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Effectiveness and Safety of Different Vascular Closure Devices: Multicentre Prospective Observational study

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Abstract

Aim The aim of this prospective, multicentre, observational study was to compare the efficacy and safety of balloon-based and non-balloon-based vascular closure devices (VCDs).

Materials and Methods From March 2021 to May 2022, 2373 participants from 10 different centres were enrolled. Among them, 1672 patients with 5–7 Fr accesses were selected. Successful haemostasis, failure and safety were evaluated. Successful haemostasis was defined as the possibility to obtain complete haemostasis with the use of VCDs, without any complication. Failure management was defined as the need of manual compression. Safety was defined as the rate of complications. Cases of haematomas/pseudoaneurysms (PSA) and artero-venous fistula (AVF) were collected.

Results VCDs mechanism of action is statistically significant associated with the outcome. Non-balloon-based VCDs demonstrated a statistically significant better outcome: successful haemostasis was obtained in 96.5% vs. 85.9%, of cases when compared to balloon occluders ($p < 0.001$). The incidence of AVF was statistically more frequent using non-balloon occluders devices (1.57% vs 0%, p: 0.007). No significant statistical difference was found in comparing haematoma and PSA occurrence. Thrombocytopenia, coagulation deficit, BMI, diabetes mellitus and anti-coagulation were demonstrated to be independent predictors of failure management.

Conclusion Our study suggests a better outcome with the same complication rate, except that for AVF incidence for non-balloon collagen plug device if compared to balloon occluders vascular closure devices.

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Abbreviations

AVF	Artero-venous fistula
BMI	Body mass index
VCD	Vascular closure device
INR	International normalized ratio
PSA	Pseudoaneurysm
PT	Prothrombin time
PTT	Partial thromboplastin time
SD	Standard deviation
VCDs	Vascular closure devices

Introduction

In the past decade, a variety of closure devices have been developed to facilitate access site management and to improve patient comfort. Although a number of new devices have been introduced in the last several years concerns remain regarding the safety, efficacy and ease of use with closure devices [1–6].

As the percutaneous interventions are pushed, VCDs are becoming increasingly valuable [1].

VCDs are categorized by their mechanism of action and fall into two main groups: active approximators (which physically close the arteriotomy site with the use of a clip or a suture) and passive approximators (which close the arteriotomy site by deploying plug, sealant or gel). There is also a separate category of devices known as external haemostatic devices or assisted compression devices that function by providing hands-free mechanical compression [7].

Some studies have already been published regarding comparison of VCDs, but no differences in access-site-related major adverse vascular events have been found in a randomized trial or in a systematic meta-analysis [1, 8–10].

We considered passive approximators VCDs that were used to close 5–7 French accesses, and among them anchor-based non-balloon devices (AngioSeal and Femo-Seal) (Terumo Corporation, Tokyo, Japan) and balloon-based devices (Mynx control, Cardinal Health (Dublin, Ohio, USA)). In daily interventional radiological practice, the use of accesses from 5 to 7 fr is the most frequent; therefore, it may be useful to have information on the effectiveness and safety of the available closure devices and possibly choose one rather than another. The purpose of this prospective, multicentre, observational study involving 10 of the major South-European Interventional Radiology centres, is to compare the efficacy and safety of the above-mentioned different VCDs.

Materials and Methods

Study Design

This STROBE compliant prospective, multicentre, observational study has been approved by the Medical Ethical Committee of the promoter Centre (Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico - Milan, IT) with approval number1954 (RadIntv04/2021) and performed according to the Declaration of Helsinki. All participants signed an informed consent for the study.

Data from endovascular procedures occurred in ten interventional radiology centres (ASST dei Sette Laghi - Varese, IT; IRCSS Azienda Ospedaliero-Universitaria di Bologna - Bologna, IT; AOU "Maggiore della Carità" - Vercelli, IT; POC SS Annunziata - Taranto, IT; Cardarelli Hospital - Naples, IT; Policlinico Casilino - Rome, IT; IRCCS "A Gemelli" - Rome, IT; A.O.U. Citta della Salute e della Scienza - Torino, IT; Azienda Ospedaliera per l'emergenza Cannizzaro - Catania, IT; Institut Mutualiste Montsouris - Paris, FR) were prospectively collected from March 2021 to May 2022.

Inclusion Criteria

- *age > 18 years old;*
- *informed consent signed;*
- *No ultrasound guidance was used for common femoral artery (CFA) access;*
- *used sheaths ≥ 5F;*
- *Use of the VCDs indicated (FemoSeal, AngioSeal, Mynx)*
- *use of VCDs following manufacturer's instructions for use (IFU);*
- *operators with at least 3 years of experience in the specific chosen VCD's positioning*
- *bed rest for at least 2–3 h after the use of VCD;*
- *in case of unsuccessful haemostasis with VCDs and manual compression is required, bed rest is suggested for at least 6 h*

Exclusion Criteria

- *CFA occlusion or stenosis ≥ 80%;*
- *history of severe allergy to contrast media or any VCDs' component;*
- *absence of valid consent to participate to the study.*

From a larger common femoral artery closure device positioning dataset, a subgroup of 5–7 Fr vascular introducer calibre was selected.

Outcome Measures

Primary outcomes were considered effectiveness and safety.

Effectiveness is meant as successful haemostasis, i.e. the possibility to obtain complete haemostasis with the use of VCDs, without any complications nor additional manual compression for AngioSeal and FemoSeal and 90 s of compression (as IFU indicate) for Mynx control.

As unsuccessful haemostasis was considered any case requiring immediate manual compression (or after 90 s of the expected compression for Mynx control) or the onset of one or more of the following complications after primary effective of VCD.

Safety is meant as the rate of complications. Complications were classified into minor and major according to CIRSE guidelines [11]. Haematoma was defined as the occurrence of perivascular blood suffusion larger than 4 cm. Pseudoaneurysm (PSA) at the access site after the VCD positioning is considered a complication regardless of the diameter. "Arterio-venous fistula (AVF)" was defined as the appearance of arterio-venous communication at the access site after the VCD positioning. Ipsilateral acute limb ischaemia is defined as the occlusion of the CFA following the use of VCDs.

Secondary outcomes were considered the relationship between the mechanism of action of the VCDs (dependent variables) and some patient's characteristics (covariates variables) with the haemostasis result.

Dependent variables and covariates variables are listed in the following paragraph.

Variables

The outcome variables considered were: successful haemostasis; haematoma (alone); pseudoaneurysm (with/without haematoma); artero-venous fistula (AVF; with/without haematoma); and failure management.

The dependent variable considered was the VCDs mechanism of action: balloon occluders (passive approximators: Cordis MynxGrip) vs. non-balloon collagen plug occluders (passive approximators: Terumo AngioSeal; Terumo FemoSeal).

Covariates variables considered were: Age; Sex (male/female); French (sheath used for vascular access); Skin/Vessel distance (mm) (evaluated at CT scan if available; otherwise by US); Arterial diameter (mm) (evaluated at CT scan if available; otherwise by US); Access direction (retrograde or anterograde); Access side (right/left); Calcifications (considered present if gross calcifications were visible on unsubtracted DSA images and/or pre-procedural CT); BMI (Kg/m^2); INR; PTL (109/l); PT %; PTT (s); Previous surgery; Diabetes mellitus; Hypertension; Smoking; Dialysis; Hyperlipidaemia; COVID-19; Cirrhosis; Haematological disorders; Anti-coagulation therapy; and Intra-procedural heparin.

Follow-up

During the hours after the procedure, clinical observation was performed in all patients included in the study.

Moreover, in all patients an ultrasound examination was performed before discharge. For discharged patients, a new hospital access within 30 days, due to complications related to the VCD, is considered a failure management.

Statistical Analysis

Data were anonymized and collected on an electronic dataset (Excel, Microsoft, Redmond, Washington, USA). Twenty-four different variables were investigated as potential predictors of four different outcomes.

Power Analysis

According to the literature, complication rates of VCDs can be approximated to 10% in clinical settings [1, 3–6, 12]. Moreover, a significant bias is the absence of randomization. To overcome this issue, a minimum enrolment ratio criterion of 1:6 was introduced. According to this data, the target sample size was fixed to 1264 (158:1106) patients, which provides 80% power at the 5% (2-sided) level of significance [13, 14].

Data Analysis

Descriptive statistics were produced for cases' demographic, clinical and laboratory characteristics. Number and percentages are presented for categorical variables, and mean and standard deviation (SD) are presented for normally distributed variables. 95% confidence interval (CI) was given when appropriate.

Shapiro–Wilk test was used to assess normality.

Crosstabs and the Fisher's exact test were used to assess relations among VCDs mechanism of action and the outcome variables. Univariate and multivariate analyses of variance were also performed to weight the effects of all variables on closure device choice upon the four outcomes.

SPSS version 25.0 (IBM, Armonk, New York, USA) was used for all statistical analyses. In all cases, two-tailed tests were used. *p values* were considered significant when < 0.05.

Results

From March 2021 to May 2022, 1672 participants were enrolled in the study: 396 (23.68%) with balloon-based device and 1276 (76.32%) without balloon-based device—455/1276 (35.66%) Terumo AngioSeal and 821/1276 (64.34%) Terumo FemoSeal, in respect of the sample size statistical requirement of the study.

All continuous variables presented normal distribution according to Shapiro–Wilk test.

There were 1145(68.52%) men and 526 (31.48%) women, with a mean age of 67.5 ± 14.3 (mean ± SD; 95% CI 66.8 to 68.2) years. The access was anterograde in 448 (26.79%) cases and retrograde in 1224 (68.52%). CFA was punctured on the right side in 76.4% of the cases. Sheaths used were subdivided as follows: 48.9%, 49.1% and 1.9% were 5F, 6F and 7F, respectively. INR value and platelets count were available, respectively, in 1660 and 1370 patients, respectively. Platelets count was normal in 1020/1370 (74.4%). Distance skin and BMI were available in 1664 and 1649 patients, respectively, with the following values ranged from 1 to 81 mm (18.1 ± 11.8–95% CI 17.5 to 18.7) and 15.2–52 (26.1 ± 4.1 5% CI 25.9 to 26.3) for distance skin and BMI, respectively. Arterial calcifications (available in 611/1672 patients) were graded in mild, moderate and severe as follows: 176/611 (28.8%), 238/611 (38.9%) and 197/611 (32.2%), respectively.

14.5% (242/1669) of the patients presented previous history of surgery at groin. Diabetes mellitus, hypertension, smoking, dialysis, hyperlipidemia, COVID-19 and cirrhosis were also reported.

Haematological disorders were observed in 73/1669 patients (4.4%); anti-coagulation was reported in 359/1565 cases (22.9%) and intra-procedural use of heparin in 816/1669 patients (48.9%). All the descriptive statistics for cases' demographic, clinical and laboratory characteristics are presented in Table 1.

Occurrence of successful haemostasis was reported in 1569/1672 (93.9%) of cases. All complications were registered during hospitalization; in particular no patients were readmitted within 30 days. Haematoma alone was registered in 32/1671 (1.9%) cases, PSA was observed in 36 (2.1%) cases, of whom 27 (1.6%) with haematoma and 9 (0.5%) without associated bleeding, AVF in 20/1672 (1.2%) cases, of whom 11 (0.5%) with haematoma and 9 (0.5%) without associated bleeding, ipsilateral acute limb ischaemia in 0/1672 (0.0%) and retroperitoneal haematoma in 0/1672 (0.0%). Thus, complication of any type was recorded in 88/1671 (5.3%) cases. Unsuccessful haemostasis (immediate manual compression or after 90 s for balloon-based VCDs) was reported in 155/1672 cases (9.3%).

Crosstabs and Fisher's exact test (Table 2) showed a statistically significant association between balloon VCD and a poorer outcome when compared to collagen plug device both for successful haemostasis and failure management ($p < 0.001$). Successful haemostasis was achieved in 340/396 (85.9%) of cases treated with balloon occluders devices, and in 1229/1274 (96.5%) of cases treated with collagen plug devices ($p < 0.001$). Interestingly, a slightly statistical significant reverse trend was observed for the occurrence of AVF, which was observed in 0/396 (0%) of cases treated with balloon occluders devices, and in 20/1275 (1.6%) of cases treated with non-balloon occluders devices (*p:* 0.007). No statistical significant difference was observed for the haematoma/PSA occurrence (*p:* 0.205 *and p:* 0.169*, respectively*). Overall complication rate was similar: 23/396 (5.8%) with balloon occluders device and 65/1275 (5.1%) with non-balloon-assisted devices. Manual compression was required in 67/396 (16.9%) of cases treated with balloon occluders devices and in 88/1276 (6.9%) of cases treated with non-balloon-assisted devices with a statistically significant association ($p < 0.001$).

Univariate and multivariate analyses (Table S1) confirmed the Fisher's exact test results and also showed other independent predictors of poor outcomes, such as thrombocytopenia, coagulation deficit, BMI, diabetes mellitus and anti-coagulation.

Discussion

Percutaneous access through the common femoral artery has become one of the most common modes of vascular access for both diagnostic and therapeutic vascular procedures.

For several years, manual compression was the only method to achieve haemostasis. It is time-consuming and requires bed rest, and some conditions (obesity, patients taking anti-coagulants or antiplatelet agents, use of large size of percutaneous access devices) make the manual compression ineffective and/or inevitably accompanied by complications [1].

The introduction of VCDs has had a considerable effect on the vascular surgery and made the percutaneous approach to vascular intervention procedures much more attractive and safe. Their introduction reduced the complications rate from 11% to 3.5%, of which only 10.5% requiring surgery [2].

Access site haematomas and pseudoaneurysms are the most common complication after peripheral vascular intervention, and they are associated with increased length of hospitalization and increased 30-day and 1-year mortality [2].

Table 1 Patients' demographic, clinical and laboratory characteristics

Variable	N	Frequency	Mean ± sd	95% CI	Range
Closure device mechanism of action	1672				
Balloon		396 (23.68%)			
Collagen Plug		1276 (76.32%)			
Age (years)	1663		67.52 ± 14.33	26.8—28.2	12—98
Sex	1671				
F		526 (31.48%)			
M		1145 (68.52%)			
Access direction	1672				
Antegrade		448 (26.79%)			
Retrograde		1224 (73.21%)			
Laterality	1672				
Right		1277 (76.38%)			
Left		395 (23.62%)			
Access calibre (Fr)	1672				
5		818 (48.92%)			
6		821 (49.1%)			
7		33 (1.97%)			
INR	1660		1.12 ± 0.27	1.11—1.13	0.59—4.62
Platelet count (10^9/L)	1370		216.53 ± 101.44	211—222	14—792
Platelet count	1370				
Normal		1020 (74.45%)			
< 150		350 (25.55%)			
< 100		186 (13.58%)			
< 50		36 (2.63%)			
Distance skin/vessel (mm)	1664		18.11 ± 11.83	7.5—18.7	1—81
BMI (Kg/m^2)	1649		26.06 ± 4.09	25.9—26.3	15.21—52
Calcification	1669	1121 (67.17%)			
Calcifications grade	611				
Mild		176 (28.81%)			
Moderate		238 (38.95%)			
Severe		197 (32.24%)			
Previous surgery	1669	242 (14.5%)			
Arterial diameter (mm)	1661		8.78 ± 2.05	8.68—8.88	2—29
Diabetes mellitus	1669	553 (33.13%)			
Hypertension	1669	906 (54.28%)			
Smoking	1668	621 (37.23%)			
Dialysis	1669	81 (4.85%)			
Hyperlipidemia	1667	599 (35.93%)			
COVID-19	1670	51 (3.05%)			
Cirrhosis	1671	251 (15.02%)			
Haematological disorders	1669	73 (4.37%)			
Anti-coagulation	1565	359 (22.94%)			
Intra-procedural heparin	1669	816 (48.89%)			
Successful Haemostasis	1670	1569 (93.95%)			
Haematoma w/o PSA/AVF	1671	32 (1.92%)			
PSA	1671	36 (2.15%)			
with haematoma		27 (1.62%)			
without haematoma		9 (0.54%)			

Table 1 continued

Variable	N	Frequency	Mean ± sd	95% CI	Range
Artero-venous fistula	1671	20 (1.20%)			
with haematoma		11 (0.66%)			
without haematoma		9 (0.54%)			
Acute limb ischaemia	1671	0 (0.00%)			
Retroperitoneal bleeding	1671	0 (0.00%)			
Complications	1671	88 (5.27%)			
Failure Management	1672	155 (9.27%)			

sd standard deviation; *CI* confidence interval; *F* females; *M* males; *Fr* French; *INR* international ratio; *mm* millimetres; *BMI* body mass index; *w/o* with or without; *PSA* pseudoaneurysm; *AVF* artero-venous fistula

Table 2 Crosstabs and Fisher exact test

	Successful haemostasis	Haematoma	PSA	AVF	Complications (haematoma + PSA + AVF)	Failure management
Balloon	340/396	11/396	12/396	0/396	23/396	67/396
	85.90%	2.78%	3.03%	0.00%	5.81%	16.92%
Collagen plug	1229/1274	21/1274	24/1275	20/1275	65/1275	88/1276
	96.50%	1.65%	1.88%	1.57%	5.10%	6.9%
Total	1569/1670	32/1670	36/1671	20/1671	88/1671	155/1672
	93.95%	1.92%	2.15%	1.20%	5.27%	9.27%
Fisher's exact test	$p < 0.0001$	p: 0,205	p: 0,169	p: 0,007	p: 0,606	$p < 0.0001$

PSA pseudoaneurysm; *AVF* artero-venous fistula

The use of VCDs has shown a considerable improvement in patient satisfaction related to the shorter bed rest required and a successful haemostasis in patients until recently considered at risk for percutaneous vascular procedures (such as obese, or with coagulation disorders) [1, 15].

The primary finding of this prospective, multicentre, observational study involving 10 of the major South-European Interventional Radiology centres is that VCDs mechanism of action (balloon occluders vs. non-balloon occluders) is statistically significantly associated with the outcome in small calibre accesses (5–7 Fr). In particular, non-balloon-assisted VCDs demonstrated a statistically significant improved outcome both for "successful haemostasis" (96.5% vs. 85.9%, respectively, $p < 0.001$) and for the need of manual compression (6.9% vs. 16.9%, respectively, $p < 0.001$). The incidence of AVF resulted in statistical more frequent using non-balloon-assisted devices (1.57% vs 0%, p: 0.007). No statistical significant difference was found for the haematoma and PSA occurrence (p: 0.205 and 0.169, respectively).

The reason of this difference is not clear: the need of a semi-compliant balloon inflated within the artery serves as an anchor to ensure proper placement of the hydrogel over the arteriotomy site. Maybe the occlusion is not immediate, and a small amount of blood flows out anyway, and therefore, a more frequent failure may be hypothesized. Moreover, haematomas and pseudoaneurysms are more frequent with the use of balloon-based devices, although the data are not statistically significant. Likewise, the higher incidence of AVF associated with the use of AngioSeal and FemoSeal is not clearly explained: arterial punctures were performed without the use of ultrasound guidance, so in both groups multiple attempts may have been done and fistula may have been created by a different hole of that in which sheath was introduced: an hypothesis is that balloon inflation and manual compression may favourite an easier occlusion of the fistula, but we do not have evidence about that. The use of the ultrasound for the arterial puncture may help us to understand if our hypothesis makes sense or not.

In the literature, some studies already tried to compare complications related to the use of VCDs and manual

compression and to evaluate efficacy and safety associated to the use of a VCD rather than another [6, 16, 17].

For example, Schulz-Schupke et al. [18] reported a lower incidence of haematoma in patients assigned to VCDs compared with manual compression (4.8% vs 6.8%, respectively; *p*: 0.006). Likewise, the time to haemostasis was shorter in patients treated with VCDs vs manual compression (1 min vs 10 min; *p*: 0.001).

Ketterle et al. [19] investigated about the complications rate differences comparing an anchor/plug-mediated VCD (AngioSeal) and an extravascular VCD (Exoseal). The incidence of haematoma and pseudoaneurysm was lower in the Exoseal group compared with the AngioSeal group (1.3% vs 1.9% and 1.3% vs 2.5%, respectively).

The STEP randomized trial [20] compared the rate of technical success obtained with intravascular polymer-based FemoSeal VCD and the suture-mediated ProGlide VCD. The findings showed higher technical success using FemoSeal suggesting to use it especially among outpatients.

At the best of our knowledge, to date our study is the first to compare outcomes using balloon and non-balloon-based VCDs. As secondary outcome, the factors that might have influenced haemostasis' results were investigated. No other study has performed this type of evaluation before.

However, certain limitations must be considered when interpreting the results. First, institutional variability may result in under-reporting or an uncorrected reporting of the data.

A true randomization was not carried out, leaving each operator the freedom to choose the device they prefer. This was due in consideration of the vast number of devices considered in the study and due to the logistical difficulty of a true randomization, given both the impossibility for the single centre to have all the devices available, and the bias that would be introduced linked to the different learning curve of each operator for each device. Otherwise, this means that any VCD was placed by a true experienced operator for that VCD model.

The exclusion of suture-assisted VCDs from our evaluations represents a limitation, since they are used to close $\leq$ 8F accesses as well. A new study may be addressed including also suture-assisted VCDs.

The current study does not explore the relationship between the management of complications (minor or major) and the length of hospital stay, morbidity and mortality.

Conclusion

In conclusion, our study suggests a better outcome with the same complication rate, except that for AVF incidence for non-balloon collagen plug device if compared to balloon occluders vascular closure devices.

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Declarations

Conflicts of interest The authors have no relevant financial or non-financial interests to disclose.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

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