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Influence of Use of a Vascular Closure Device on Incidence and Surgical Management of Access Site Complications after Percutaneous Interventions☆

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Abstract *Aim:* The study aimed to evaluate vascular access site complications (ASCs) after percutaneous interventions (PIs) in our institution for changes in annual incidence and surgical management after increased usage of a vascular closure device (VCD; in all cases: Angioseal™).
Material and Methods: All patients who underwent repair of arterial pseudo-aneurysms or access site stenosis/occlusion leading to leg ischaemia (LI) or new-onset disabling claudication (CI) after PIs between 2001 and 2008 were included. Annual rates of procedures and methods of repair of ASC were evaluated.
Results: After a total of 58 453 PIs, 352 patients (0.6%) were operated on for: pseudo-aneurysms ($n = 300$; 0.51%); and local stenosis/occlusion leading to LI/CI ($n = 52$; 0.09%). Numbers increased significantly with more widespread VCD use: group A (2001—2004: 2860 VCDs; 28 284 PIs; 10.1%): $n = 132$ (0.47%); and group B (2005—2008: 11,660 VCDs; 30,169 PIs; 38.6%): $n = 220$ (0.73%) ($p < 0.001$). In contrast to similar rates of pseudo-aneurysms (group A: $n = 124$; 0.44%; group B: $n = 176$; 0.58%; not significant), a significant increase of operations for local stenoses/occlusions was seen with widespread VCD use: $n = 8$ versus $n = 44$ ($p < 0.001$).
Conclusions: In the era of VCDs, complications are rare. However, use of these devices is not without complications, and may require complex reconstructions.

Abbreviations: ASC, access site complication; CI, intermittent claudication; LI, leg ischaemia; OP, operation; PI, percutaneous intervention; VCD, vascular closure device.

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Vascular access site complications (ASCs) remain a concern of percutaneous interventions (PIs). Therefore, management of the arterial puncture site is an important issue in endovascular procedures. Local control after PI is traditionally accomplished by manual compression. Since the mid-1990s, a number of different vascular closure devices (VCDs) were introduced to replace manual compression at the arterial puncture site. The primary advantage attributed to VCDs is a shortened period to haemostasis and avoidance of prolonged immobilisation so that earlier patient discharge can be achieved.[1–6] However, recently published large meta-analyses analysing VCDs and ASCs failed to demonstrate benefits of VCD use.[1,5,7] Moreover, ASCs were reported as a consequence of VCD use, including local stenosis/occlusion at the access site and pseudo-aneurysms due to device dislocation.[8–13]

To analyse and compare ASCs after PIs in years with sporadic VCD use versus the era with more widespread VCD use, we evaluated data in our institution, a high-volume university hospital. Our primary interest was focussed on incidence and results of operative repair of pseudo-aneurysms and local stenoses or occlusions at the puncture site leading to limb ischaemia (LI) or new-onset severe claudication (CI).

Patients and Methods

Patients who underwent surgical repair of arterial ASCs after transfemoral or transbrachial catheter interventions between 2001 and 2008 in our institution were identified by searching our institutional diagnosis registry. Patients were included for further analysis, if they had surgical repair of arterial pseudo-aneurysms at the puncture site or access site stenoses/occlusions leading to LI or new-onset disabling CI after PI. The medical records of all individuals were reviewed. Data collection included demographic parameters, details of coronary and vascular intervention such as the use of an arterial closure system, clinical presentation, diagnosis and therapy of the ASC. Outcome was evaluated including complications (death, limb loss, need for re-operation or re-intervention and need for transfusion), and length of hospital stay. Annual rates of surgical procedures and methods of repair of ASC were analysed. Annual numbers of VCDs used were estimated on the basis of yearly purchase lists. Patients were grouped by the years 2001–2004 (group A; sporadic use of VCD) and 2005–2008 (group B; more widespread use of a collagen-plug based VCD; in all cases: Angioseal™, St. Jude Medical, St. Paul, Minnesota, USA), and, for comparison of both groups, the chi-square test was used. In addition, Bonferroni correction for multiple testing was applied.

Results

A total of 58,453 PIs were performed in our institution between 2001 and 2008 (group A, 2001–2004: $n = 28\,284$; group B, 2005–2008: $n = 30\,169$). Surgical repair of arterial ASCs was indicated in 352 patients (0.6%) (194 female; median age: 67.3 years, range: 5.1–89.3 years) for: repair of pseudo-aneurysm ($n = 300$; 0.51%); and acute LI or new-onset severe CI caused by stenosis or occlusion at the access site ($n = 52$; 0.087%). Annual numbers of PIs and numbers/rates of operations are summarised in Table 1. As shown, there were only slight fluctuations of the annual numbers of PIs performed, with lowest numbers in 2001 ($n = 6482$) and highest in 2004 ($n = 7834$). When numbers/rates of operations for ASCs in years with sporadic VCD use (group A) and with frequent VCD use (group B) were compared, there was a significant increase in the era of more widespread VCD use (group A: $n = 132$; 0.47%; group B: $n = 220$; 0.73%; $p < 0.001$). This increase was caused by a more than fivefold increment in the number of patients presenting with acute LI or new-onset severe CI due to stenosis or occlusion at the access site (group A: $n = 8$; 0.028%; group B: $n = 44$; 0.146%; $p < 0.001$). By contrast, the frequency of operations for pseudo-aneurysms was similar in both time periods (group A: $n = 124$; 0.44%; group B: $n = 176$; 0.58%; not significant).

For closure of the arterial puncture site, a VCD (in all cases: Angioseal™) had been used in 2860 of 28,284 patients (10.1%) in group A and in 11 660 of 30 169 patients (38.6%) in group B ($p < 0.001$). In general, no VCDs were used for brachial access. Annual numbers of procedures with and without VCD use and operations in group A and B are summarised in Tables 2 and 3. In patients without VCDs, the numbers/rates of operations for pseudo-aneurysms (group A: $n = 120$; 0.5% of 25 424 PIs; group B: $n = 111$; 0.6% of 18 509) and local stenosis/occlusion leading to LI/CI (group A: $n = 4$; 0.02% of 25 424 PIs; group B: $n = 10$; 0.05% of 18,509) were similar. In patients with VCDs, operations for pseudo-aneurysms (group A: $n = 4$; 0.1% of 2860 PIs; group B: $n = 65$; 0.6% of 11,660) and local stenosis/occlusion leading to LI/CI (group A: $n = 4$; 0.1% of 2860 PIs; group B: $n = 34$; 0.3% of 11,660) increased with widespread use of VCDs. This was mainly caused by a significant increase in the rate of operations for local stenoses and occlusions in patients with VCD use (with VCD: 38 of 14,520 patients (0.26%); without VCD: 14 of 43,933 patients (0.03%); $p < 0.001$).

ASCs were located in the femoral ($n = 338$; 96%) or brachial artery ($n = 14$; 4%). The arterial puncture sites, as identified from the operation reports, were as follows: iliac ($n = 18$), common femoral ($n = 244$), profunda femoris ($n = 21$), superficial femoral ($n = 45$), their combination ($n = 10$) and brachial ($n = 14$). Surgical repair of ASCs was performed after previous unsuccessful thrombin injection for treatment of pseudo-aneurysms in a group of 87 patients (29% of 300). Arterial repair included simple sutures for oversewing of arterial defects ($n = 287$; 82%), patch angioplasty ($n = 51$; 14%), interposition grafts ($n = 4$; 1%) or other techniques such as thrombectomy ($n = 10$; 3%). Whereas patients with puncture site defects leading to pseudo-aneurysms were repaired mainly by simple stitches ($n = 287$ of 300; 95.7%), patients with stenoses or occlusions needed more complex arterial repair, such as patch angioplasties (39 of 52; 75%) or graft interpositions ($n = 3$; 6%). When patients with and without VCD use are considered (see Table 4), only 9.4% of patients without VCD had repair other than simple oversewing stitches, whereas, in patients with VCDs, this rate was 39.3% ($p < 0.001$; Fisher's exact test; Table 4). This indicates that VCD-associated ASCs need more complex procedures for arterial repair.

Table 1 Annual number of percutaneous interventions (PI total) and annual numbers/rates of surgical repair indicated for access site complications (ASCs). OP = operation; PsA = pseudo-aneurysm; LI = limb ischemia caused by stenosis/occlusion at access site; CI = severe claudication caused by stenosis/occlusion at access site; years 2001–2004: no use of VCDs; years 2005–2008: frequent use of VCDs.

	PI total [n]	All OP [n]	All OP [%]	PsA [n]	PsA [%]	LI or CI [n]	Li or CI [%]
2001	6482	41	0.63	41	0.63	0	0
2002	6836	36	0.53	34	0.50	2	0.029
2003	7132	28	0.39	26	0.36	2	0.028
2004	7834	27	0.34	23	0.29	4	0.051
2001 to 2004	**28,284**	**132**	**0.47**	**124**	**0.44**	**8**	**0.028**
2005	7651	61	0.80	44	0.58	17	0.222
2006	7484	53	0.71	39	0.52	14	0.187
2007	7380	50	0.68	42	0.57	8	0.108
2008	7654	56	0.73	51	0.67	5	0.065
2005 to 2008	**30,169**	**220**	**0.73**	**176**	**0.58**	**44**	**0.146**
Total	**58,453**	**352**	**0.60**	**300**	**0.51**	**52**	**0.087**

Secondary end points

Perioperative outcome within 30 days after surgery: Nine patients died during the perioperative period (30-day mortality: 2.5%). No early limb loss occurred within 30 days after surgery for ASCs. A total of 50 re-operations were performed in 32 patients (9% of 352), including 25 re-operations for wound infection in 13 patients (4% of 352) and 13 revisions for haematoma in 13 patients (4% of 352). In the perioperative period, a group of 83 patients (23%) required substitution of packed red blood cells. Median length of hospital stay was 6 days (maximum: 73 days).

Discussion

ASCs remain a concern of percutaneous interventions. Most frequently, surgical repair of ASCs is indicated for pseudo-aneurysms at the access site.[1,5,7,14] In our analysis, repair of ASCs was performed in a total of 352 individuals (0.6% of 58,453 patients undergoing PIs) including 300 pseudo-aneurysms (0.51%). It is noteworthy that our pseudo-aneurysm rate of 0.51% is rather low when compared with other series. Large studies in patients with VCD or manual compression detected pseudo-aneurysm in up to 2% in diagnostic PIs and even higher rates in therapeutic coronary interventions.[15–22]

When our series is analysed, the introduction and frequent use of a VCD after 2004 was not associated with a reduction of surgical repairs of pseudo-aneurysms. The fact that VCDs do not reduce the incidence of pseudo-aneurysms after PIs is clearly supported by recently published large meta-analyses.[1,5,7,14] Biancari reviewed 31 prospectively randomised studies including 7528 patients: when the patients were randomised to manual compression or different VCDs, the risk to develop a pseudo-aneurysm was similar in both treatment arms.[1]

Concerning arterial ischaemic complications due to ASCs, namely new-onset claudication and acute LI, our data strongly indicate that widespread use of a VCD is associated with significantly higher complication rates; when compared with the years with sporadic use of VCDs, ischaemic complication rates increased from 0.028% to 0.146%. Furthermore, use of VCD itself was significantly associated with higher ischaemic complication rates: 0.26%

Table 2 Annual number [n]/rates [%] of percutaneous interventions (PI) with and without use of a vascular closure device (VCD).

	PI total [*n*]	With VCD [*n*]	With VCD [%]	Without VCD [*n*]	Without VCD [%]
2001	6482	0	0%	6482	100%
2002	6836	220	3.2%	6616	96.8%
2003	7132	1320	18.5%	5812	81.5%
2004	7834	1320	16.8%	6514	83.2%
2001 to 2004	**28,284**	**2860**	**10.1%**	**25,424**	**89.9%**
2005	7651	2260	29.5%	5391	70.5%
2006	7484	2760	36.9%	4724	63.1%
2007	7380	3590	48.6%	3790	51.4%
2008	7654	3050	39.8%	4604	60.2%
2005 to 2008	**30,169**	**11,660**	**38.6%**	**18,509**	**61.4%**
Total	**58,453**	**14,520**	**24.8%**	**43,933**	**75.2%**

Table 3 Annual number of operations (OP) (all; PsA = pseudo-aneurysm; LI/CI = limb ischemia or new-onset claudication caused by stenosis/occlusion at access site) in patients with and without Vascular Closure Device (VCD) use.

	All OP [*n*]	OP for PsA [*n*]	With VCD [*n*]	Without VCD [*n*]	OP for LI/CI [*n*]	With VCD [*n*]	Without VCD [*n*]
2001	**41**	**41**	0	41	**0**	0	0
2002	**36**	**34**	2	32	**2**	1	1
2003	**28**	**26**	0	26	**2**	0	2
2004	**27**	**23**	2	21	**4**	3	1
2001 to 2004	**132**	**124**	**4**	**120**	**8**	**4**	**4**
2005	**61**	**44**	2	42	**17**	12	5
2006	**53**	**39**	11	28	**14**	13	1
2007	**50**	**42**	28	14	**8**	6	2
2008	**56**	**51**	24	27	**5**	3	2
2005 to 2008	**220**	**176**	**65**	**111**	**44**	**34**	**10**
Total	**352**	**300**	**69**	**231**	**52**	**38**	**14**

in patients with VCD versus 0.03% in individuals without VCD. Femoral artery stenosis/occlusion caused by VCDs was described earlier.[23–29] Nevertheless, ischaemic complications due to ASCs are very uncommon. In Biancari's meta-anaylsis, there had been no ischaemic complication in the pooled data of control groups in 2295 patients who underwent manual compression, but eight events (0.3%) in 2598 individuals after VCD deployment.[1]

In our series, the only VCD used was the Angioseal™ device, one of the most widely used VCDs. It consists of an absorbable intravascular anchor, a small bovine plug and an absorbable traction suture.[8,14,20,30–32] VCD failure in clinical series was relatively uncommon, and occurred in 1–3% of patients.[3,11,32–34] Device deployment in calcified vessels was associated with higher complication rates, and VCD use was discouraged in the external iliac artery or below the femoral bifurcation, as well as in vessels <5 mm in diameter.[25,26,32,35–39] In our retrospective data analysis, we were unable to correlate ASCs to anatomic details of the puncture site, as such documentation was insufficient or unavailable from many patients' charts retrospectively. Nevertheless, strategies for prevention of ASCs should be aimed at detection of such anatomic risk situations, for example, pre-procedural duplex ultrasound for assessment of the femoral arteries.

Do different VCDs perform differently? As there are many different devices on the market, our data reporting on Angioseal™-associated complications may not reflect complications associated with other VCDs. Nevertheless, it is shown that major vascular complications can occur with all different VCDs. There is no large randomised study aimed at comparison of different VCDs with each other. However, a randomised study evaluated three different VCDs in a total of 705 patients undergoing percutaneous coronary interventions, and all VCDs tested had similar surgical repair rates of approximately 1–2%.[40] Similarly, others used two different VCDs in comparison to manual compression and, if major vascular end points are evaluated, could not describe a superiority of a particular VCD in most series.[17,33,34,41,42]

However, a VCD with reported higher complication rates in patients undergoing percutaneous coronary interventions was the first generation of the VasoSeal device, which was modified thereafter.[3,7,14] The question whether new-generation VCDs – after revision and improvements – are associated with fewer complications is discussed controversially.[1,3,18,43,44] Biancari evaluated the impact of technical improvements and a learning curve in VCD use: they concluded that the trend towards increased risk for arterial complications and need for vascular surgery was observed also in the most recently published series.[1]

It is of particular concern that prospective studies on VCD use are very heterogeneously performed. If they are aimed at comparison of different VCDs, or comparison between VCDs and manual compression, many of them are certainly underpowered to detect differences in major vascular complications requiring surgery. As shown in our retrospective analysis in more than 58,000 patients, repair of pseudo-aneurysms is performed in approximately 1 out of 200 individuals, and arterial repair of ischaemia caused by ASCs

Table 4 Overall number and rates of different types of arterial repair in patients with and without use of VCDs: A more than three-fold increase in more complex operations (patch angioplasty or graft interposition) was seen in the era of VCDs (29.9% vs. 9.4%; $p < 0.001$; Fisher's Exact Test).

	With VCD [*n*]	With VCD [%]	Without VCD [*n*]	Without VCD [%]
Simple Stitch	65	60.7	222	90.6
Patch Angioplasty	29	27.1	22	9.0
Graft Interposition	3	2.8	1	0.4
Other	10	9.4	0	0
Total	**107**		**245**	

in 1 out of 1000. Consecutively, the analysis of low complication rates need larger studies than performed so far.

Several limitations have to be considered when our data are analysed: Our data were collected retrospectively. Thus, data collection was incomplete and could not include several parameters that might have been of interest, such as the size of the introducer sheet, antegrade versus retrograde arterial punctures and different anticoagulation regimens. The number of VCDs used was calculated on the basis of annual purchase lists; however, those data may slightly differ from the annual numbers of VCDs used. In addition, the decision to use VCDs or not in the individual patient was not based on randomisation, but on the investigator's preference or risk calculation, which could not be analysed retrospectively. Only patients who underwent surgery were analysed, and patients treated conservatively were not included. As a consequence, the overall numbers/rates of ASCs might be underestimated. Moreover, patients with ASCs after PIs performed in our institution might have been operated on elsewhere and, therefore, not included in our analysis; however, the number of such cases is presumably low, as our centre is the only large-volume hospital in this particular part of our country, and almost exclusively performs PIs.

In summary, with the increase of percutaneous arterial procedures, definitive control of the access site is an ongoing problem. Although VCDs are associated with earlier haemostasis and time to ambulation, their cost and potential associated complications limit their use. ASCs after use of VCDs are rare, but continue to occur with especially ischaemic complications occurring at a higher rate. As a consequence, in the era of VCDs, patient selection and monitoring for these infrequent but potentially serious complications is essential.

Conflict of Interest/Funding

None.

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