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Comparative Analysis of Vascular Closure Devices to Traditional Manual Compression in OBLs

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Abstract: Objective. Using a vascular closure device (VCD) in an office-based lab (OBL) is controversial. Some see this as an extra cost with little gain in terms of safety. Others advocate for the use because of improved patient satisfaction, increased revenue from faster room turnover, and decreased procedure complications. In this multicenter study, we assessed safety, cost-effectiveness, and ambulation/recovery time parameters in patients treated with VCDs against those who underwent manual compression for common femoral artery access in the OBL. **Methods.** This retrospective, multi-satellite study evaluated 187 patients who underwent diagnostic or interventional angiograms. The average age of patients who met inclusion criteria was 72.99 (53%) males and 88 (47%) females enrolled. The patients who underwent closure via common femoral artery access were eligible for inclusion in the study with one of 3 methods: MynxGrip vascular closure device (Cordis), StarClose SE vascular closure system (Abbott), and traditional manual compression (TMC). Costs, complications, and time to ambulation were the factors evaluated. **Results.** This study included 187 patients who underwent common femoral artery closure by one of 3 methods: MynxGrip vascular closure device (55 patients, 29.4%); StarClose SE vascular closure system (69 patients, 36.9%); and TMC (63 patients, 33.7%). The mean times to ambulation post procedure, achieving hemostasis, and spent in recovery were all statistically shorter with the use of a VCD. Reported complications included pseudoaneurysm and hematoma. Although not significant, there was a higher overall number of reported complications in the TMC group. The costs were derived by including the device cost, mean time spent in the recovery room, and hourly registered nurse and medical assistant salaries (caring for the patient in recovery). The mean cost for MynxGrip, StarClose, and TMC was $337.15, $387.79, and $290.50, respectively. These calculations resulted in TMC having a statistically significant ($P<.001$) lower cost than both MynxGrip and StarClose. **Conclusions.** There is a reduced time to hemostasis, ambulation, and length of stay in recovery using a VCD. There was an overall increased number of complications with TMC, but not significantly. There is a higher cost post procedure with the use of a VCD compared with TMC. However, these results are limited and depend on the volume of cases, recovery bed space, and time spent caring for the patient at the end of the operating day. These numbers could easily result in higher costs with the use of TMC. The use of a VCD or lack thereof should be tailored to the individual patient and lab.

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Introduction

Vascular closure devices (VCDs) and traditional manual compression (TMC) are well-established methods for obtaining hemostasis after an endovascular procedure. The use of a percutaneous VCD was introduced in the mid-1990s to remedy the high bleeding rates and long bedrest times required for TMC.[1] Since the inception of VCDs, there has been a rapid rise in the number of devices and their usage. The use of a VCD is now commonplace in hospitals.

An increasing number of vascular specialists are moving to an office-based lab (OBL) and/or ambulatory surgical center (ASC).[2] There are many possible reasons for the move; perhaps one of the most important is the ability to perform endovascular care at much lower costs than when performing an equivalent procedure in a hospital.[3] Interventionalists working out of an OBL/ASC aim to provide the highest quality of care to their patients while also being cost-conscious about the equipment they choose. One area of

controversy, particularly in the OBL, is the use of a VCD. Although there are many studies evaluating the efficacy of VCDs, none to our knowledge primarily focuses on the safety and costs in the OBL.[4,5,6]

Methods

This retrospective, multi-satellite study evaluated 187 consecutive patients who underwent diagnostic or interventional angiograms by physicians at Palm Vascular Centers between February 5, 2021, and August 3, 2021. All closures were performed via a common femoral artery approach. Vascular closure occurred by one of 3 methods: MynxGrip vascular closure device (Cordis) (55 patients, 29.4%); StarClose SE vascular closure system (Abbott) (69 patients, 36.9%); and TMC (63 patients, 33.7%). Perioperative and postoperative variables assessed include time to hemostasis, time to ambulation, postoperative recovery time, and total postoperative length of stay. Complications evaluated included postoperative hematoma, pseudoaneurysm, and arteriovenous fistulas. Economic factors assessed included registered nurse (RN) and medical assistant (MA) hourly rates and device-related costs. The following were evaluated on the day of the procedure and at a 2- to 4-week follow-up: time to hemostasis, time to ambulation, length of overall recovery, presence of hematoma, presence of arteriovenous fistula, presence of pseudoaneurysm, or any adverse event determined by the investigator.

Statistical Analysis

When appropriate, times and costs were analyzed using normal linear models for continuous data. Binary adverse events were analyzed using binary logistic models when appropriate. Ordinal adverse events with a scale were analyzed using a cumulative logistic proportional odds model in which the cumulative odds of adverse events were appropriate.

The method of estimation used was least squares for times and costs. The penalized maximum likelihood was used for binary adverse events to accommodate sparse adverse events data, while Bayesian statistics were appropriate for ordinal adverse events.

Wald-based 95% confidence intervals (CIs) and *P*-values were used for times and costs and binary adverse events. Based on the percentile method, Bayesian 95% CIs, were used for ordinal adverse events. Our definition of a *P*-value in Bayesian statistics was the number *P* corresponding to the 100 (1-*P*) % CI, rejecting the null hypothesis.

All models were estimated using SAS/STAT 14.1.[5] The GENMOD (generalized linear models) procedure was used for normal linear models (times and costs); the LOGISTIC procedure was used for binomial models (binary adverse events). In contrast, the MCMC procedure was used for proportional odds models (ordinal adverse events).

Results

Of the 187 patients, 55 (29.4%) underwent closure with the MynxGrip vascular closure device (group A), 69 (36.9%) with the StarClose SE vascular closure system (group B), and 63 (33.7%) with TMC (group C). The mean time to hemostasis (in minutes) for groups A, B, and C was 6.43, 6.04, and 19.29, respectively. Results showed a statistically significant faster time to hemostasis ($P<.001$) for both MynxGrip and StarClose compared with TMC. The mean time to ambulation post procedure (in minutes) for groups A, B, and C was 83.62, 84.59, and 233.29, respectively, indicating a statistically significant faster time to ambulation ($P<.001$) for both MynxGrip and StarClose when compared with TMC. The mean time spent in recovery (in minutes) for groups A, B, and C was 130.25, 140.0, and 266.19, respectively, which resulted in statistically significant reduced time spent in recovery ($P<.001$) for both MynxGrip and StarClose when compared with TMC.

Adverse access site complication events evaluated included pseudoaneurysm, hematoma, and arteriovenous fistula. There were no documented arteriovenous fistula complications across all 3 groups. The number of hematomas observed with MynxGrip, StarClose, and TMC was 4, 5, and 7, respectively. This value was not statistically significant when comparing either closure device with TMC ($P=.508$, $P=.457$). For groups A, B, and C, the observed frequency of pseudoaneurysms was 1, 0, and 4, respectively. There was no significant difference in pseudoaneurysm occurrence comparing MynxGrip or StarClose with TMC ($P=.297$ and $P=.120$, respectively).

The costs were calculated by factoring in the cost of the devices, mean time spent in recovery, and hourly cost of an RN and MA to care for the patient in the recovery phase. The cost of the devices was the same at each institution: MynxGrip $195, StarClose $235, and TMC $0. The RN and MA hourly salaries were $44.78 and $20.70, respectively. The mean time spent in recovery (in minutes) for groups A, B, and C was 130.25, 140.0, and 266.19, respectively, as previously stated. When adding the cost of the device with the cost of caring for the patient in recovery utilizing RN and MA salaries, the mean cost of groups A, B, and C was $337.15, $387.79, and $290.50, respectively, which resulted in TMC having a statistically significant ($P<.001$) lower cost than both MynxGrip and StarClose.

Discussion

In our study, the mean time to hemostasis, ambulation, and time spent in recovery was significantly shorter than patients treated with TMC, which is in accordance with multiple previously done studies. Due to the retrospective nature of this study, we were unable to evaluate patient satisfaction. However, numerous other studies have shown improved patient satisfaction with VCDs related to ambulation time and time spent in recovery.[1] Regarding an OBL, some would argue that improved patient satisfaction is even more important than with a procedure done in a hospital setting because OBLs rely on physician referrals and patients making the conscious decision to return to the OBL for continued care. Interventionalists in OBLs need to consider this when deciding on VCD use.

The access site complications observed in this study included pseudoaneurysms and hematomas. It should be noted that there

were more complications in both categories with TMC than those resulting from VCD usage, all of which were not significant. These findings are concordant with other more extensive studies that failed to show a statistically significant difference in pseudoaneurysm or hematoma occurrence when comparing TMC with VCDs.[5]

The actual costs of performing a procedure in the OBL with a closure device vs TMC is difficult to determine retrospectively. In this study, we evaluated the RN and MA salaries required to care for the patient and the cost of the device itself, which showed a statistically significant reduced cost with TMC compared with VCDs. These results are very limited. A moderately busy OBL has a high hourly operating cost. The use of VCDs showed a statistically significant reduced recovery time, which has the potential to reduce staff requirements and close facilities in less time post last procedure of the day. Also, some OBLs have a lower number of recovery beds, which can become a rate-limiting step in the number of procedures that can be performed in a day thus potential profit.

To determine which closure method is advantageous for OBLs, safety, patient satisfaction, and the net economic gains or losses need to be considered. Less like the hospital setting, physicians in the OBL setting often rightfully scrutinize every cost decision to ensure they are doing what is best for the patient while also being cost-conscious. Every OBL is different, and the decision to use a VCD needs to be tailored to the individual parameters of that doctor, patient, and office. ■

Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.

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