HHS Public Access

Author manuscript

J Cardiovasc Electrophysiol. Author manuscript; available in PMC 2023 August 01.

Published in final edited form as:

J Cardiovasc Electrophysiol. 2022 August ; 33(8): 1737–1744. doi:10.1111/jce.15555.

Patient-reported Outcomes and Costs Associated with Vascular Closure and Same-Day Discharge following Atrial Fibrillation Ablation

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Abstract

Background: We aimed to measure patient reported outcomes (PROs) and costs associated with same day discharge (SDD) for AF ablation and vascular closure device implantation in clinical practice.

Methods: PROs were prospectively measured in 50 AF ablation patients, comparing complete vascular device closure (n=25) versus manual compression hemostasis (n=25). Health-system costs for SDD patients receiving vascular device closure were compared to matched controls with one-night stays who did not receive any closure device.

Results: Prospectively-enrolled patients receiving vascular device closure for AF ablation had mean age of 65 years, 17% were female, with a mean CHA_2DS_2-VASc score 3. Mean number of venous sheaths was higher among patients receiving vascular device closure (3.8 vs. 3.1,p<0.001), and there was 1 case of re-bleeding in a patient receiving vascular closure device (no other complications). Same-day discharge rates (76% vs. 8.3%,p<0.001), patient satisfaction with bedrest time (8.5 vs. 6,p=0.004) and with pain (8 vs. 5.1,p=0.009) were significantly better among patients receiving vascular closure. In matched analyses of health-system costs, patients with vascular closure had mean age 66, 32% were female, and mean CHA_2DS_2-VASc score was 2 (p=NS vs. controls). SDD with vascular closure was associated with significantly lower facility, pharmacy, and disposable costs, but higher implant costs. Overall costs for ablation were not significantly different (mean difference 1.10%, 95% CI −3.03–5.42).

Conclusions: Vascular closure for AF ablation improves patient experience in routine care. Use of vascular closure and SDD after AF ablation reduces several components of healthcare system costs, without an overall increase.

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Keywords

atrial fibrillation; ablation; costs; value driven healthcare; patient reported outcomes

Catheter ablation is the most efficacious approach to rhythm control for atrial fibrillation (AF), and has been demonstrated to improve quality of life, arrhythmia outcomes, and possibly clinical outcomes.[1–3] It has become among the most common heart rhythm procedures in the US.[4] However, owing to primarily vascular access considerations around bleeding and hemostasis in often elderly patients with comorbidities and procedural trends that favor uninterrupted anticoagulation, patients are routinely kept overnight after ablation for AF for extended monitoring. Recently there has been heightened interest in early discharge for these patients,[5,6] and vascular closure represents an opportunity to achieve faster and safer hemostasis to facilitate earlier discharge.

In 2020, a pivotal randomized clinical trial demonstrated improved patient reported outcomes (PROs) associated with use of vascular closure among patients undergoing broad catheter ablation procedures.[7] However, there are no data in broad, routine clinical care among patients undergoing AF ablation. Furthermore, use of vascular closure devices is associated with increased financial cost to health systems that is not routinely reimbursed, and therefore warrants important examination regarding financial balance of possible improved outcomes with vascular closure (e.g., PROs, earlier discharge) versus more traditional manual compression hemostasis without the associated costs of implant. The objectives of the present analysis were (1) to compare PROs associated with vascular closure versus manual compression hemostasis among patients undergoing AF ablation in clinical practice and (2) to compare cost to the healthcare system associated with AF ablation and same-day discharge with vascular closure versus overnight stay without vascular closure.

Methods

Study Populations

All patients in this study underwent catheter ablation for AF at the University of Utah. In order to achieve the objectives of the study, two cohorts were developed; these were not necessarily mutually exclusive (Figure 1).

Prospective PROs Cohort—In order to assess patient reported outcomes among patients undergoing AF ablation, we enrolled patients prospectively and measured post procedure patient reported outcomes (Figure 1A). Patients were eligible if they were undergoing anticipated left atrial catheter ablation in the setting of prior AF, and were anticipated to be candidates for vascular closure to achieve hemostasis. Ablation procedures are performed under uninterrupted anticoagulation with intra-procedural heparin boluses and infusion targeting an activated clotting time (ACT) of 300–400 seconds. Sheath selection was guided by the primary operator's routine vascular access for AF ablation, and all venous access were performed using the Seldinger technique, with micro-puncture needles and ultrasound guidance. All groin management was as directed by the primary operator; however, when deployed, vascular closure devices were used consistent with the manufacture's labeling and

the Vascade MVP™ device is the only device used for AF ablation at our center. The device was used for sheaths with French sizes 6 up to 12, and in patients with body mass indices 20–45 kg/m^2. Vascular accesses that were not managed with vascular closure were expected to receive manual compression hemostasis: this was typically performed in recovery, with sheaths pulled after ACT less than 200 seconds and included a 20 minute hold time. No other approaches are routinely used in our center. Patients were stratified post hoc based on whether or not any manual compression was used as the primary approach to hemostasis for any femoral vascular access, with anticipated enrollment of 25 patients who underwent complete vascular closure hemostasis and 25 patients who required a traditional manual compression approach to achieve hemostasis. Post procedure PROs were measured in these patients, and compared between patients with complete vascular closure versus patients who required any manual compression hemostasis. The primary outcomes of this analysis were post procedure PROs identical to those studied in the pivotal randomized trial;[7] namely these included measures of satisfaction with post procedure time lying supine, discomfort, and pain, graded on a scale of 0 to 10 with 10 signifying greater satisfaction (see Supplemental Material, Figure S1). Patients rated their response on the scale, and the scores averaged across cohorts for each question

Retrospective Cost Analysis Cohort—In order to assess impact of vascular closure and same-day discharge on costs of care, we developed a retrospective cohort (Figure 1B). All adults who underwent AF ablation, as defined by current procedural terminology code 93656, at the University of Utah beginning 2013 were eligible for the cost analysis. Patients in whom at least one vascular closure device was used and who were discharged the same day as the ablation were identified as cases. These cases were matched to controls who received no vascular closure devices and were discharged the next day. Patients who remained in the hospital for more than one midnight following ablation were not eligible for this analysis. As the objectives of the analysis were to ascertain differences in routine costs, we excluded the following cases: the patient was not discharged the next day; the procedure was performed by an operator who performed fewer than 10 such procedures in our data set; the procedure was performed on an inpatient basis.

Data Sources

Baseline characteristics including demographics, prior medical history, medications, prior procedures, and AF history recorded from the medical record and from administrative medical data within our health system.[8] These methods have been previously described, and are consistent with proven methods for the use of the administrative health data for research.[9,10]

Cost Data Collection—As part of an institution-wide initiative to measure value of care, the University of Utah began in 2013 to track costs of care to the health system. This initiative, labeled the Value Driven Outcomes system, has enabled institution to track costs of delivering care across the health system and including not just direct financial expensive supplies and therapeutics, but also resources such as facility time, therapist time, and professional fees. Details of this unique system have been previously described.[11] In summary, costs directly related to purchases are counted based on the contracted service

cost to the institution. Aggregate services not directly paid or billed for are approximated based on the patient's estimated use of such resources. In general, cost analyses from this program are separated into the following categories: facility (primarily labor costs outside the electrophysiology lab), imaging, implant supplies (e.g., vascular closure device), lab management, pharmacy, other supplies (e.g., diagnostic and ablation catheters), and other services (in these cases, generally, labor costs within the electrophysiology lab). In the current study, costs for the AF ablation procedure are limited to the procedural encounter, including any preoperative testing on the same day, overnight costs, and any costs associated with care prior to discharge. Any post-discharge and/or pre- or post-operative outpatient costs are not included, nor are costs for physician services. Absolute cost values were inflation-corrected using the using the monthly Consumer Price Index for All Urban Consumers healthcare inflation cost index. Due to (1) limited external validity and (2) the sensitive and competitive nature of disclosing absolute costs of care, costs reported herein are normalized and described as relative differences, as per institutional policy.

Statistical Methods

In the prospective PRO cohort, the distributions of (1) baseline demographic characteristics and (2) post-procedure PRO outcomes were summarized and compared between complete vascular device closure and manual compression hemostasis using chi-squared tests (or Fischer's exact test) for categorical variables and two-sample Student's t-test (or Wilcoxon rank-sum test) for continuous variables. For retrospective cost analysis cohort, we first matched individuals who have SDD with vascular closure to those who has next-day discharge without vascular closure using propensity score matching approach at a ratio of 1 to 4.[12] Specifically, we used a logistic regression model to estimate the propensity score, defined as the probability of being the case of SDD with vascular closure, as a function of age, gender and provider. The distributions of baseline patient characteristics were summarized and compared between cases and matched controls. We used the generalized linear regression to fit the log transformed total cost outcome and estimate the percentage difference in the average total cost between cases and matched controls.[13] Since the log transformed category-specific cost outcomes are not approximately normally distributed, we employed quantile regression approach to estimate the percentage difference in the median of those category specific costs between two groups.[14]

Data processing were performed using R (Version 3.6.3), RStudio (Version 1.2.5033), with appropriate packages. Statistical analysis was performed using R (Version 4.1.0), RStudio (Version 1.0.153). This study was approved by the University of Utah Institutional Review Board, and all patients participating in the prospective collection of PROs provided written informed consent. For patients included only in retrospective analyses of data collected as part of routine clinical care, and subsequent reporting of anonymized, aggregate data, a waiver of consent was approved by the University of Utah Institutional Review Board.

Results

Post-procedure Patient Reported Outcomes

For measurement of PROs, 50 prospective patients were enrolled from August 25, 2020 to March 12, 2021. Baseline and periprocedural characteristics for this cohort are shown in Table 1. Compared with patients who required primarily manual compression for hemostasis, patients with complete vascular closure were of similar age (mean 65.2 vs. 65.7, p=0.873), sex balance (24% female vs. 28%, p=1), and mean $CHADS_2$-VA_2Sc scores (2.6 vs. 2.8, p=0.693), with an identical number of patients having had a prior ablation (n=8 in each group). Patients with complete vascular closure, on average, had a higher average number of femoral venous sheaths per procedure (3.8 vs. 3.1, p<0.001) and smaller maximum sheath size (8.9 F vs. 9.6 F, p=0.001).

Post procedure PROs are shown in Figure 2. The use of complete vascular closure was associated with significantly higher patient satisfaction with time lying supine (8.5 vs. 6, p=0.004) and pain (8 vs. 5.1, p=0.009). Among patients with a history of a prior catheter ablation, these differences were similar in magnitude but not statistically significant. There was only 1 access-site adverse event – one patient in the vascular device closure group had re-bleeding requiring additional bedrest and no other intervention.

Procedure Costs

Among patients in the cost analysis, AF ablation procedures were performed from January 2013 to March, 2021. We identified 28 patients who underwent catheter ablation for AF and were discharged the same day following vascular closure – 7 (25%) of these patients had a body mass index >30 kg/m^2. These patients were matched (1:4) to 112 cases of patients who were discharged the next day after AF ablation without any vascular closure devices used. Overall, the cohorts were well-matched for age, sex, and $CHADS_2$-VA_2Sc scores (p=NS for each; Table 2). Prior anti-arrhythmic drug use was more common (76% vs. 39%, p<0.001) and mean body mass index was higher (32 vs. 28, p=0.03) among the matched-control patients.

In comparison of costs of care, vascular closure with SDD was associated with a 7% lower supply cost, 71% less pharmacy cost, and 88% lower facility utilization cost, at the expense of the cost of vascular closure implants (Table 3). This translated to net even healthcare system costs for the procedure between the 2 groups (mean difference 1.35%, 95% CI −2.88 – 5.77). The hypothetical trade-off between use of vascular closure device costs (depending on number used per procedure) and overnight stay costs is shown in Figure 3.

Discussion

We present the results of the first assessments of vascular closure and same-day discharge for PROs and costs associated with AF ablation in routine clinical care. There are several main conclusions from our study. First, post-procedure PROs are significantly better among patients with complete vascular closure following AF ablation, in comparison to manual compression hemostasis. These differences were consistent with those identified in a prior more closely-controlled clinical trial setting. Second, in routine clinical care, we did not

observe a numerical difference in post procedure complications or adverse events associated with complete vascular device closure. Lastly, the use of vascular closure to facilitate same-day discharge following AF ablation was not associated with increased costs in comparison to manual compression hemostasis with an overnight stay.

Our findings have important implications for cost effective and patient-centered deployment of AF ablation. While the pivotal randomized control trial suggested improved post procedure PROs,[7] our study confirms these outcomes can be achieved in routine clinical care in an academic hospital setting. The differences are significant enough that they can be detected in our modest cohort of 50 patients, and thus represent a relatively straightforward mechanism to dramatically improve patient experience. Furthermore, prior data has suggested that post procedure recovery time is one significant barrier to same-day discharge following AF ablation.[15,16]

The reduction in bedrest time associated with vascular closure can also help facilitate same-day discharge. There remains intense interest in that care pathway in order to both reduce resource utilization as well as improve patient experience. Emerging data suggests this is a safe approach for a large proportion of patients undergoing AF ablation.[16] There has also been interest in the financial impact of same-day discharge. However such cost analyses performed to date have been limited due to: (1) being conducted outside the US and in nationalized healthcare systems (e.g., the United Kingdom);[5,17] and (2) relying on generic costs of care from national entities (e.g., The Kaiser Family Foundation State Health Facts) without assessment of disease- or procedure-specific costs to the health systems providing the care.[7,15] Furthermore, the vast majority of cost analyses for such care delivery are based either on payer costs or patient out of pocket costs; few institutions track systematically the direct costs to the health system of providing each element of care, particularly aggregate services not directly paid or billed for (e.g., facility costs).

Our unique healthcare system data demonstrates that the use of vascular closure devices in order to facilitate same-day discharge from AF ablation is not associated with increased health system costs associated with the procedure. In fact, we did not detect significant overall differences in cost, and this does not account for the opportunity gain to the health system by freeing up an overnight bed, an extremely important consideration in times and locales of strained health system resources. That is, AF ablation patients are kept overnight frequently as ‘bedded outpatient’ status which is not consistently reimbursed. If instead that bed is occupied by a patient in greater need of care and under inpatient status, there is overall benefit in the form of: (a) improved access for those patients more in need of acute, inpatient care; (b) more efficient utilization of overnight beds by health system (as has been demonstrated by others); (c) additional access to other patients in need of procedures requiring overnight stay; and (d) relief of healthcare system resources if that bed is not filled, in the form of fewer personnel required (e.g., nurses).[15] In an era of limited healthcare system resources, as well as challenges in personal recruitment and retention (e.g., nursing), any opportunity for ‘unloading’ of the system is welcomed.

Limitations

This is a relatively small cohort, and there was no blinding among the prospectively-enrolled patients who provided PROs, and it is a cohort of modest size. The cost data are derived from a single center within a specific geography and therefore the absolute costs cannot be translated to other locales with differing local cost of living and contracts. This is one reason absolute costs are not provided. Instead, the proportional costs as we have analyzed them are less likely to be dramatically different for other health systems performing AF ablation – for example, disposable supplies are likely to consume a large proportion of cost related to the procedure at any institution. However, we acknowledge that the cost data, as presented, can be difficult to digest in the absence of exact dollar amounts (an institutional restriction on the use of these data).

Conclusions

In conclusion, AF ablation with vascular closure in clinical practice is associated with improved post-procedure PROs when compared to manual compression hemostasis. The use of vascular closure to facilitate same-day discharge is not associated with increased overall cost, and is associated with reductions in facility utilization and pharmacy costs at the expense of the costs of implant. Taken together, these data support the use of vascular closure and same-day discharge for AF ablation to improve both resource utilization and patient centered outcomes for this procedure.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Disclosures and Acknowledgements

Research reported in this publication was supported by Cardiva Medical. Dr. Steinberg was supported by the National Heart, Lung, And Blood Institute of the National Institutes of Health under Award Number K23HL143156. Dr. Yue Zhang and Haojia Li were supported by the University of Utah Population Health Research (PHR) Foundation, with funding in part from the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR002538. The content is solely the responsibility of the authors and does not necessarily represent the official views of the sponsor or National Institutes of Health.

The following relationships exist related to this presentation: BAS reports research support from AltaThera, Cardiva, Abbott, Sanofi, and Janssen; and consulting to AltaThera; TJB receives grants from Boston Scientific, AltaThera, and Boehringer Ingelheim; the remaining authors do not report any relevant disclosures.

Abbreviations

AF	atrial fibrillation
PROs	patient reported outcomes
wRVUs	work relative value units
SDD	same-day discharge

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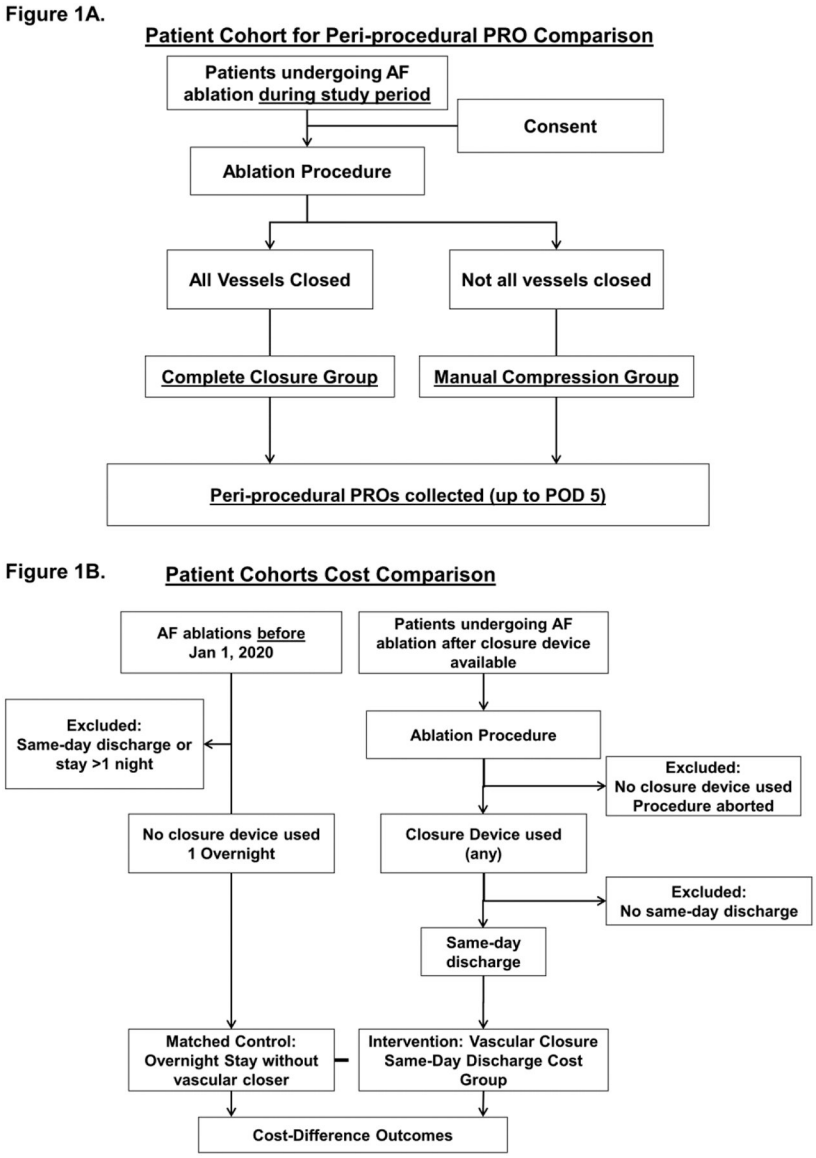

Figure 1.

Schematic of analytic cohorts for the current study, including prospective assessment of post-procedure patient reported outcomes (PROs, Panel A) and matched cohort to compare costs (Panel B). These cohorts were not necessarily mutually exclusive.

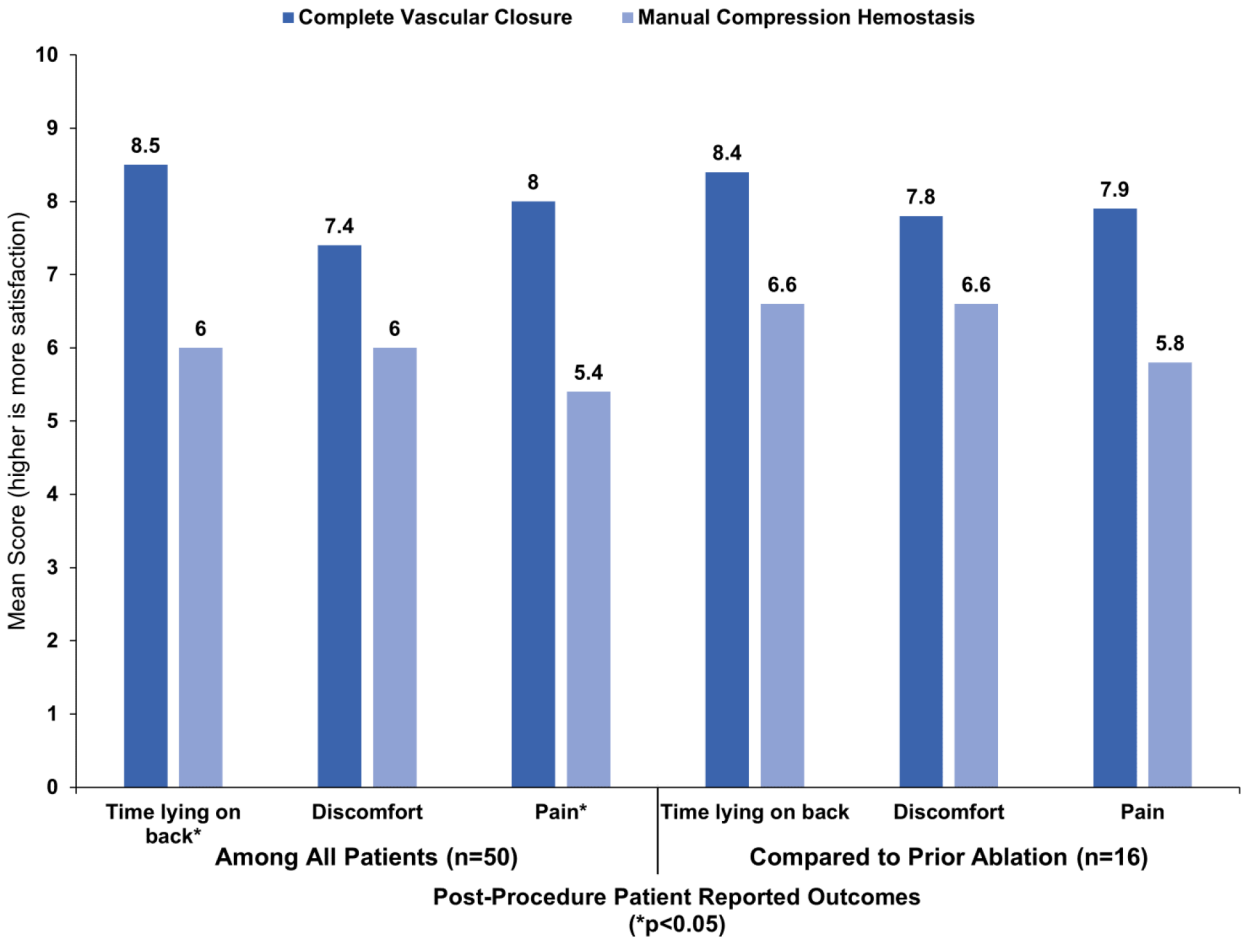

Figure 2.

Post-procedure patient reported outcomes (PROs) for patients undergoing ablation for atrial fibrillation (AF) with complete vascular device closure for hemostasis compared with those receiving manual compression hemostasis.

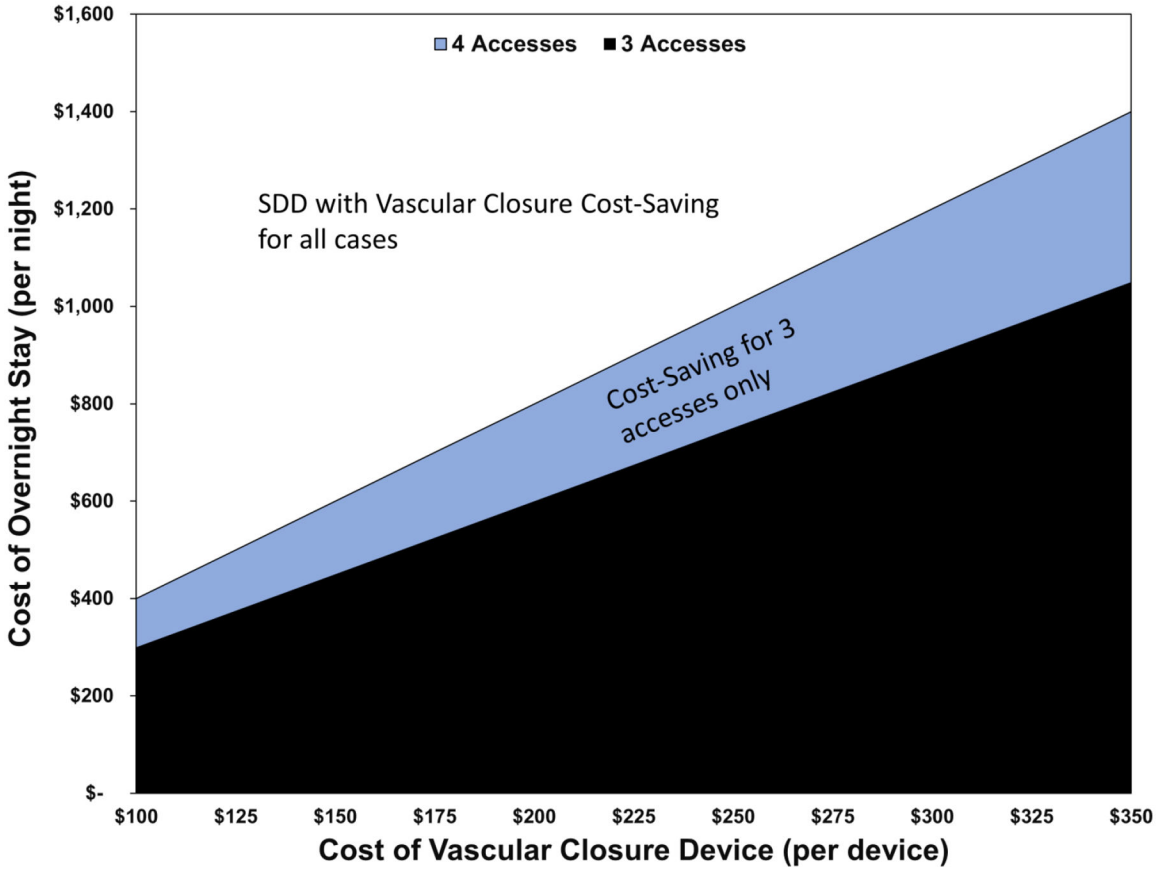

Figure 3.

The hypothetical trade-off between use of vascular closure device costs (depending on number of accesses used per procedure) and overnight stay costs. The data in this figure are hypothetical and unrelated to any real-life scenario at ours or any other institution, provided for demonstration only. They were calculated by simply taking the cumulative, hypothetical costs of all devices implanted (3x or 4x the x-axis value)and comparing those to the hypothetical cost of an overnight stay (y-axis values). For example, if the cost of a closure device is hypothetically $250 per device for a given institution, and 4 devices are used per procedure, vascular closure with same-day discharge becomes a cost saving proposition for the institution if an overnight stay costs $1,000 or more to provide. This does not account for any potential change to *payments* that may result from the different scenarios.

Table 1.

Baseline characteristics of the patient-reported outcomes comparison cohort.

	Complete Vascular Closure (n=25)	Manual Compression Hemostasis (n=25)	p
Age, years	65.16 (12.10)	65.68 (10.75)	0.873
Female Sex	6 (24.0)	7 (28.0)	1.000
Hypertension	11 (44.0)	8 (32.0)	0.560
Diabetes mellitus	4 (16.0)	8 (32.0)	0.321
Sleep apnea	10 (40.0)	12 (48.0)	0.776
Chronic kidney disease	5 (20.0)	5 (20.0)	1.000
Congestive heart failure	8 (32.0)	11 (44.0)	0.560
Coronary artery disease	12 (48.0)	13 (52.0)	1.000
Prior MI	8 (32.0)	8 (32.0)	1.000
Peripheral arterial disease	7 (28.0)	4 (16.0)	0.495
Prior stroke or TIA	3 (12.0)	3 (12.0)	1.000
Prior catheter ablation (any)	8(32%)	8(32%)	>0.99
$CHADS_2$-VA_2Sc score	2.60 (1.89)	2.80 (1.66)	0.693
Body mass index (kg/m^2)	30.75 (6.48)	30.17 (5.55)	0.736
Left-ventricular ejection fraction	54.22 (7.38)	57.36 (12.10)	0.505
Relevant medications prior to ablation			
Non-steroidal anti-inflammatory drugs	4(16%)	3(12%)	>0.99
Aspirin	0(0%)	1(4%)	>0.99
Clopidogrel	2 (8%)	2 (8%)	>0.99
Anticoagulation			0.316
Warfarin	3 (12%)	4 (16%)	
Dabigatran	0 (0%)	1 (4%)	
Rivaroxaban	4 (16%)	7 (28%)	
Apixaban	18 (72%)	12 (48%)	
None	0 (0%)	1 (4%)	
Procedural Characteristics			
Procedure duration, minutes	170.3 (46.9)	229.8 (77.9)	**<0.001**
Femoral Venous Access			
Number of sheaths	3.8 (0.4)	3.1 (1.1)	**<0.001**
Minimum sheath size (Fr)	7.1 (0.6)	7.4 (1.1)	0.15
Maximum sheath size (Fr)	8.9 (0.5)	9.6 (0.9)	**0.001**
No. attempted vascular closures *	3.8 (0.4)	0.2 (0.6)	**<0.001**
No. successful vascular closures *	3.8 (0.4)	0.1 (0.4)	**<0.001**
Ablation Lesion Set			
Pulmonary vein isolation	22(88%)	25(100%)	0.235
LA roof line	6(24%)	5(20%)	>0.99
LA floor line	3(12%)	2(8%)	>0.99
Other posterior wall	0(0%)	0(0%)	-

	Complete Vascular Closure (n=25)	Manual Compression Hemostasis (n=25)	p
Mitral annular	4(16%)	5(20%)	>0.99
LAA	0(0%)	0(0%)	-
Other LA	5(20%)	0(0%)	0.05
CTI	7(28%)	6(24%)	>0.99
SVC	0(0%)	1(4%)	>0.99
Other RA	0(0%)	1(4%)	>0.99
Anticipated bedrest, hours	2.4 (0.8)	4.4 (0.9)	**<0.001**
Actual bedrest, hours	2.6 (1.1)	5 (1.2)	**<0.001**
Same-day discharge	19(76%)	2(8.3%)	**<0.001**

Values presented as number (%) or mean (standard deviation) unless noted otherwise.

* Two patients were initially planned to undergo complete vascular device closure were subsequently converted to manual compression in the electrophysiology lab.

Table 2.

Baseline characteristics of the matched cost outcomes cohort.

	SDD with Vascular Closure Cases (n=28)	Matched cohort - Next-day discharge without vascular closure (n=112)	p
Age, years	66.2 (10.4)	64.6 (10.9)	0.698
Female sex	9(32.1%)	41(36.6%)	0.826
Past Medical History			
Hypertension	9(32.1%)	55(49.1%)	0.138
Diabetes mellitus	3(10.7%)	32(28.6%)	0.055
Sleep apnea	12(42.9%)	43(38.4%)	0.671
Chronic kidney disease	3(10.7%)	17(15.2%)	0.764
Peripheral arterial disease	6(21.4%)	32(28.6%)	0.635
Coronary artery disease	11(39.3%)	51(45.5%)	0.672
Congestive heart failure	6(21.4%)	39(34.8%)	0.258
Prior stroke/TIA	1(3.6%)	6(5.4%)	>0.99
$CHADS_2$-VA_2Sc score, mean	2.2 (1.5)	2.8 (1.9)	0.167
Any prior antiarrhythmic drug	22(78.6%)	91(81.2%)	0.79
Prior catheter ablation for AF	0(0%)	18(16.1%)	**0.024**
Prior cardioversion	8(28.6%)	51(45.5%)	0.135
BMI, (kg/m^2)	27.8 (4.3)	32.2 (6.9)	**<0.001**
Creatinine	1 (0.2)	1.1 (0.4)	0.307

Values presented as number (%) or mean (standard deviation) unless noted otherwise.

Table 3.

Cost differences associated same-day discharge and vascular closure following AF ablation, compared with next-day discharge without vascular closure.

	Cost Difference* (%)	Lower Bound (2.5%)	Upper Bound (97.5%)
Total cost	1.10	−3.03	5.42
Supply cost	−7.14	−11.13	−4.22
Pharmacy cost	−70.69	−87.14	−20.82
Other services	0.1	−7.11	13.19
Facility utilization	−89.1	−91.77	−83.29
Implant supplies	447.62	367.54	495.82

Cost differences between same-day discharge with vascular closure compared with next-day discharge without any vascular closure device, expressed as percentage of costs within the category. Negative values indicate lower relative cost for same-day discharge, positive values indicate higher cost for same-day discharge.