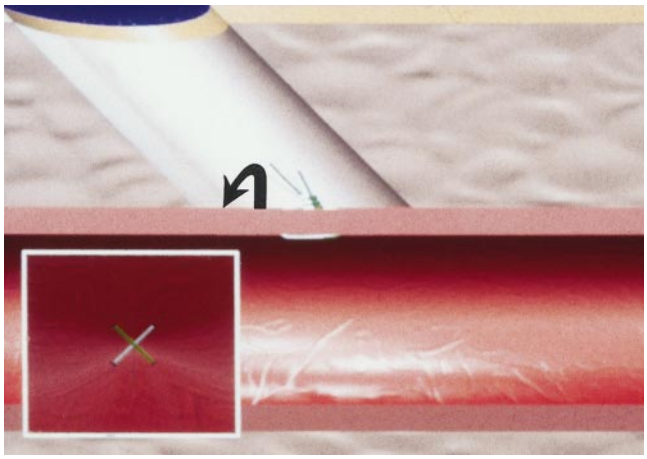

Figure 5. Schematic drawing of the closed arterial access site after the removal of the percutaneous vascular suturing device and the cutting of the sutures. The area magnified in the box in the lower left corner is indicated by the curved arrow.

backbleed from the femoral artery indicated the proper intraarterial positioning of the needles (Fig 2).

The barrel could be rotated independently from the central core to prepare the subcutaneous track and to facilitate device positioning. All devices tracked over a standard 0.035 or 0.038 guide wire. In this study, the hydrophilic wire (Glidewire; Terumo, Tokyo, Japan) that was already in use for the recanalization procedure was used for device insertion in all instances. A knot pusher was used to advance the knots through the subcutaneous track to the arterial surface.

Technique

Users of any hemostatic devices on the market must have appropriate training to avoid complications due to poor technique. All vascular closures were performed by one operator (S.H.D.), who underwent 1 hour of hands-on training with a vascular model before using the device in the clinical setting. Then the closure procedure was performed after retrograde puncture on the first 30 patients under the supervision of a clinical specialist. Before the commencement of this study, the operator performed an additional 20 retrograde closures and 30 antegrade closures. Care was taken to puncture the anterior wall of the common femoral artery. A single puncture of the arterial wall could be accomplished in 52 (65%) of the 80 patients. Imaging studies in which contrast material was administered through the needle or introducer sheath were not performed to confirm that the common femoral artery was punctured. We did not use any guidance such as US guidance for the puncture. There were no prior studies that confirmed a lack of disease in the common femoral arterial access.

At completion of the angioplasty, a scalpel was used to extend the incision slightly (ie, 7–8 mm), and a mosquito clamp was used to dilate the subcutaneous tissue adjacent to the introducer sheath. The introducer sheath was replaced by using the vascular closure device along the standard guide wire. Appropriate positioning of the device was evident when a pulsatile flow of blood was seen at the marker port (Fig 2). Radiographs of the devices were not obtained, and fluoroscopy was not performed to control device positioning. The needles and sutures were deployed through the arterial wall (Fig 3), and the sutures were freed from the device. Surgical knots (ie, one square knot and two overhand throw knots) were tied and advanced to the artery by using the knot pusher (Fig 4) and tightened to bring the arterial tissue into apposition (Fig 5). Neither manual compression nor a compression bandage was applied. The patients were allowed to sit up immediately after the closure procedure. Patients were encouraged to ambulate early, that is, to leave their bed 1 hour after deployment of the closure device. According to the study protocol, the patients were discharged from the hospital the day after the closure procedure.

Follow-up Protocol

The day after percutaneous intervention, all patients underwent clinical follow-up examinations, which comprised a physical examination performed by an interventional radiologist (S.H.D.) and a vascular surgeon (M.E., K.K., J.A.) and a determination of ankle-arm pressures. Color-coded duplex US was performed in obese patients and in patients who complained of pain or had unclear clinical findings such as local tenderness in the groin, discoloration of the skin, or a bruit; these control US scans were obtained in 27 (33%) of the 80 patients. After 3 months, all 80 patients were contacted by phone and questioned with regard to their well-being. Because there were no complaints, every third patient (n = 26) was asked to undergo the same clinical examination at the hospital as that performed on day 1 after the procedure—a physical examination and a determination of the ankle-arm pressures.

Study Definitions

The primary safety end point was the combined number of major complications at 30 days after the interventional procedure, and the primary effectiveness end point was the time to hemostasis (ie, the time from obtaining the final angiogram to achieving hemostasis, including the preparation and placement of the closure devices). Major complications included the need for surgery or US-guided compression for repair of vascular or nerve injury, the need for groin-related transfusion, a groin-related infection for which antibiotics were required, or prolonged hospitalization.

The secondary end point was the combined number of minor complications during the first 30 days after the vascular closure procedure. These minor complica-

tions were reversible nerve injury, a US-confirmed pseudoaneurysm or arteriovenous fistula that did not necessitate surgery, a groin hematoma that did not necessitate transfusion, distal arterial embolization, a lymphatic fistula, and localized skin infection treated with oral antibiotics. Procedural success was measured as an additional secondary end point. On the basis of intent-to-treat analysis, procedural success was defined as the hemostasis achieved with the suture-mediated device alone or with adjunctive compression. Adjunctive compression was defined as the use of light, nonarterial compression after primary hemostasis was achieved with the device. Reintroduction of the introducer sheath or immediate nonadjunctive arterial compression was termed ''crossover to compression.''

Failure to deploy the device, regardless of whether the outcome was final hemostasis or complication, referred to the inability to gain access with the device sheath, the inability to obtain arterial marking, or the inability to deliver or successfully secure the suture. Failure to deploy was further categorized as either device malfunction or device complication. Device malfunction meant failure to deploy the device, with final hemostasis achieved by using manual compression and without any complication. Device complication meant failure to deploy the device, with a result of any complication.

RESULTS

Closure procedures were attempted in 80 patients. No patient was excluded. The activated partial thromboplastin time at vascular closure was at least 40 seconds in all patients. In 34 (42%) patients the activated partial thromboplastin time was at least 70 seconds, and in 13 (16%) patients it was at least 120 seconds.

Primary End Points

Four hours after an initially successful closure procedure, one diabetic patient with an activated partial thromboplastin time of 75 seconds developed a hematoma in the retroperitoneum, which was proved at computed tomography. After blood transfusion, she underwent surgical repair and recovered. Thus, the rate of major complications at 30 days was 1%. The mean time (± SD) to hemostasis for all 78 patients who had successful deployment of the closure device was 5.2 minutes ± 3.8. Because immediate hemostasis was obtained in 76 patients after securing the final suture, the time to hemostasis was practically equal to the time necessary for preparation and placement of the closure devices.

Secondary End Points

Procedural success for obtaining hemostasis was achieved in 77 (96%) of the 80 patients because, in addition to the patient who required surgery and transfusion, in two patients there was failure to deploy the device (Table). In one of these patients, we were not able to introduce the 6-F device sheath into the artery owing to a steep angulation caused by excessive obesity. In the other patient, there was a device malfunction; the suture was trapped inside the device. These patients were crossed over to conventional compression therapy, which led to hemostasis after 30 minutes in the obese patient and after 45 minutes in the patient with device malfunction. Thus, the device failed in both of these patients. Adjunctive compression was performed in two (3%) of the remaining 78 patients to stop oozing from the subcutaneous track.

There was a 6% (in five of 80 patients) rate of minor complications. US scans of the punctured groin in 27 patients revealed small (3–5-cm) hematomas in three patients. There was one 2.5-cm-diameter pseudoaneurysm that closed spontaneously during the 30-day follow-up. The results of Doppler waveform analyses performed in these 27 patients did not reveal any sign of luminal abnormality; this confirmed that the closure procedure did not modify the arterial wall integrity. No arteriovenous fistulas or true aneurysms were reported. The results of clinical examination and of ankle-brachial index evaluation in all patients did not show any signs of peripheral ischemia that was attributable to the suture-mediated closure. In a very thin (44-kg) patient, a lymphatic fistula that arose from the subcutaneous track was observed. This fistula closed spontaneously after 3 weeks. There was no distal embolization. All femoral arterial access sites healed without signs of inflammation or infection. In clinical terms, all 26 patients seen at 3 months after angioplasty were free of access site abnormalities. No late bleeding or nerve injury had occurred.

End Points after Suture-mediated Percutaneous Closure of Femoral Arterial Access Sites

End Points	No. of Patients*
Procedural success†	77 (96)
Crossover to compression required	2 (2)
Adjunctive compression required	2 (3)
Major complication	
Retroperitoneal hematoma	1 (1)
Minor complications	
Nerve injury	0 (0)
Pseudoaneurysm treated without surgery	1 (1)
Arteriovenous fistula	0 (0)
Groin hematomas treated without transfusion	3 (4)
Localized infection	0 (0)
Lymphatic fistula	1 (1)
Distal embolization	0 (0)

* The numbers in parentheses are percentages. All percentages, except that of the number of patients who needed adjunctive compression ($n = 78$), are based on a total of 80 patients.

† Procedural success refers to the hemostasis achieved with the suture-mediated device alone or with adjunctive compression.

DISCUSSION

The results of our study showed that suture-mediated percutaneous closure of antegrade puncture sites in the groin is feasible. The rate of procedural success for antegrade closure was 96% (in 77 of 80 patients) in unselected patients. One patient had to undergo a surgical repair. The results of the operation revealed that the need for repair was due to a fascial closure instead of an arterial closure. Our follow-up data suggest that there is no danger of more delayed arterial bleeding with this remote suturing technique. The 1% rate of major complications is in the range reported for complications with the retrograde approach—0.8% (8).

The patients in this study were ambulatory 1 hour after the closure procedure. The primary effectiveness end point in this study was the time to hemostasis, the mean of which was 5.2 minutes ± 3.8. This compares favorably with a mean time to hemostasis of 9.6 minutes when collagen plugs are used and a reported mean time of 23.6 minutes when manual compression is used in patients after cardiac catheterization (9). In a multicenter trial (1) that involved more than 3,000 patients, the mean time to hemostasis with hand-held arterial compression was 33.5 minutes. An average time to hemostasis of 19.9 minutes with mechanical clamps has been reported (1). However, due to different study designs and definitions, these data can only be viewed with caution.

All of the patients in our study were receiving an anticoagulation regimen of nonfractionated, intravenously administered heparin and orally administered aspirin, and we concluded that the 1-hour immobilization helped to reduce the oozing from the subcutaneous track because of this regimen. However, in two cases, we had to use adjunctive (ie, light nonarterial) compression. Carere et al (10) reported an oozing of blood in four (12%) of 32 suture-mediated closures during heparin treatment. This is also a well-known phenomenon with collagen plug devices. Aker and colleagues (11) reported the need for supplemental manual pressure in 11 (37%) of 30 patients who underwent closure with the Angioseal device. In published series (5,12) on the use of collagen plugs, a reduced compression time was reported; however, a superiority over manual compression for achieving primary hemostasis or substantially reducing vascular access site complications was not reported.

Access site complications of vascular interventional procedures include the formation of hematomas (6.0% incidence), pseudoaneurysms (0.5%–0.9% incidence), arteriovenous fistulas (0.1% incidence), and infectious processes (1,13). These complications are dependent on the anatomic location of the access site, patient weight, size of the introducer sheath, and coagulation status (14–20). In a study by Skillman and colleagues (21), the necessity of an operative repair arose in 0.9% of transfemoral coronary angioplasties. For peripheral arterial interventions, the transbrachial approach and transradial approach are usually inappropriate. The results of a recently published randomized comparison of different access sites for angioplasty (22) revealed a 0% rate of major entry site complications with the transradial approach, a 2.3% rate with the transbrachial approach, and a 2.0% rate with the transfemoral approach. Gardiner and colleagues (23) reported that hematomas occurred at a rate of 4.4% with transluminal angioplasty. Most bleeding disorders such as severe thrombocytopenia have to be corrected before the patient can safely undergo transarterial intervention (18). The EPILOG (ie, evaluation of percutaneous transluminal coronary angioplasty to improve long-term outcome by c7E3 platelet glycoprotein complex IIb/IIIa receptor blockade) trial (24) recommends that the activated partial thromboplastin time be less than 50 seconds before sheath removal and that compression be applied to the groin for a minimum of 30 minutes after sheath removal.

To achieve secure closure of arterial puncture sites, use of C clamps or the Femostop mechanical compression device (Bard Interventional Products, Billerica, Mass) in addition to compression bandages has been advocated (1,25). As early as 1974, vascular surgeons investigated the use of collagen for improving local hemostasis (26). More recently, the use of collagen plugs percutaneously has become clinically feasible (4–6,12,27). Successful preclinical work with fibrin sealants enhanced with collagen also has been performed (28). The absorbable collagen plugs aim at sealing the puncture track by promoting platelet adhesion and clot formation. Because dislodgment of the collagen plug and delayed bleeding have been a concern with the initial closure device (ie, the Vasoseal) (4,6), Kenneth R. Kensey, MD, developed a modified device (ie, the Angioseal) that has an additional intravascular absorbable anchor (12,29). Each of the various percutaneous closure devices has specific complications. A 21% rate of hematomas, 7% rate of pseudoaneurysms, and 2% rate of arterial occlusions (4,27) have been reported with the use of the anchorless collagen plug. All collagen plug systems are associated with a 1.5%–2.0% rate of distal embolization of either the collagen plug itself or the intravascular anchor (12,30). The rate of substantial bleeding after using the Angioseal device has been reported to be 13% (12).

Suture-mediated percutaneous vascular closure systems in which the surgical suturing technique is used allow closure of the arterial access site without placement of any occlusive material in the subcutaneous tissue track (10). This technique can also be referred to as ''remote suturing.'' All of the current closure devices seem to preclude access to the same arterial puncture site for a period after placement. In principle, this is not true of suture-mediated percutaneous arterial closure. However, we did not have a case that necessitated a repeat arterial puncture. By using this suturing technique, a reduced rate of complications at the common femoral arterial access site has been reported compared to the complication rate reported with manual compression, even in patients who have received full anticoagulation therapy (8,10). One of the unique characteristics and potential advantages of the described suturing technique is that it currently allows percutaneous closure of arterial puncture sites with use of sheath sizes of up to 10 F.

We encountered one technical failure in an obese patient, in whom the angulation of the device was too steep to be inserted in the antegrade direction. The antegrade approach to the superficial femoral artery through the common femoral artery frequently involves a steeper angle from the puncture track when entering the artery; however, this steeper angle of the puncture needle can be avoided with careful technique. The other technical failure was attributable to suture entrapment. Since the time of this failure, the process for manufacturing the second-generation devices has been modified to incorporate some design changes that make suture flossing between device components very unlikely. These third-generation devices received U.S. Food and Drug Administration approval for retrograde access to the common femoral artery in November and December 1997. Antegrade closures of the femoral arteries have not yet been approved. To our knowledge, up to now, there has been no report of arterial stenoses that are attributable to an overclosure of the artery with the suture-mediated technique. Our US data did not reveal any sign of luminal compromise or alteration of flow dynamics. In conclusion, suture-mediated percutaneous closure of the common femoral arterial access site is feasible after antegrade puncture, even in patients who are receiving heparin intravenously on an ongoing basis. Whether this technique eventually results in a reduced risk of complications after interventional procedures in ambulated patients remains to be clarified in further studies.

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