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Comparing Obtura Vascular Closure Device to Manual Compression for Achieving Hemostasis After Percutaneous Transfemoral Procedures: A Randomized Study

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Abstract

Purpose: This trial was designed and aimed to compare safety and efficacy of Obtura™ vascular closure device (VCD) to manual compression (MC) among patients undergoing transfemoral catheterization.

Material and Methods: This prospective, randomized, controlled, multicenter trial of Obtura VCD against MC randomized patients in 1:1 (n=268; 134:134) ratio. Safety and efficacy were measured by primary endpoints (time to hemostasis [TTH] and deployment success) and secondary endpoints which included technical success, device-related adverse events, and time to ambulation (TTA).

Results: The procedural access using right femoral artery was performed in 95.52% of patients in Obtura VCD versus 96.27% in standard MC method, whereas 2.99% of patients in each group underwent left femoral access. Bilateral access was performed in 1.49% (n=2) versus 0.75% (n=1) in Obtura VCD versus MC, respectively. Both the technical success and deployment success were 100%. Patients in Obtura VCD group had shorter TTH (3.26±3.39 vs 23.95±8.24 minutes; $p<0.0001$) and TTA (155.44±125.32 vs 723.84±197.98 minutes; $p<0.0001$) than MC group. No access site complications (re-bleeding, infection, arteriovenous fistula, and transient access site nerve injury) were noted at 2-week, 1-month, and 3-month follow-ups. There were 4 (3%) and 6 (4.5%) cases of hematoma, respectively, in Obtura VCD versus MC and 1 case (0.7%) of post-procedural arterial pseudoaneurysm each in both the groups which were successfully resolved and patients were discharged with no further complications. Further follow-up was without any adverse events.

Conclusions: The study demonstrated favorable safety and efficacy of Obtura™ VCD with a significantly short TTH and TTA compared to MC.

Clinical Impact

In patients undergoing cardiac catheterization, vascular closure devices (VCDs) can achieve hemostasis faster after successful implantation of the device with fewer complications such as bleeding and ambulation can be achieved faster. In terms of effectiveness, Obtura VCD was found to be better than manual compression in achieving early hemostasis and higher technical and deployment success was accomplished. Obtura VCD does not require enlargement of the route through the tissues, uses the same existing arterial sheath as its conduit, and does not cause patients' access sites to feel uncomfortable while it is being deployed.

Keywords

angiography, hemostasis, manual compression, Obtura vascular closure device, percutaneous transfemoral procedures

Introduction

Percutaneous coronary interventions (PCIs) are increasingly being performed through a trans-radial approach, but the transfemoral route remains the most common access site.[1] There are various strategies to prevent access site bleeding and minimize vascular access–related complications, such as diagnostic or therapeutic interventions[2] and usage of vascular closure devices (VCDs), which are broadly termed as bleeding avoidance strategies. Closure of

arteriotomy site is typically accomplished by either manual compression (MC) or using VCD.[2]

The reported rate of access site complications (ASCs) ranges from 0% to 9%, which is associated with significant morbidity and mortality, especially among women.[3,4] Manual compression has traditionally been the gold standard and cost-effective procedure for hemostasis with a complication rate of 1% to 6%.[3] Hemostasis using MC is achieved after 15 to 20 minutes of compression and is often associated with local pain as a result of pressure, restriction of further procedure, prolonged limb mobilization, increased ambulation time (at least 4–6 hours), decreased patient compliance and satisfaction, and risk of hematoma, especially among obese patients or patients receiving anticoagulant therapy.[5–8] Vascular closure devices have been used as an alternative and carry many advantages over MC. They have shown a substantial decrease in hemostasis time, leading to early mobilization and faster recovery, resulting in increased comfort and early discharge of patients.[3,9] Despite the significantly lower complication rate of VCD (0%–4%), their uses are still limited.[9] Ortiz et al,[10] in the retrospective study involving 27 048 peripheral vascular interventions, reported that ASC was frequently observed in procedures needing the larger sheath size of 7 to 8 Fr in comparison to those in which smaller Fr size was used (4–6 Fr; 4.5% vs 3.2%; $p<0.001$). Access site complications were also found to occur less frequently in patients who received heparin or bivalirudin along with VCDs (2.5% vs 4.2%; $p<0.001$) or (1.5% vs 2.5%; $p=0.008$), respectively, compared with those who did not.

Obtura™ VCD (Meril Life Sciences Pvt. Ltd., India) is a novel device for femoral hemostasis, and it works with existing arterial sheaths without the need for sheath exchange. This trial was designed to assess the safety and efficacy of Obtura VCD compared to MC among patients undergoing various transfemoral catheterization procedures.

Materials and Methods

Study Design and Population

This was a prospective, multicenter, randomized controlled trial of Obtura VCD to standard MC (Trial Registration: CTRI/2018/01/011597) and was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee. Inclusion criteria were patients ≥18 years who underwent various catheterization procedures through transfemoral route after receiving written informed consent. Exclusion criteria were (1) patients having previous arterial access at the same site within 30 days, (2) access through vascular graft, (3) re-puncture at same site previously punctured within 48 hours, (4) history of bleeding diathesis, thrombolytic therapy, or treated with warfarin within 24 hours, (5) heavily calcified vessel, (6) allergy to bovine materials, (7) uncontrolled hypertension with systolic blood pressure (>180 mmHg), and (8) pregnancy. Femoral artery was punctured either by palpatory method or under fluoroscopic guidance using standard fluoroscopic landmark. The diameter of common femoral artery (CFA) and superficial femoral artery (SFA) was measured. The entry of sheath was noted in all patients before putting the Obtura VCD or MC by injecting the contrast through the sheath. Pre-deployment fluoroscopy was used among patients receiving device to evaluate local vessel wall calcification and atherosclerotic disease. If the procedural sheath had been placed through the SFA and into profunda femoris artery, device was not deployed as it could have resulted in collagen deposition into SFA. Similarly, if the puncture site was at or distal to the bifurcation of SFA and profunda femoris, the device was not used.

Study Randomization

A total of 269 patients were enrolled, and during screening evaluation 1 patient was excluded from the study. A total of 268 patients were randomized in 1:1 ratio to receive either Obtura VCD (n=134) or standard MC method (n=134) using stratified randomization to allocate the treatment arms (Figure 1). A password-protected web-based program was used for centralized randomization.

Device Description and Procedure

Obtura™ VCD is indicated for closure of femoral artery puncture site using standard 6, 7, and 8 Fr introducer sheath with working length up to 12 cm. Artery with 6 and 7 Fr sheath can be secured with 6 Fr Obtura VCD while those having 8 Fr sheath can be secured with 8 Fr Obtura VCD. The implant contains a bio-absorbable polymer anchor, type-I bovine collagen sponge, and bio-absorbable suture

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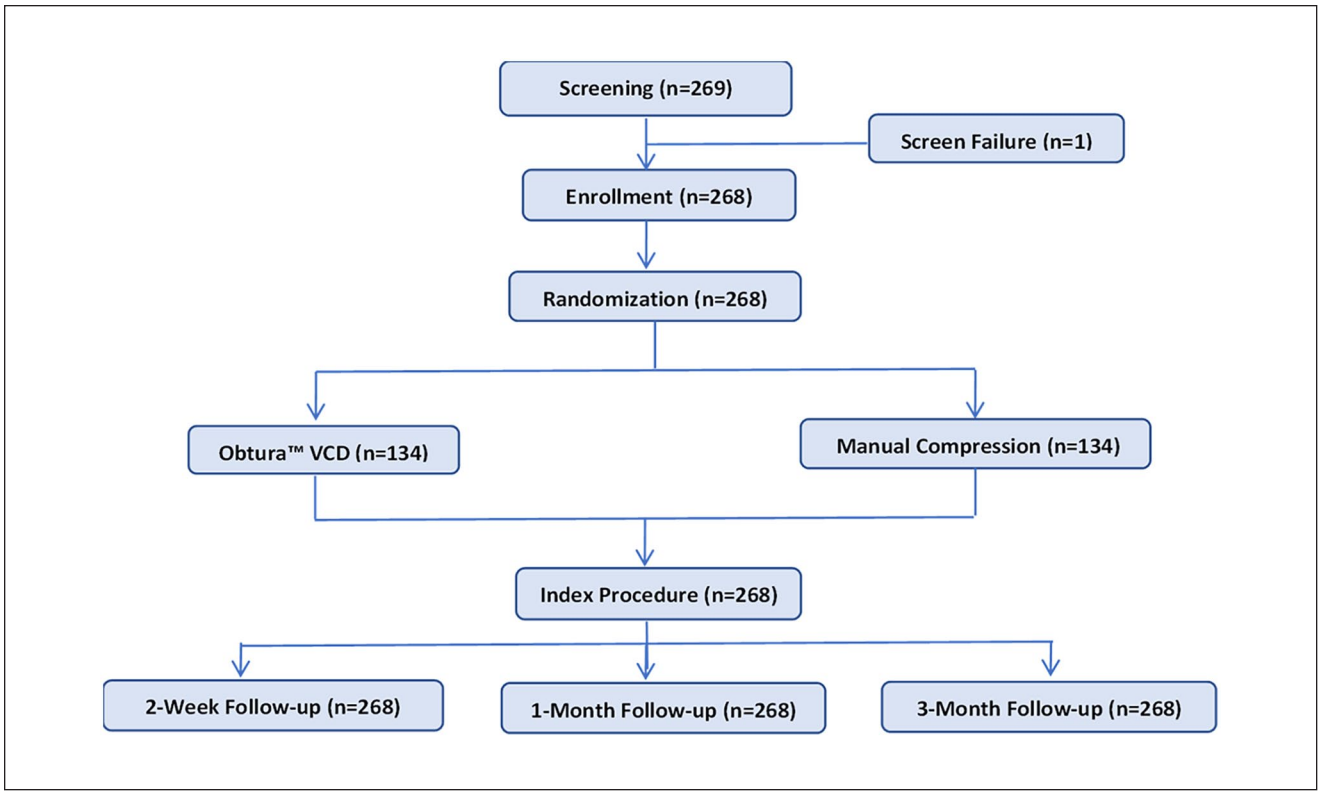

Figure 1. Study design: Obtura vascular closure device (VCD) versus manual compression.

that connects the anchor and collagen by self-tightening knot. The delivery components comprise of the bypass tube that facilitates easy delivery insertion through standard introducer sheath, the dual tube that houses the suture, tamper tube, and the locking tube that acts as device shaft. The hub color and marking indicate the Fr size compatibility of the device. The hub and slider hub connect with inner tube and outer tube, respectively, and help in device deployment by pulling the hub back till the indicative markers appear (Figure 2). During deployment, bioresorbable plug is released on outer surface of the artery that extends within the perivascular tissue to secure hemostasis. Once the knob is pulled over the thread, it exposes the collagen which is pushed by temper over the femoral artery at arteriotomy site. Once it encounters blood, it completely seals the entry. The collagen plug, which remains entirely extravascular, is subsequently metabolized into amino acids by macrophages and gets completely absorbed within 90 days. All investigators from the study sites were trained as qualified interventional cardiologists.

The device was inserted into the arterial sheath in situ until it snugly fits into it (Figure 3A and B), its knob was pulled, and then the device along with the sheath was pulled with right hand while the pusher of the device was held with left hand (Figure 4A). A pusher was used to push the collagen. Permuted block plugs the device over the artery using left hand while gentle traction was maintained with right hand (Figure 4B). When oozing completely stopped, the pusher was pulled, and thread was cut near the skin (Figure 5A). Light compression using dynaplast was applied locally and the patient was shifted (Figure 5B). Patients were kept supine for 2 and 6 hours in Obtura VCD arm and MC arm, respectively. Ambulation was gradually allowed. If any ooze or swelling at the local site was observed, bed rest was further prolonged. They were reassessed at 12, 18, and 24 hours for any complication and the patients were discharged if no further complications were noted.

Study Endpoints and Definitions

The primary endpoints were deployment success and time to hemostasis (TTH), defined as time taken for successful achievement of hemostasis. Secondary endpoints were time to ambulation (TTA), adverse events related to vascular closure, and technical success rate. Ambulation was defined as the patient standing and walking at least 20 feet without re-bleeding or significant oozing requiring MC. Time to ambulation was the total time from removal of the introducer sheath to achievement of ambulation. Vascular closure–related adverse events were monitored clinically

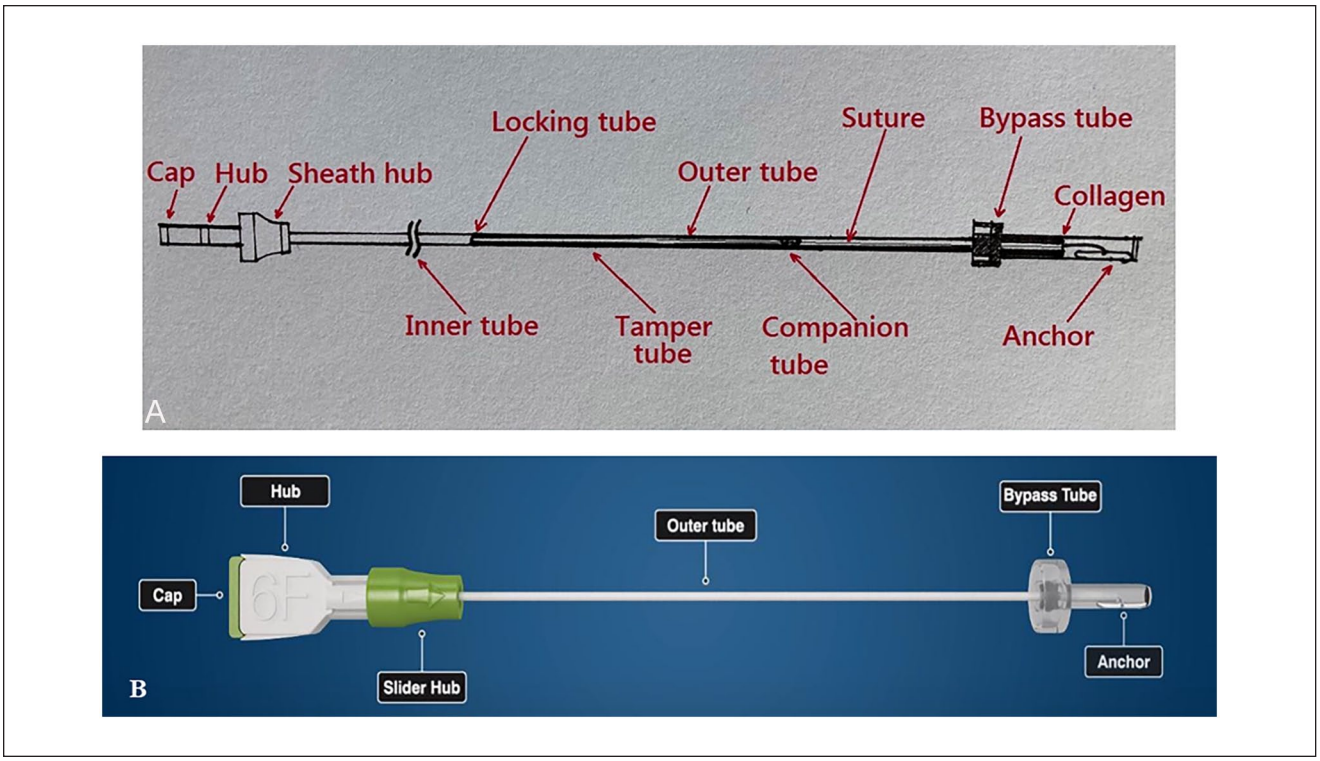

Figure 2. Obtura vascular closure device. (A) Schematic presentation of Obtura VCD. (B) Picture showing Obtura VCD.

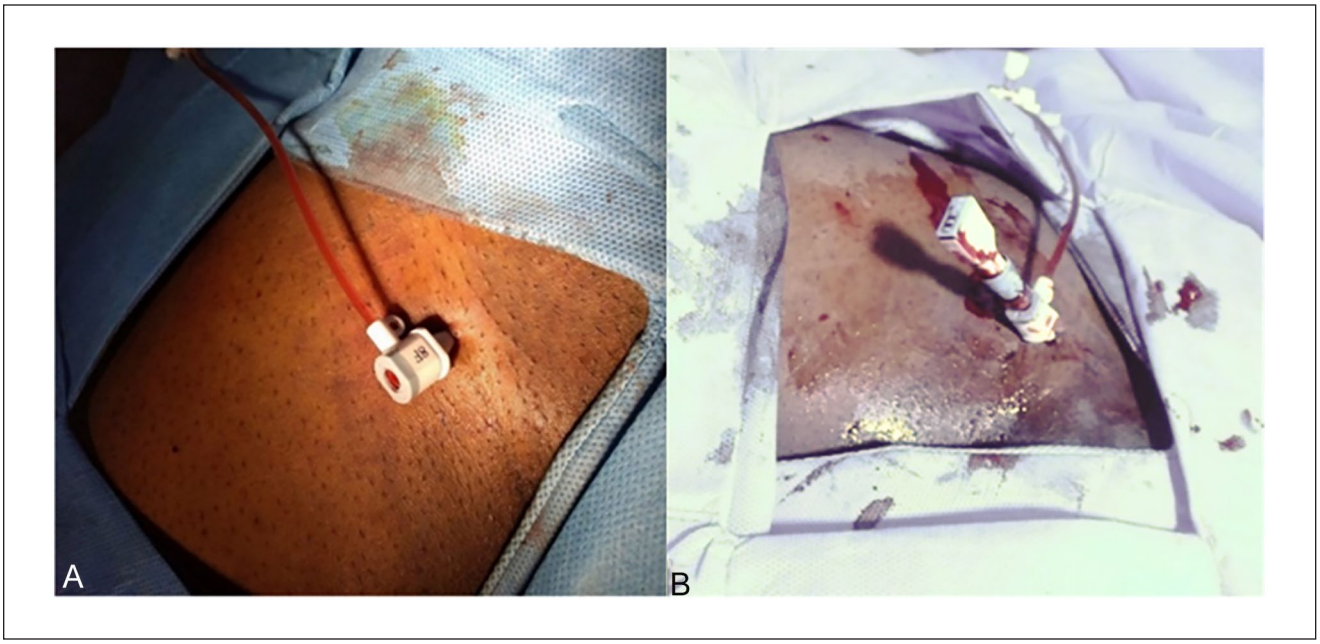

Figure 3. (A and B) Access site closure in patients with Obtura vascular closure device (VCD). Insertion of VCD into the arterial sheath in situ.

for re-bleeding following initial hemostasis, access site–related bleeding requiring >30 minutes for hemostasis, infection requiring prolonged hospitalization, or treatment with intravenous antibiotics and lymphedema, and by using duplex sonography (as per investigator's discretion) for access site hematoma (≤3 cm, 3–6 cm, ≥6 cm), arterial pseudoaneurysm, transient access site–related nerve injury, and arteriovenous fistula. Technical success was calculated

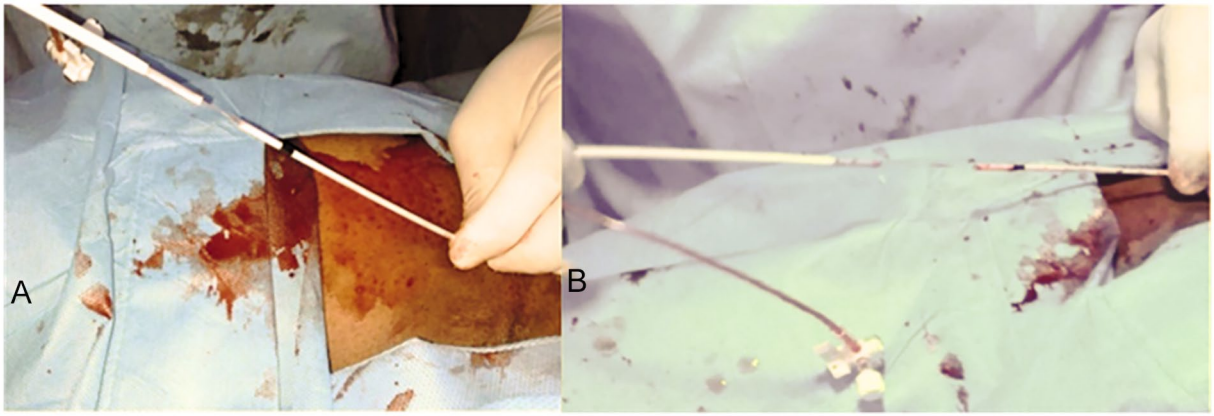

Figure 4. (A and B) The working of Obtura vascular closure device. (A) Knob was pulled and then the device along with the sheath was pulled with right hand while the pusher of the device was held with left hand. (B) Permuted block plugs the device over the artery using left hand while gentle traction was maintained with right hand.

Figure 5. Access site closure with Obtura vascular closure device. (A) The pusher was pulled, and thread was cut near the skin when oozing stopped completely. (B) Light compression using dynaplast was applied locally.

as a percentage of patients not requiring alternative therapy to achieve hemostasis for the Obtura VCD arm.

Statistical Considerations

Sample size of patients was estimated using a two-sided 95% confidence interval to detect 2 minutes difference in TTH with an overall type-I error of 5% (two-sided) and 10% attrition rate. The study was designed to have an 80% power to detect a 2 minutes difference in TTH with an overall type I error rate of 0.05 (two-sided). The sample size was calculated to be at least 98 patients in each group. Mean TTH will be estimated to be 15 minutes in the VCD group and 13 minutes in the MC group with a common standard

Table 1. Demographics, Baseline, and Clinical Characteristics of the Study Population.

Variables	Obtura VCD (n=134)	MC (n=134)	p value
Age (years, mean±SD)	58.78±12.05	62.92±12.11	0.005
Male, n (%)	95 (70.90)	100 (74.63)	0.500
Female, n (%)	39 (29.10)	34 (25.37)	0.500
BMI (kg/m2, mean±SD)	23.78±4.20	24.89±5.14	0.053
SBP (mmHg, mean±SD)	127.13±14.24	128.39±19.02	0.540
DBP (mmHg, mean±SD)	78.52±9.67	76.13±11.26	0.060
Co-morbidities, n (%)			
DM	28 (20.90)	38 (28.36)	0.160
HTN	32 (23.88)	44 (32.84)	0.100
CAD	104 (77.6)	106 (79.1)	0.520
Previous CABG	01 (0.92)	03 (2.78)	0.620
Smoking/chewing tobacco	08 (7.34)	05 (4.59)	0.390
Alcoholics	06 (5.5)	04 (3.67)	0.750
Others	09 (6.72)	11 (8.21)	0.640
Medications, n (%)			
Aspirin	106 (79.1)	106 (79.1)	1.000
Ticagrelor	79 (58.9)	80 (59.7)	0.900
Clopidogrel	25 (18.7)	29 (21.6)	0.540
Statins	106 (79.1)	106 (79.1)	1.000
NOAC	4 (2.9)	3 (2.2)	0.700
Heparin	134 (100)	134 (100)	—

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; CAD, coronary artery disease; DBP, diastolic blood pressure; DM, diabetes mellitus; HTN, hypertension; MC, manual compression; NOAC, novel oral anticoagulants; SBP, systolic blood pressure; SD, standard deviation; VCD, vascular closure device.

deviation (SD; sigma) of 5 minutes. So, a total of 218 patients (109 patients for VCD and 109 patients for MC method) needed to be enrolled in the study with an assumed drop-out rate of 10%. Comparison and analysis of continuous data in both the groups were done using analysis of variance and $p<0.05$ considered significant. Categorical variables are described as counts and percentages and were compared using Pearson's chi-square test or Fisher's exact test. Continuous variables are described as mean±SD or as median and compared using *t*-test or Mann-Whitney test, as appropriate. Survival analyses were done graphically with Kaplan-Meier Curve, and mathematically with the log-rank test. For statistical significance, a two-sided p value of less than 0.05 was considered.

Ethical Compliance Statement

The study was conducted after protocol approval by Institutional Review Boards of the respective sites according to local regulations. This study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all the patients prior to enrolment.

Table 2. Procedural Characteristics of the Study Population.

Variables	Obtura VCD (n=134)	MC (n=134)
Size of Obtura VCD 6 Fr	134 (100.0)	NA
Procedural access site, n (%)		
Right femoral access	128 (95.52)	129 (96.27)
Left femoral access	4 (2.99)	4 (2.99)
Bilateral access	2 (1.49)	1 (0.75)
Type of procedures, n (%)		
Coronary angiography	121 (90.30)	125 (93.28)
Peripheral angiography	13 (9.70)	9 (6.72)

Abbreviations: MC, manual compression; NA, not applicable; VCD, vascular closure device.

Results

Baseline and Demographic Characteristics

Majority of patients were males in both arms (Obtura VCD: 70.9% [n=95] and MC: 74.63% [n=100]). Patients in Obtura VCD arm compared to MC had significantly lower mean age (58.78±12.05 vs 62.92±12.11 years; p=0.005) and body mass index (23.78±4.20 vs 24.89±5.14 kg/m^2; p=0.053). The patients with diabetes (20.90% vs 28.36%, p=0.16) and hypertension (23.88% vs 32.84%, p=0.10) were numerically lower in Obtura VCD arm as compared to MC. However, other baseline characteristics of both groups were similar. Similarly, anticoagulants and antiplatelets were not significantly different between the two groups (Table 1).

Procedural Details

Procedural characteristics are shown in Table 2. Coronary angiography was performed in 90.30% and 93.28% Obtura VCD and MC groups, respectively, while 9.70% and 6.72% of patients in respective groups underwent peripheral angiography. All patients were treated with 6 Fr Obtura VCD. In the majority of patients, procedural access was performed using the right femoral artery in Obtura VCD versus MC [128 (95.52%) vs 129 (96.27%)] followed by 2.99% left femoral artery in both the groups and 1.49% and 0.75% patients in respective groups had bilateral access.

Clinical Outcomes

Obtura VCD successfully achieved hemostasis in all patients with 100% technical and deployment success. Access site complications such as re-bleeding, infection, arteriovenous fistula, and transient access site–related nerve injury were not reported at 2-week, 1-month, and 3-month follow-ups. Time to hemostasis was significantly shorter in Obtura VCD arm (3.26±3.39 vs 23.95±8.24 minutes; $p<0.0001$; Figure 6). Time to ambulation was also

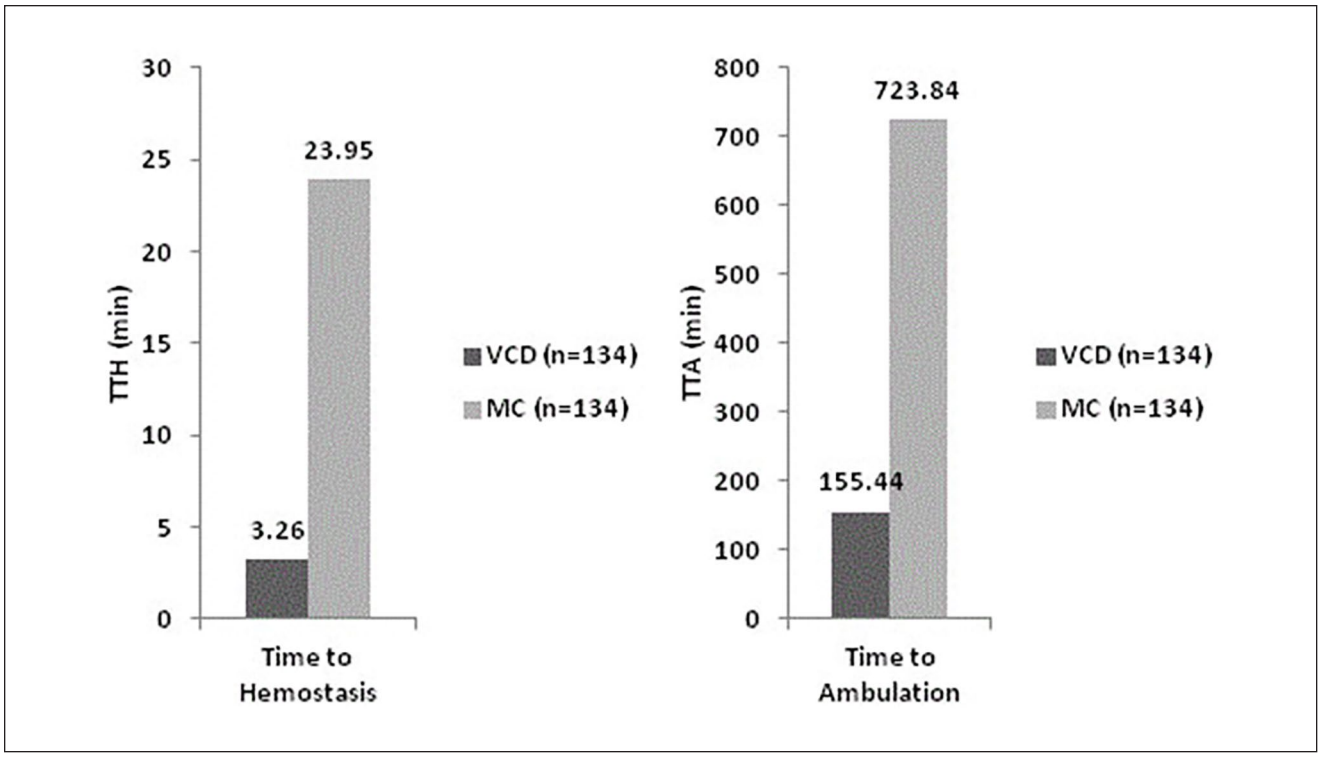

Figure 6. Showing lesser time required by Obtura vascular closure device (VCD) in comparison to manual compression (MC) to achieve hemostasis and time to ambulation.

Table 3. Clinical Outcomes of the Study Populations.

Variables	Obtura VCD (n=134)	MC (n=134)	p value
Deployment success, n (%)	134 (100)	NA	—
Time to hemostasis (minutes, mean±SD)	3.26±3.39	23.95±8.24	<0.0001
Time to ambulation (minutes, mean±SD)	155.44±125.32	723.84±197.98	<0.0001
Vascular closure–related adverse events, n (%)	5 (3.7)	7 (5.2)	0.5547
Re-bleeding	0	0	—
Access site infection	0	0	—
Hematoma	4 (3.0)	6 (4.5)	—
Arterial pseudoaneurysm	1 (0.7)	1 (0.7)	—
Arteriovenous fistula	0	0	—
Transient access site–related nerve injury	0	0	—
Technical and deployment success, n (%)	134 (100)	NA	—

Abbreviations: MC, manual compression; NA, not applicable; SD, standard deviation; VCD, vascular closure device.

significantly lower in Obtura VCD arm (155.44±125.32 vs 723.84±197.98 minutes; p<0.0001; Figure 6). Post-procedure, 4% (3.0%) cases of hematoma were observed in the case of Obtura VCD arm, whereas 6 (4.5%) cases of hematoma were reported in patients who underwent MC. Similarly, one case (0.7%) of post-procedure arterial pseudoaneurysm was observed in both groups (Table 3), which was successfully resolved and patients were discharged with no further complications. No re-occurrence or any other adverse events were noted during the follow-up period. Patients were discharged on following medications: aspirin (79.1% in both groups), ticagrelor (58.9% vs 59.7%), clopidogrel (18.7% vs 21.6%), statins (79.1% in both groups), novel oral anticoagulants (2.9% vs 2.2%), and heparin (100% in both groups).

Discussion

This study demonstrated favorable safety and performance outcomes of Obtura VCD among patients undergoing

transfemoral interventions showing its high success rate in the form of significantly shorter TTH and TTA and lower vascular ASCs at 3-month follow-up.

Since the first demonstration of percutaneous access by Seldinger seven decades ago, MC has remained the gold standard to secure hemostasis. Vascular closure devices have been introduced in the past two decades to achieve faster and better hemostasis as they reduced vascular complications up to 50% compared to MC.[8,11,12] They are classified into passive and active devices. Active devices can be collagen based [Obtura, VasoSeal (Datascope Corporation, Mahwah, New Jersey) and Angio-Seal (St Jude Medical, St Paul, Minnesota)], clip based [StarClose (Abbott Vascular, Santa Clara, California)], and suture based [Perclose Proglide (Abbott Vascular Santa Clara, California), Prostar (Abott Vascular Santa Clara, California), and Super Stitch (Sutura, Fountain Valley, California)]. Hemostasis was successfully achieved with Obtura VCD in all 134 patients. Technical success and deployment success were achieved in all cases (100%). Its success rate was similar to other contemporary devices like FemoSeal (St Jude Medical, St Paul, Minnesota; 97.2%),[3] ExoSeal (Cordis Europe, Waterloo, Belgium; 98.1%),[8] Angio-Seal (98%), and StarClose (94%).[13] No case of deployment failure was noted in our study compared to 6.4% with FemoSeal in CLOSE-UP study,[11] 6.9% with Duett (Vascular Solutions, Minneapolis, Minnesota) device (VasoSeal) in SEAL trial,[14] and 3.7% with Proglide (Abbott Vascular, Santa Clara, California).[15] It was attributed to novel design, less complexity, and ease in deployment of device. Failure to deployment is associated with increased risk of large hematoma. Another novelty with Obtura VCD is that 6 Fr device can easily close 7 Fr sheath unlike Proglide where 8.5 Fr size is required to seal a 6 Fr sheath, thus making it sleeker.[16] As Obtura VCD uses the same existing arterial sheath as conduit for its deployment, it does not require widening of track through the tissues, and therefore causes no discomfort at access site during its deployment to the patients.

Obtura VCD was also found to be significantly effective in reducing TTH in comparison to MC (3.26±3.39 vs 23.95±8.24 minutes; $p<0.0001$). There is a need to lower the incidence of vascular complications as inadequate hemostasis may lead to various bleeding complications including death if not done in timely manner. Time to hemostasis in our study was concordant with other devices like InSeal (Medical Ltd., Caesarea, Israel; 2.5 minutes),[1] Duett device (7 minutes),[16] and Proglide (Abbott Labs, Redwood City, California; 3 minutes).[15] Easier deployment through the same working sheath was reason behind it as it helped in better anchoring and securing the device. Time to ambulation was significantly lower in Obtura™ VCD arm compared to MC arm (155.44±125.32 vs 723.84±197.98 minutes; $p<0.0001$) which was pivotal in recovery and satisfaction of patients. It was also shorter than other contemporary devices like ExoSeal (252 minutes) and Proglide (222 minutes).[16] After the procedure, TTA is critical for recovery and comfort of the patient making them self-reliant.

A prospective study among patients undergoing PCI evaluated the performance of two different VCDs namely Angio-Seal (n=210) and StarClose (n=196) to MC (n=214), and reported large hematoma in 5% patients in VCD arm. In this study, hematoma ≤3 cm and 3 to 6 cm was noted in 35% and 12% of subjects.[13] Another study among 1014 patients using FemoSeal VCD reported large hematoma in 2.2% cases.[12] Favorable safety profile with Obtura™ VCD was proved as low rates (3%) of hematoma were reported in our study.

Women population in our study was 29.1% and Obtura VCD achieved 100% success in them. Smaller diameter and shorter length of CFA and increased susceptibility to overdosing of adjunct antithrombotic are few of the contributing factors responsible for higher rate of vascular complications among female patients. In the ISAR-CLOSURE trial, 1309 women were assigned to FemoSeal VCD (n=469), ExoSeal VCD (n=448), and MC (n=478). Hematoma was observed in 56 (6.1%) patients in VCD arm and 2 patients (0.2%) reported major bleeding complications requiring transfusion.[4] The female population in our study was lower (29.1% vs 25.37% in Obtura VCD vs MC, respectively) and overall rate of hematoma was reported to be 3%, and role of gender play affecting the outcomes on the study was not observed.

In our study, no device-related infections were observed compared to 0.1% with FemoSeal,[4] 0.1% with Angio-Seal,[13] and 2% with Proglide.[15] Obtura VCD is completely absorbable device leaving no foreign bodies behind unlike nitinol clip in FemoSeal, anchor in Angio-Seal, and suture in Proglide. These residual foreign bodies can act as a nidus for infection.[7]

Furthermore, no vascular complications were observed at 3-month follow-up in this study which proved the complete safety profile of the device as Obtura VCD was totally absorbed at 90 days. It was discordant to findings from study by Fujihara et al,[16] who observed periprocedural or 30 days incidence of major or minor ASCs in 8.4% patients. This was attributed to baseline complexities which included elderly, diabetic, obese, on hemodialysis, or suffering from critical limb ischemia in their cohort. Obtura VCD was safe despite the fact that our patients also shared these risk factors.

Recent analysis of 26 113 patients undergoing diagnostic catheterization (14 401) or PCI (11 712) revealed the efficacy of using VCDs over MC.[17] Majority of the patients underwent MC (~52%) and rest underwent closure with either Angio-Seal (22.15%), Mynx (Cardinal Health, Dublin, Ohio; ~18%), or Perclose (8.2%). The study revealed that using a lower profile access sheaths (either 4 Fr or 5 Fr as used in the study) reduced the

risk of hematoma, infection, and pseudoaneurysm. Similar outcomes were observed in our study where 6 Fr access sheath was used, and lower cases of hematoma (n=4) and no infection were observed post-procedure or during follow-up period in case of Obtura VCD in comparison to MC group where cases of hematoma was higher (n=6).

A CLOSE-UP III trial comparing the MynxGrip (Cardinal Health, Dublin, Ohio) VCD with MC showed the TTH of 4 (range 3–5) versus 10 (range 7–11) minutes and device failure was observed in 7% of patients who then underwent MC.[18] No such incidence of device failure was observed with Obtura™ VCD and TTH was found to be 3.26±3.39 minutes comparable with MynxGrip in the study.

Although VCDs have several advantages over MC devices, users must be familiar with the device to accomplish hemostasis following femoral artery puncture safely. This is because there is a chance that the device may malfunction during deployment. Vascular closure devices are often utilized for anterior wall punctures; they cannot be used to close posterior wall punctures (large diameter punctures). In very rare instances closure complications such as vascular occlusion, infection, and embolization may occur with the usage of the device.

Limitations

Limited follow-up (3-month), male-dominant population, and small sample size are some of the limiting factors. Hence, a larger multicentric prospective study may further validate the findings of this study. Another limitation of the study is the lack of ultrasound-based closure, which can assist in preventing the anchor from becoming trapped in posterior wall plaque and can also prevent pseudoaneurysms during the procedure. However, patients with weak or absent arterial pulses as well as individuals who are obese are the typical candidates for this approach to closure.

Conclusions

Obtura™ VCD is safe, effective, and significantly reduces hemostasis and ambulation time in comparison to MC to achieve vascular hemostasis. Moreover, the absence of acute ipsilateral leg ischemia and hematoma give enough assurance that serious adverse events with Obtura™ VCD are exceedingly rare.

Author Contributions

TD, RKP, SKS, AR, KP, and JA conceptualized, planned, recruited, and conducted the trial protocol at their respective sites. All authors have reviewed the manuscript and agree to take responsibility for the content of the published manuscript.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Data Availability

The authors declare that data supporting the findings of this study are available within the article.

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CTRI/2018/01/011597.

Informed Consent

All subjects provided written informed consent.

References

1. Barbash IM, Kornowski R, Berkovitch A, et al. Percutaneous nitinol-based vascular closure device for large bore arterial access hemostasis: results of a prospective multicenter study. *Catheter Cardiovasc Interv*. 2020;96(2):473–478.
2. Schulz-Schupke S, Helde S, Gewalt S, et al. Comparison of vascular closure devices vs manual compression after femoral artery puncture: the ISAR-CLOSURE randomized clinical trial. *J Am Med Associa*. 2014;312(19):1981–1987.
3. Gabrielli R, Rosati MS, Millarelli M, et al. FemoSeal® device use for femoral artery closure by different techniques. *Ann Vasc Surg*. 2018;51:18–24.
4. Gewalt SM, Helde SM, Ibrahim T, et al. Comparison of vascular closure devices versus manual compression after femoral artery puncture in women. *Circ Cardiovasc Interv*. 2018;11(8):e006074.
5. Tagliaferro FB, Orgera G, Mascagni L, et al. FemoSeal® vascular closure device for antegrade common femoral artery access: safety and technical notes. *J Vasc Access*. 2020;21(1):79–85.
6. Dahal K, Rijal J, Shahukhal R, et al. Comparison of manual compression and vascular hemostasis devices after coronary angiography or percutaneous coronary intervention through femoral artery access: a meta-analysis of randomized controlled trials. *Cardiovasc Revasc Med*. 2018;19(2):151–162.
7. Stiebellehner L, Nikfardjan M, Diem K, et al. [Manual compression versus mechanical compression device (FemoStop) after diagnostic coronary angiography with/without intervention]. *Wien Klin Wochenschr*. 2002;114(19–20):847–852.
8. Wei X, Han T, Sun Y, et al. A retrospective study comparing the effectiveness and safety of EXOSEAL vascular closure device to manual compression in patients undergoing percutaneous transbrachial procedures. *Ann Vasc Surg*. 2020;62:310–317.
9. Wong SC, Laule M, Turi Z, et al. A multicenter randomized trial comparing the effectiveness and safety of a novel

vascular closure device to manual compression in anticoagulated patients undergoing percutaneous transfemoral procedures: the CELT ACD trial. *Catheter Cardiovasc Interv*. 2017;90(5):756–765.
10. Ortiz D, Jahangir A, Singh M, et al. Access site complications after peripheral vascular interventions: incidence, predictors, and outcomes. *Circ Cardiovasc Interv*. 2014;7(6):821–828.
11. Holm NR, Sindberg B, Schou M, et al. Randomised comparison of manual compression and FemoSeal vascular closure device for closure after femoral artery access coronary angiography: the CLOSure dEvices Used in everyday Practice (CLOSE-UP) study. *Eurointervention*. 2014;10(2):183–190.
12. Kerré S, Kustermans L, Vandendriessche T, et al. Cost-effectiveness of contemporary vascular closure devices for the prevention of vascular complications after percutaneous coronary interventions in an all-comers PCI population. *Eurointervention*. 2014;10(2):191–197.
13. Yeni H, Axel M, Örnek A, et al. Clinical and subclinical femoral vascular complications after deployment of two different vascular closure devices or manual compression in the setting of coronary intervention. *Int J Med Sci*. 2016;13(4):255–259.
14. SEAL Trial Study Team. Assessment of the safety and efficacy of the DUETT vascular hemostasis device: final results of the safe and effective vascular hemostasis (SEAL) trial. *Am Heart J*. 2002;143(4):612–619.
15. Vinayakumar D, Kayakkal S, Rajasekharan S, et al. 24h and 30 day outcome of Perclose Proglide suture mediated vascular closure device: an Indian experience. *Indian Heart J*. 2017;69(1):37–42.
16. Fujihara M, Haramitsu Y, Ohshimo K, et al. Appropriate hemostasis by routine use of ultrasound echo-guided transfemoral access and vascular closure devices after lower extremity percutaneous revascularization. *Cardiovasc Interv Ther*. 2017;32(3):233–240.
17. Kreutz RP, Phookan S, Bahrami H, et al. Femoral artery closure devices vs manual compression during cardiac catheterization and percutaneous coronary intervention. *J Soc Cardiovasc Angiograp Interv*. 2022;1(5):100370.
18. Jakobsen L, Holm NR, Maeng M, et al. Comparison of MynxGrip vascular closure device and manual compression for closure after femoral access angiography: a randomized controlled trial: the closure devices used in every day practice study, CLOSE-UP III trial. *BMC Cardiovasc Disord*. 2022;22(1):68.