Use of a Novel Access Technology for Femoral Artery Catheterization: Results of the RECITAL Trial

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ABSTRACT: Objective. To present results of a registry of a novel vascular access device. **Background.** Arterial access has been largely unchanged for 60 years. The Arstasis device creates a novel shallow-angle arterial access designed to facilitate hemostasis without use of a vascular closure device (VCD) or implantation of a foreign body for closure. This is the first publication to report the outcomes of Arstasis access. **Methods.** Patients (n = 346) underwent routine diagnostic cardiac catheterization (Dx) at 8 sites in the United States. Patients were assessed for device success, time to hemostasis (TTH), early sit up, time to ambulation (TTA), time-to-discharge-eligibility (TTDe) as well as safety; 249 patients had Dx only, 97 crossed over to PCI. **Results.** Device deployment was successful in 97%; the other 3% converted to routine access. Mean TTH and TTA for Dx were 4.0 ± 2.5 minutes and 1.5 ± 1.2 hours, respectively; for PCI it was 6.9 ± 5.1 minutes and 3.2 ± 3.3 hours. A subset of 245 patients (72.9%) sat up within 30 minutes after hemostasis; early sit-up was successful in all but 1 (99.6%). TTDe for Dx was 2.7 ± 1.6 hours. There were no major access-site related complications; minor complications were primarily subclinical hematomas in 1.2%. **Conclusions.** Arstasis access is associated with short TTH and TTA, early sit up after sheath pull, and accelerated TTDe, achieved without use of VCDs or implantation of a foreign body, with high success and minimal complication rates.

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The technique of femoral artery access has remained static since the initial description by Seldinger,[1] prior to which insertion of catheters required surgical cutdown. With the near universal adoption of percutaneous access for all except the very largest-bore catheter insertions, manual or device-assisted compression became the *de facto* standard for vessel closure for 4 decades. This required long periods of bed rest and prolonged pressure, with associated patient discomfort and requirement for extended hospital stay. The introduction of vascular closure devices (VCDs) in the 1990s improved both time to hemostasis (TTH) and time to ambulation (TTA) and shortened the time to hospital discharge (TTD). However, the early meta-analyses comparing VCDs to manual compression (MC) demonstrated higher complication rates with VCD use.[2,3] These meta-analyses incorporated studies that were widely appreciated to be of generally poor quality, and in addition described outmoded platforms and incorporated physician learning curves. More recent comparisons of VCD use versus MC have utilized a higher-level evidence base, but in the absence of large randomized trials, the data continue to reflect at best parity or in a few cases superiority for VCDs,[4-6] the latter based primarily on propensity analyses. These do not rule out the common problem of selection bias in assigning patients to MC based on less favorable anatomies and intraprocedural observations. Regardless, the rates of certain complications are demonstrably additive to those of MC when VCDs are used,[7] including retroperitoneal hemorrhage[8,9] and access-site infection,[10] both of which have mortality rates in the 5% range. In the case of the latter, the infection risk is augmented by the deposition of a temporary or permanent foreign body. Further, VCDs that leave foreign bodies behind in the tissue tract, artery wall, or intraluminally all increase the risk of arterial obstruction.[11]

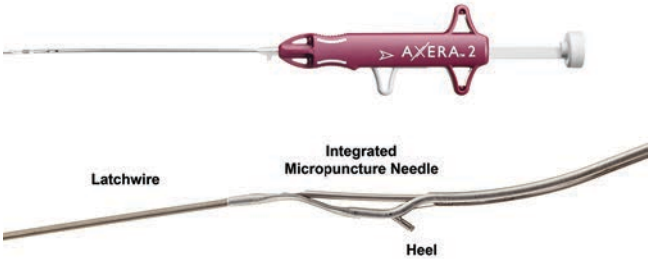

Figure 1. *The Arstasis device is seen at the top, with enlarged view below of deployed boot (heel) and fully advanced Arstaotomy needle.*

Since the original description of the Seldinger technique, needle access to the femoral artery has generally been described to be at a 45˚ angle. A novel technology, the Arstasis device (Arstasis; Figure 1), creates a shallow-angle arteriotomy (Figure 2) that is designed to create larger tissue-to-tissue contact for a potentially stronger bond after sheath removal. Blood pressure from within the arterial lumen, combined with relatively brief MC, may therefore facilitate rapid hemostasis without any foreign body left behind after the sheath is pulled. The Arstasis device has been cleared by the United States Food and Drug Administration for use in diagnostic femoral artery catheterization. This study was designed to address the potential benefits of Arstasis access and to report any complications associated with the procedure.

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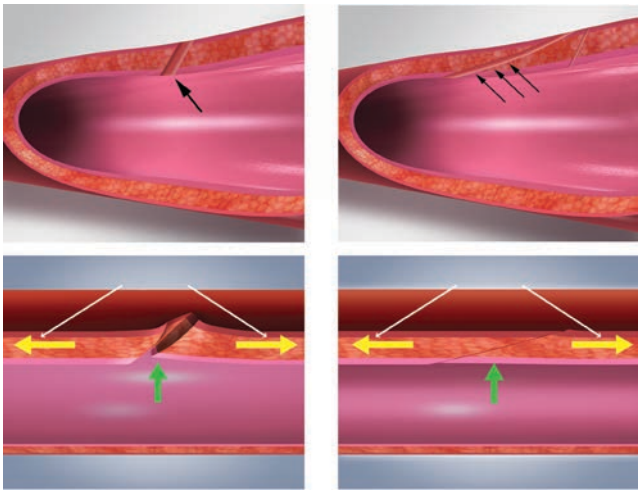

Figure 2. *The appearance of the tissue tract after conventional Seldinger technique (first column) and after vascular access using the Arstasis technique (second column). The primary channel used for the procedure sheath with the Arstasis technique is at a much shallower angle (multiple arrows) than conventional cannulation (single arrow). The theoretical benefit of Arstasis access is shown by the effect of axial pull with standard arteriotomy (first column) and Arstasis access (second column). In case of the latter, internal hydrostatic pressure facilitates closure of the shallow-angle access tract.*

Table 1. Demographic and baseline characteristics.

Description	All Patients	Diagnostic	Interventional	Diagnostic vs Interventional *P*-Value
Number	346	249	97	
Age (years)	64.4 ± 10.8	63.5 ± 11.4	66.7 ± 8.8	.01
Body mass index	31.4 ± 6.6	31.7 ± 6.9	30.6 ± 5.4	.04
BP systolic	136.7 ± 16.6	137.2 ± 16.6	135.5 ± 16.6	.22
BP diastolic	76.8 ± 12.1	77.0 ± 12.6	76.2 ± 10.8	.48
Male	195 (56.4%)	122 (49.0%)	73 (75.3%)	<.0001
Previous access through CFA	179 (51.7%)	121 (48.6%)	58 (59.8%)	.07
Diabetes mellitus	100 (28.9%)	64 (25.7%)	36 (37.1%)	.05
History of smoking	152 (43.9%)	108 (43.4%)	44 (45.4%)	.81
Aspirin	220 (63.6%)	158 (63.5%)	62 (63.9%)	1
Clopidogrel	77 (22.3%)	48 (19.3%)	29 (29.9%)	.04
Warfarin	16 (4.6%)	13 (5.2%)	3 (3.1%)	.57
Heparin	14 (4.0%)	9 (3.6%)	5 (5.2%)	.55
Bivalirudin	56 (16.2%)	0	56 (57.7%)	<.0001
Any anticoagulant or antiplatelet agent	248 (71.7%)	178 (71.5%)	70 (72.2%)	1

CFA = common femoral artery.

Methods

The RECITAL study was a prospective, non-randomized, single-arm, open-label registry of patients undergoing planned diagnostic catheterization at 8 sites. Operators underwent a period of training prior to enrolling patients in the study. Patients aged 18 to 85 years were eligible if they had planned diagnostic catheterization with 5 Fr or 6 Fr sheath placement and were able to ambulate at least 20 feet unassisted. Patients who had uncontrolled hypertension, bleeding diathesis, active systemic or cutaneous infection, prior thrombolytic therapy within 72 hours, prior vascular surgery or vascular graft at the access site, prior femoral artery closure with a collagen or polyethylene glycol VCD within 90 days, hemodynamic instability, need for emergency surgery, were pregnant or lactating, had life expectancy less than 1 year, or who had compromised femoral artery access site were excluded from enrollment. Patients with sheaths larger than 6 Fr were excluded from analysis. The Institutional Review Board at each study site approved the protocol and informed consent was obtained in writing from all patients.

Study procedures. Using standard techniques, micropuncture access to the femoral artery was obtained. Arstasis device deployment was then performed as described in Figure 3. Femoral angiography to assess location of access was performed either after placement of the procedure sheath or at the end of the catheterization procedure. Activated clotting times (ACTs) were obtained in patients who received heparin.

At the end of diagnostic procedures, MC was applied after sheath withdrawal and pressure released after 1 minute of compression. If hemostasis was not achieved, compression was reapplied and subsequent assessment made at prespecified time intervals (3, 5, 6, 8, 10, 12, 14, 16, 18, and 20 minutes after sheath removal) until hemostasis was achieved. For patients who crossed over to PCI, ACT was allowed to decrease to the institution's standard value prior to sheath removal, and in all cases was 180 seconds or less. The same compression times as above were used in PCI patients as well, with the exception that the first assessment for hemostasis was at 1 or 3 minutes depending on individual operator preference. Within 15 minutes after hemostasis (range, 1 to 30 minutes), operators were asked to consider sitting patients up at 45 degrees if warranted by clinical condition and level of sedation. Patients were asked to report their comfort level and pain level; for those who had undergone prior catheterization, they were asked to compare their experience with Arstasis access versus their prior catheterization. Patients were monitored for the occurrence of any complications in-house until discharge. A 30-day follow-up interview was performed during an office visit or via telephone to assess any access-site related complications or adverse events.

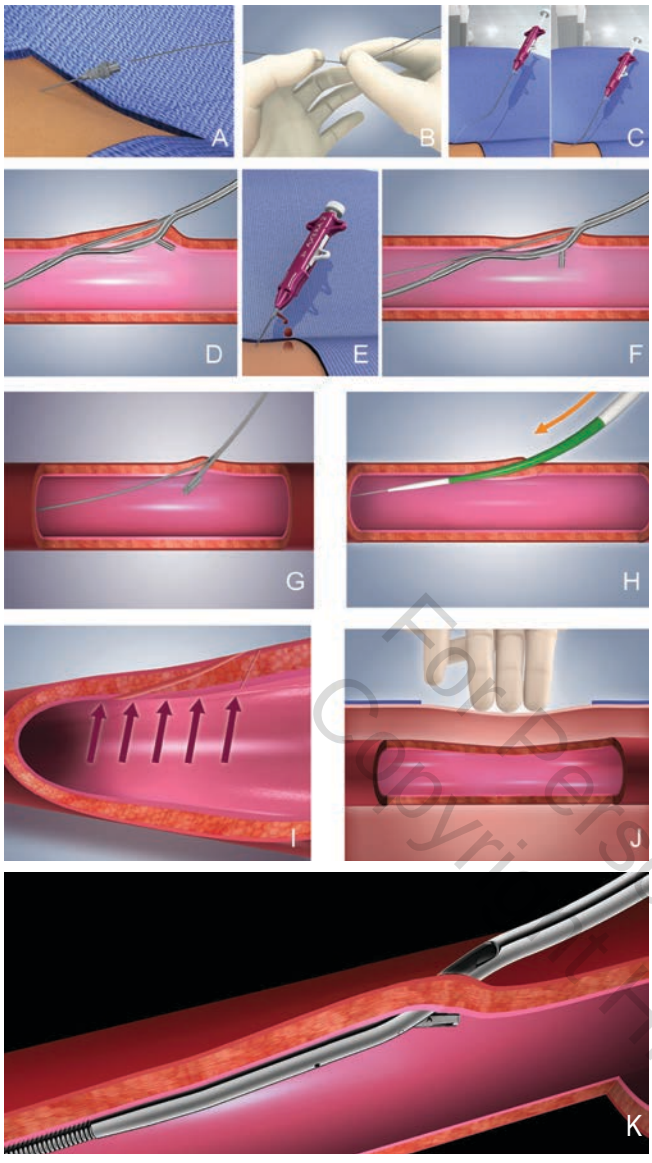

Figure 3. *Arterial access with the Arstasis device.* **(A)** *19 gauge needle is shown inserted into the common femoral artery and the Arstasis latchwire has been threaded through the needle.* **(B)** *The latchwire is attached to device.* **(C)** *The device is inserted into the artery.* **(D)** *The device 'heel' has been deployed and the device drawn back against the vessel wall; the integrated needle has been deployed creating the shallow angle access tract (Arstaotomy).* **(E)** *Blood marking confirms intraluminal position of needle.* **(F)** *A 0.018˝ guidewire is inserted through the integrated needle; the heel is released and the needle retracted.* **(G)** *The device is removed, leaving only the wire in place through the Arstaotomy.* **(H)** *Procedural sheath is placed over the guidewire.* **(I)** *At end of case, introducer sheath is withdrawn and hydrostatic pressure facilitates hemostasis.* **(J)** *Minimal manual compression is applied.* **(K)** *Close-up of Arstasis device positioned in artery just prior to deployment of needle.*

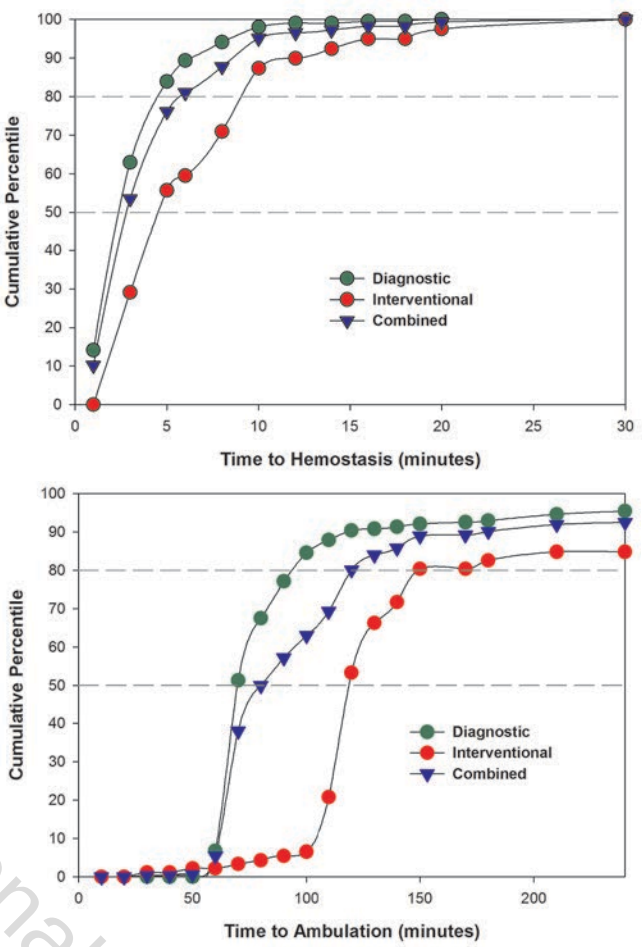

Figure 4. *Time to hemostasis (top) and time to ambulation (bottom) shown as cumulative distribution curves plotting all data points for diagnostic, interventional and all cases (n = 336). Horizontal lines denote the 50th and 80th percentiles. P<.001 for diagnostic versus interventional cases.*

Study endpoints. The primary efficacy endpoints were *device success*, defined as the achievement of femoral artery access and sheath placement using the Arstasis Access System, and the standard time interval endpoints used in VCD trials: TTH, TTA, TTD, and TTDe. In addition, unique to this study, the ability to sit up within 15 minutes after obtaining hemostasis (TTS) was determined as well. *TTDe* was defined as the time from sheath removal until the patient was deemed suitable for discharge from the standpoint of vascular access. This was considered to have been reached following successful ambulation when the access site was considered stable (presence of distal pulses and normal neurovascular status of the extremity), regardless of whether the patient was actually kept in the hospital for a longer period. *Secondary endpoints* were TTH and TTA compared with historical controls for MC.[12,13] The *primary safety endpoint* was the occurrence of any major or minor access-site related complications through 30-day follow-up. Causality for all adverse events was adjudicated by an investigator experienced in vascular closure who did not otherwise participate in the clinical trial (AK).

Study populations. All consented and enrolled patients who underwent needle access with intention to introduce the Arstasis device were included in the intention-to-treat and safety analyses. Those patients in whom introduction of the Arstasis device was successful were included in the evaluable population; those in whom the device was not successfully placed were analyzed separately but are described in detail. Results are presented for the population as a whole as well as separately for diagnostic and PCI cohorts, the latter comprising the subset of patients who crossed over to PCI during the same catheterization.

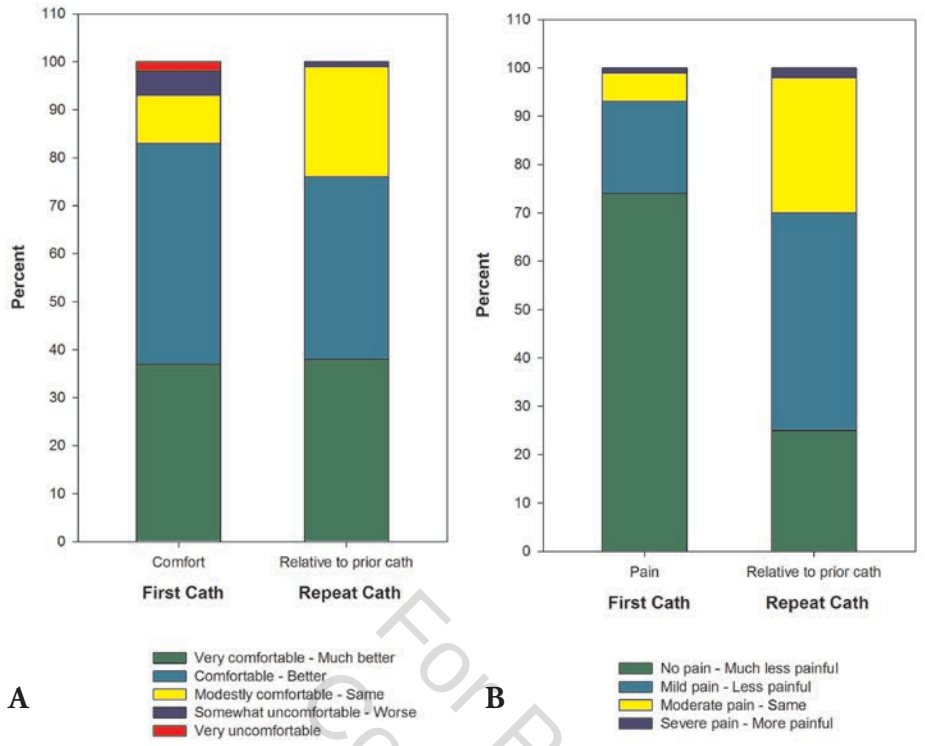

Figure 5. *The stacked bars on the left side of each panel show comfort levels* **(A)** *and pain levels* **(B)** *associated with Arstasis access (n = 156). The right-sided bars compare comfort and pain levels relative to prior non-Arstasis access for the patients who had prior catheterization (n = 167).*

Statistical methods. Continuous data are summarized using descriptive statistics; mean and standard deviations are used unless otherwise specified. Categorical variables are summarized using frequency counts and percentages. For categorical and ordinal variables, percentages were calculated based on non-missing data. The secondary endpoint of a reduction in TTH and TTA compared to historical outcomes were analyzed using the one-sample t-test; the historical controls were derived from the MC arms of published recent randomized vessel closure trials. TTH and TTA comparisons between the diagnostic and interventional cohorts used the two sample t-test. *P*-values ≤.05 were considered statistically significant.

Results

Patient demographics are outlined in Table 1. Enrollment commenced November 3, 2010 and concluded June 3, 2011. A total of 346 patients who underwent routine diagnostic catheterization through 5 or 6 Fr sheaths were enrolled in the study; 249 patients had diagnostic catheterization only, while 97 crossed over to PCI. Interventional patients were older, had a slightly lower body mass index, and were more likely to be male, diabetic, and taking clopidogrel. Over half of the patients had undergone prior femoral access (44.5% via the same femoral artery), and more than one-third (37.3% of diagnostics and 44.2% of PCI patients) had 2 or more prior catheterizations via the same femoral artery. Arstasis access was successful in 336 of the 346 patients (97.1%); the 10 patients with unsuccessful Arstasis access were all converted to routine Seldinger technique. TTH, TTA, TTD and TTDe are shown in Table 2A; Figure 4 provides TTH and TTA data showing all patients. TTH compared to historical controls in recent trials using similar sheath sizes was substantially shortened: 4.0 ± 2.5 minutes vs 17.2 ± 6.7 minutes[13] for diagnostic patients and 6.9 ± 5.1 minutes vs 29.1 ± 35.3 minutes[12] for interventional patients (both *P*<.0001). Similarly, time to ambulation was significantly shorter for both groups when compared to historical controls: 1.5 ± 1.2 hours vs 4.3 ± 1.0 hours for diagnostic[13] and 3.2 ± 3.3 hours vs 7.6 ± 7.0 hours[14] for interventional patients (both *P*<.0001).

A subset of 245 patients (72.9%) sat up to a 45° gatch within 30 minutes after hemostasis (1 patient at 33 minutes), two-thirds within 15 minutes; there were no associated adverse events except in 1 patient who had minor bleeding treated with MC without sequelae. We compared our results to some standard clinically relevant time points (Table 2B); all but a relatively small minority of patients achieved hemostasis within 5 minutes (diagnostic) or 10 minutes (PCIs), and similar percentages of both groups were able to sit up within 20 minutes. Median TTA was quite low and TTD for diagnostic patients early; as seen from our TTDe data, TTD for PCI cases was heavily influenced by hospital protocols for postprocedure stay, and was still low compared with historical controls for MC.[15]

Of the 10 patients who had unsuccessful Arstasis access and were converted to routine Seldinger technique, one developed a small hematoma (3 x 2 cm) that resolved with compression; the patient was discharged the following day. In addition to the 346 patients described, 4 patients were upsized to a 7 Fr sheath and 1 patient to an 8 Fr sheath during catheterization to accommodate complex PCI procedures. Per protocol, these patients were excluded from the overall analysis; the Arstasis device is currently approved only for 5 Fr and 6 Fr sheaths. All 5 had interventional procedures. Data were recorded for 4 of the 5 patients, with median TTH of 4.5 minutes and TTA of 108 minutes. No vascular adverse events were documented in these 5 patients.

A pain and comfort level survey was conducted in 156 patients undergoing their initial femoral artery procedure and in 167 patients with prior femoral access. These results are shown in Figure 5. The majority of patients (83%) undergoing initial femoral artery access rated their comfort level as "comfortable" or "very comfortable," with 74% describing no pain at all. In the survey obtained in patients with prior (non-Arstasis) femoral access, 76% reported comfort level as "better" or "much better" and 70% rated the pain level as "less" or "much less" painful than their previous experience with conventional access and closure.

There were no major access-site related complications. There were 15 minor access-site related complications in 14 patients (4%), 5 in the diagnostic cohort and 10 in the interventional (Table 3). Minor bleeding occurred in 1 interventional patient, as did pain at

Table 2A. Overall efficacy outcomes.

Description	All Patients	Diagnostic	Interventional	Diagnostic vs Interventional *P*-Value
N	336	242	94	
Time to hemostasis (minutes)	4.8 ± 3.7	4.0 ± 2.5	6.9 ± 5.1	<.0001
Time to ambulation (hours)	2.0 ± 2.1	1.5 ± 1.2	3.2 ± 3.3	<.0001
Time to discharge eligibility (hours)	6.0 ± 7.6	2.7 ± 1.6	14.5 ± 10.1	<.0001
Time to actual discharge (hours)	9.3 ± 22.1*	7.1 ± 24.9*	15.2 ± 10.0*	<.0001

*Results reported as mean ± standard deviation. *Time to actual discharge includes hospital stay for non-vascular access-related issues (eg, coronary bypass). For median values, see Table 2B.*

Table 2B. Efficacy outcomes for selected time intervals.

	Protocol	Results			
Patient Cohorts	Sheath Pull	Achieved Hemostasis (%, x/n)	Elevated Bed to 45° (%, x/n)	Ambulation (Median)	Discharge (Median)
Diagnostic	End of procedure	≤5 min (85%, 204/241)	≤20 min (89%, 168/189)	1 hr 12 min (n = 240)	2 hr 24 min (n = 242)
Intervention	ACT <180 sec (heparin)*	≤10 min (88%, 82/93)	≤20 min (96%, 53/55)	2 hr 12 min (n = 92)	17 hr 48 min (n = 93)

Hemostasis by 5 minutes in diagnostic and 10 minutes in interventional patient cohorts and head of bed elevation by 20 minutes showing that early hemostasis and sit up is achieved in a high percentage of patients. The median time to ambulation and discharge is shown as well. ACT = activated clotting time.
**<180 seconds or lower if dictated by hospital protocol.*

the access site; 3 diagnostic patients described self-limited numbness, 1 interventional patient developed a small pseudoaneursym, and 4 patients had access-site related hematoma >6 cm. The latter were all in the interventional group and required no additional treatment. Two patients had a re-bleed after initial hemostasis — 1 from the diagnostic and 1 from the interventional group. Additional compression was >30 minutes in the interventional patient only; that patient had a subclinical hematoma >6 cm and there were no sequelae. Two patients had transient vagal episodes. One patient had a dissection at the femoral access site; this was non-flow limiting and resolved with sheath removal without additional intervention. During a subsequent catheterization for a previously planned renal artery stenting done 3 weeks later, a well-healed common femoral artery with no residual abnormality was noted. Of the patients with prior femoral access, 8 of 179 (4.5%) had a minor adverse event compared with 6 of 167 (3.6%) who were undergoing their initial catheterization (*P*=NS).

Discussion

Arstasis use resulted in substantial shortening of TTH and TTA compared to historical controls in both the diagnostic and interventional cohorts. Device deployment success was high and the small number of complications were all adjudicated as minor. Although shortened TTH and TTA compared with MC alone is almost universal in the VCD literature, nearly 100% of closure device deployments leave a foreign body in place, which in turn is associated with significant morbidity and mortality.[8-11,16] Because over 50% of the patients had undergone prior catheterization, comparison with previous access was possible; the results show that patients deemed Arstasis access to be associated with heightened patient comfort, an important parameter by which to judge vascular access and closure technologies. The reasons for heightened comfort level are likely severalfold: for patients with prior MC, compression after Arstasis use is shorter than historical controls, as already described. Where conventional VCDs were used during prior catheterizations, patients may have experienced the pain associated with deployment of plugs, sutures. and clips, all of which apply substantial traction to the arteriotomy site during device delivery, cause occasional strangulation of minor femoral nerve branches, or result in peri-adventitial inflammation and nerve irritation after device deployment. Patients also complain of discomfort associated with the foreign bodies left in place, particularly during the resorption processes that take place over several months. None of these should apply to patients undergoing Arstasis access.

In addition, this study contained a management algorithm unique to the femoral access and closure literature: patients were allowed to sit up to a 45° angle at 15 minutes. Early sit up enhances patient comfort and prevents complications.[17] It is likely that this superior comfort level was related to the early sit up incorporated in our protocol: the vast majority of all patients surveyed (84.8%) indicated it was "very important" or "important" to be able to sit up following the procedure. We postulate that the ability to sit up early may be related to the stability achieved by tissue apposition of the shallow-angled Arstasis access tract.

Study limitations. This study was not randomized and therefore historical controls were used. However, there have been a substantial number of prospective randomized controlled trials comparing VCDs to MC and we chose values for comparison to an MC arm that were well within the range of the results for MC in those studies.[12-15] In order to provide a reasonable comparison to methodologies from the current era, we limited our use of historical controls to data from randomized studies published in the past decade. Because of the unblinded nature of the study, potential patient and operator bias may be inherent in evaluation of some endpoints, in particular

Table 3. Access-site related adverse events.

Category	All Patients	Diagnostic	Interventional
Number	346	249	97
All access-site related AEs	15 (4.3%)	5 (2.0%)	10 (10.3%)
Major	0	0	0
Minor	15	5	10
Bleeding, post procedure	1 (0.3%)	0 (0.0%)	1 (1.0%)
Arrhythmia	2 (0.6%)	0 (0.0%)	2 (2.1%)
Dissection	1 (0.3%)	1 (0.4%)	0 (0.0%)
Puncture site pain or discomfort	1 (0.3%)	0 (0.0%)	1 (1.0%)
Other access-site related complication (numbness)	3 (0.9%)	3 (1.2%)	0 (0.0%)
Other access-site related complication (re-bleed)	1 (0.3%)	1 (0.4%)	0 (0.0%)
Pseudoaneurysm (subclinical and non-treated)	1 (0.3%)	0 (0.0%)	1 (1.0%)
Access-site related hematoma >6 cm (subclinical & non-treated)	4 (1.2%)	0 (0.0%)	4 (4.1%)
Access site re-bleed requiring >30 min compression	1 (0.3%)	0 (0.0%)	1 (1.0%)

Of the adverse events (AEs), 9 were possibly device related and 5 were not related; only the 1 dissection was adjudicated as probably device related. There were 5 hematomas below the AE threshold (<6 cm in size), none of them requiring additional treatment.

in the case of comfort assessment; unblinded subjective patient comfort surveys have not been validated and may of themselves elicit a favorable result. However, investigators are inherently limited in the ability to perform unblinded studies in the vascular access and closure arena. This study was designed to assess the use of the Arstasis device in patients undergoing diagnostic catheterization. Cardiac catheterization practices almost invariably include a significant number of *ad hoc* crossovers to intervention at the same sitting dependent on the findings during the diagnostic portion of the catheterization. We felt that the outcomes in these patients needed to be presented on intention-to-treat principles and as such both a pooled analysis and a separate analysis were performed of patients undergoing PCI. Time intervals were longer in interventional than diagnostic patients (although still significantly shorter than historical controls for MC); this is in keeping with the existing VCD literature. TTD and TTDe are significantly affected by individual physician and institutional practices, time of day when procedure is performed, patient transportation issues, level of sedation, and other variables that are not related to VCD performance *per se*; this is particularly true in PCI patients. Hence, as seen in Table 2B, the median TTD is substantially shorter than the mean; our data compare favorably with prior VCD results described by Wong and colleagues.[15] Our separate analysis comparing the minor complications seen in patients with and without prior access suggests no difference between these groups; however, the small overall number of adverse events in this study gives us insufficient power for a definitive comparison.

Conclusion

Arstasis access resulted in short TTH and TTA, early sit up, and accelerated TTD and TTDe. Success rates were high without any major complications; a low rate of minor adverse events was seen. This unique technology is associated with patient comfort, likely in part related to the ability to sit patients up early after hemostasis is obtained. The results were achieved with only short periods of adjunctive compression and without use of VCDs that require implantation of a foreign body.

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