

Same-Day Discharge after Cryoballoon Ablation of Atrial Fibrillation: A Multicenter Experience

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Abstract

Background: It is common practice to observe patients during an overnight stay (ONS) following a catheter ablation procedure for the treatment of atrial fibrillation (AF). Objectives: To investigate the safety and economic impact of a same day discharge (SDD) protocol after cryoballoon ablation for treatment of AF in high-volume, geographically diverse US hospitals. Methods: We retrospectively reviewed 2,374 consecutive patients (1,119 SDD and 1,180 ONS) who underwent cryoballoon ablation for AF at three US centers. Baseline characteristics and longer-term safety were recorded during follow-up. The mean cost of an ONS was used to evaluate yearly cost savings as a function of the percentage of SDD cases/year. Results: There was no difference between SDD and ONS in the 30 day total complication rate [n=15 (1.26%) versus n=24 (2.03%); p=0.136 respectively]. The most common complication was hematoma in both the SDD (n=8; 0.67%) and ONS (n=11; 0.93%) cohorts. Sensitivity analysis demonstrated that when 50% of every 100 patients treated were discharged the same day, hospital cost savings ranged from \$45,825 to \$83,813 per year across US hospitals. Conclusions: SDD following cryoballoon ablation for AF appears to be safe and is associated with cost savings across different US hospitals.

Introduction

Catheter ablation is an effective, minimally invasive therapy for patients with symptomatic drug-refractory atrial fibrillation (AF), and pulmonary vein isolation by cryoballoon ablation is an established treatment option.¹ The risks associated with catheter ablation for the treatment of AF are generally low; however, patients are typically observed overnight following the ablation procedure to monitor for complications that may manifest within the first 24-hours post-procedure (*e.g.* , access site complication, pericardial effusion and cardiac tamponade).¹

Same-day discharge (SDD) protocols have been used effectively in other cardiac interventions,^{2, 3} and recently SDD protocols have been evaluated for catheter ablation of patients with AF using both radiofrequency and cryoballoon catheters.^{4, 5}

In the present study, a multicenter retrospective chart-review analysis was utilized to evaluate safety and efficacy of SDD following a cryoballoon ablation for AF across three high volume and geographically diverse

centers within the US in a large group of patients. The economic impact of a SDD protocol was also evaluated and compared between the centers.

Methods

Study Design and Patient Population

The main objective of this multicenter retrospective observational study was to describe the safety outcomes following a cryoballoon ablation of AF in a SDD cohort compared to patients discharged via a standard-of-care route that encompassed an overnight hospitalization (ONS) for patient observation. At each hospital, the SDD cohort was comprised of consecutive patients discharged the same day as their cryoballoon ablation, and the ONS cohort was a pair-matched collection of patients at these centers (matching based on gender, age, BMI, and AF classification). The study was completed at three different US centers (Staten Island University Hospital a Northwell Health Hospital, Staten Island, NY; Mercy General Hospital/Dignity Health Heart and Vascular Institute, Sacramento, CA; and Spectrum Health Medical Center, Grand Rapids, MI) from January 2014 to March 2019. Subject inclusion criteria included any patient undergoing a cryoballoon ablation of atrial fibrillation at the three hospitals and willingness to complete in-office follow-up examinations. Patients who had a complication during the procedure were excluded from the analysis, as the decision to discharge home the same day was made by the operator after the procedure and was then based on clinical standards-of-care at each hospital with most patients not eligible for SDD. Institutional review board approval was granted at each hospital, and all patients gave informed consent for the data collection and the catheter ablation procedure. This project and the data collection activities conformed with the principles outlined in the Declaration of Helsinki. Data warehousing was hosted by the Staten Island University Hospital using REDCap (project-redcap.org). A subject-key system was used to de-identify patients which was not shared between hospitals in order to maintain the privacy of protected health information.

Cryoballoon Ablation Procedure

The general description of a cryoballoon ablation procedure has been previously published^{6, 7} and each center utilized their own standard-of-care practices during the cryoballoon ablation procedure. Transesophageal echocardiogram was performed prior to each procedure.

Venous access was obtained bilaterally with ultrasound guidance. Number of access sites were determined by the operator but on average, patients had two catheters on each side. In brief, patients were treated under general anesthesia or conscious sedation. A transeptal needle puncture for left atrial access was immediately followed by a heparin bolus delivery. Activated clotting time was monitored (every 15-20 minutes) throughout the procedure and was targeted to [?] 300 seconds. A purpose-built delivery sheath (FlexCath; Medtronic, Inc, Minneapolis, MN) was used to advance the cryoballoon (23- or 28-mm Arctic Front Advance; Medtronic, Inc) and the Achieve mapping catheter (Medtronic, Inc) into the left atrium. Pulmonary vein occlusion with cryoballoon was assessed by retrograde contrast agent retention under fluoroscopy imaging and/or intracardiac echocardiography under Doppler imaging and pressure wave-form monitoring.^{6, 7} The number of freeze applications and duration of freezes were determined by the center's standard-of-care and individual physician preferences; however, in general, the three centers practiced a freeze dosing methodology that utilized acute time-to-isolation monitoring to adjust cryoballoon freezing durations and overall number of freeze applications.^{7, 8} Testing for bidirectional block was utilized at each pulmonary vein to establish acute pulmonary vein isolation. At the end of the procedure, intracardiac echocardiogram or transthoracic echocardiogram was performed to exclude pericardial effusion, a protamine delivery was administered when a reversal of heparin was desired, and groin sheaths were pulled with compression on the femoral vein puncture site or insertion of a figure-8 stich. Figure-8 stich was removed 4 hours after the end of the case and patient was ambulated prior to discharge. No closure devices were used in any patient. Antiarrhythmic drugs were utilized within the 90-day blanking period at the discretion of the treating physician.

Same Day Discharge Versus Overnight Stay

At the end of each procedure, patients were observed in a bed-side waiting room setting (*e.g.* , critical

care unit or intensive care unit). The operator made the decision for SDD immediately after the procedure but patient's discharged status could be changed during recovery. All patients were observed for acute indications of pericardial effusion or cardiac tamponade; if either complication was suspected, a chest x-ray or transthoracic echocardiogram was utilized to triage the patient. The occurrence of either event nullified the potential for SDD consideration. Each hospital utilized an individualized checklist of criteria that were mandatory before a patient was considered for SDD (**Table 1**), and importantly, each patient had to agree to a SDD preference with adequate arrangements for "secure-to-home" transportation. At each hospital, the nursing staff and treating physician provided detailed instructions on next-day care to all patients with a SDD. If SDD was used, the patient was discharged from the hospital within 6-hours of the procedure and before an overnight stay was recorded. Patients in the overnight cohort were discharged via normal and typical next-day standard-of-care policies, which included a review of patient status during the observational period. Similarly, each hospital used an individualized checklist of next-day discharge requirements, and these criteria are also provided for each hospital (**Table 1**). Each procedure was performed on uninterrupted anticoagulation and patients maintained anticoagulation therapy for a minimum of 60 days after the index ablation.

Data Collection, Follow-up, and Reporting

Demographic, procedural, and follow-up data were obtained from electronic medical records. All procedure-related adverse events were collected and reported throughout the individual patient's follow-up period of 30 days. Average procedure costs and costs associated with an overnight stay were collected for each center.

Statistical Analysis

Baseline characteristics and clinical data have been summarized using the appropriate summary statistics. Variables on a continuous scale were described as mean, standard deviation, median, and interquartile range. Variables on a categorical scale were presented as count and percentage. All percentages have been presented on the number of data points recorded. The complications were reported as rates amongst the cohort. Continuous variables were analyzed using the 2-sample *t*-test or Mann-Whitney test for parametric and nonparametric variables, respectively. The Chi-square or Fisher exact test was used for categorical variables. To allow an unbiased comparison between SDD and ONS, a propensity score analysis was employed. The derived propensity scores with separate multivariable models (including age, sex, CHA₂DS₂-VASc score, hypertension, and BMI) were calculated when $p < 0.10$ was achieved in the univariate analysis. Propensity scores were then matched with a caliper range of ± 0.1 to obtain matched pairs of patients. The propensity score-based greedy matching algorithm successfully matched all patients who were sent home on the same day with patients who stayed overnight. XLSTAT 19.4 (Addinsoft, New York, NY) was used to perform statistical analyses. Statistical tests were based on a 2-sided significance level of 0.05.

Results

Baseline Characteristics

A total of 2,374 patients underwent cryoballoon ablation for the treatment of AF during the study period. Of this total, 1,194 patients followed a SDD protocol and 1,180 patients were observed during an ONS. Patient demographics of each group are presented in **Table 2**. The SDD cohort was significantly younger (64 ± 11 versus 66 ± 10 ; $p < 0.0001$), had lower BMI (30 ± 6 versus 31 ± 6 ; $p < 0.0001$) and CHA₂DS₂-VASc scores (1.4 ± 1.0 versus 2.2 ± 1.4 ; $p < 0.0002$), and had less chronic heart failure (10% versus 16%; $p < 0.0001$) than the ONS cohort. There was no difference in sex (69% versus 67% male; $p = 0.3$), diabetes (18% versus 21%; $p = 0.2$) or history of transient ischemic attack (5% versus 6%; $p = 0.4$) between SDD and ONS, respectively.

Procedural Safety

There was no significant difference in the number of observed complications between the SDD and ONS cohorts within 30 days after hospital discharge following the cryoballoon ablation (**Table 3**). Patients who followed a SDD protocol suffered a total of 15 (1.26%) complications while patients who were observed during an ONS had a total of 24 (2.03%) complications observed during the 30 day follow-up ($p = 0.13$) (**Figure 1**).

Hematoma within the immediate post-op period was the most common complication in both groups, which accounted for almost half of the complications in both the SDD and ONS cohorts (0.67% versus 0.93%, respectively). None of the complications in the SDD group occurred during the first 24 hours after discharge from the hospital; therefore, these events would not have been prevented by monitoring during an overnight hospital stay.

Economic Impact of SDD

Total hospital costs associated with cryoballoon ablation include both the procedure cost and the cost associated with the duration of hospital stay. Since the procedure costs were similar for the SDD and ONS groups, the expense associated with an overnight hospital stay determined the total cost difference to the hospital between SDD and ONS cohorts. The hospital cost savings for each patient who followed a SDD protocol was \$917, \$1,437, \$1,676 for the East Coast, Midwest, and West Coast hospitals, respectively. The one-way economic sensitivity model predicted yearly hospital cost savings as a percentage of SDD patients to every 100 cryoballoon ablation cases/year (**Table 4**). The greatest annual hospital savings were found in the West Coast hospital with savings of \$8,381 when 5% of every 100 treated patients followed a SDD protocol to \$83,813 in savings when 50% of every 100 treated patients were discharged the same day. The annual savings for the Midwest hospital ranged between \$7,185 and \$71,850 when 5% to 50% of patients followed a SDD protocol, and from \$4,583 to \$45,825 when 5% to 50% of cryoballoon ablation patients were discharged the same day as the procedure in the East Coast hospital. The higher the percentage of patients discharged home on the same day the greater the saving for all three hospitals evaluated (**Figure 2**). Although difficult to quantify, a SDD protocol frees a bed for an additional admission. The value of this would depend on the overall hospital census and the type of admission.

Discussion

The principal finding of this study is that a SDD strategy after an uncomplicated elective cryoballoon ablation for AF is safe and effective. The patient selection and triage for SDD was different at the three geographically diverse centers, supporting the notion that this strategy is generally safe across a wide variety of physician user habitats and hospital discharge policies. Importantly, none of the complications in the SDD cohort occurred less than 24 hours from the time of discharge; therefore, complications observed in the SDD cohort would not have been identified had the patients been observed during an overnight stay. Additionally, there may be some positive impact on local healthcare economics. Specifically, our study found that the SDD of a patient following a cryoballoon ablation for treatment of AF is associated with cost savings to the hospital that increase with the percent of patients discharged the same day.

Patient Selection for a SDD Protocol

Differences in the baseline characteristics of SDD patients versus ONS patients were observed; SDD patients were younger and tended to have fewer comorbidities than the ONS cohort. One possible reason for these differences is the operator likely selected younger patients with fewer comorbidities and lower CHA₂DS₂-VASc score for SDD. Each facilities SDD protocol was structured to exclude higher risk patients in whom there is a higher propensity for complication. Further, patients were only eligible for SDD if they had an uncomplicated cryoballoon ablation procedure. Overall, patient selection for SDD at the three geographically diverse hospitals relied upon similar criteria, with some key differences. Specifically, similar criteria for systolic blood pressure, heart rate, oxygen saturation, and mental status existed at each site. Residential location requirements varied by center. No specification for a patient's residential location existed for patients treated at the West Coast hospital, while patients were required to live [?]30 min or <75 miles from the East Coast and Midwest hospitals, respectively. Similar ambulatory and hemodynamic requirements for SDD eligibility following cryoballoon ablation existed at the hospitals.

Two previous studies evaluated the safety and feasibility of same day discharge for patients who underwent AF ablation. Both studies were single center with a small number of patients. Haegeli *et al.* included 230 patients who underwent radiofrequency ablation and reported no late peripheral or cerebral thromboembolic events.⁹ Bartoletti, *et al.* reported a single center study that included 169 patients who underwent cryoballoon

and radiofrequency AF ablation and were discharged home the same day.¹⁰ The study compared SDD cohort to 642 patients who stayed overnight and found no difference in complication rates.¹⁰ The SDD cohort in this study was compared to historical controls who were monitored overnight following cryoballoon ablation procedure. A better understanding of patient criteria is essential for defining candidates for SDD and standardization of procedural adaptations implemented to enable earlier discharge may improve how SSD can be safely performed across a large group of patients. For example screening and scheduling candidates for SDD as an earlier case in the day is a simple policy step that would allow a SDD strategy succeed.

Safety of SDD following Cryoballoon Ablation

SDD has been previously evaluated in other sections of cardiology and demonstrated cost benefits.² Importantly, in any SDD procedure, the rate of intraprocedural and post-procedural complications must remain low for patient safety and economic benefit(s). In this analysis, the complication rate in SDD and ONS cohorts was not different from each other and comparable to previous reports. A systematic review of 192 studies by Gupta *et al* . determined the overall incidence of complications associated with catheter ablation of AF was 2.9%,¹¹ which is similar to the rate of patients who stayed overnight in this analysis. The systematic review did not mention the method of discharge in the literature search; however, given the fact that it included all studies prior to 2012, it is likely that most of these patients were kept overnight.¹¹ A worldwide survey on safety of AF ablation agnostic of ablation modality collected from 182 centers reported a slightly higher complication rate of 4.5%.¹² The reasons for higher rate in the global survey may include that it incorporated earlier catheter technology and techniques and centers with a wide range of volume and experience. By contrast, this study included patients from three high volume centers with experienced operators. The overall complication rate in the SDD group was numerically lower than the ONS group. This might be explained by a selection bias by the operator. As represented in the baseline characteristics, the operators most likely chose younger and healthier patients to be discharged the same day while patients with more comorbidities were observed overnight following the cryoballoon ablation.

Hematoma or vascular complication were the most common complication observed in our study, consistent with other reports.^{1, 11, 12} The rate of hematoma has been reported between 1.2-1.4%; however, the rate of hematoma in our study was slightly lower at 0.67-0.93%. Ultrasound guidance to obtain vascular access may have contributed to the low rate of vascular complications in our trial.¹³ The risk of stroke in previous studies has been reported between 0.23-0.30%, which is slightly higher than observed in our study.^{11, 12} Uninterrupted anticoagulation with warfarin or DOAC facilitated early ambulation on continued anticoagulation, which may have contributed to a low risk of stroke complications. Most pericardial effusion and tamponade events generally occur during the procedure or are observed immediately after the procedure.¹ In our study, all transseptal punctures were performed under intracardiac echocardiographic guidance. The presence or absence of pericardial effusion was examined via imaging (*e.g.* fluoroscopy and ultrasound) both during the case and after the catheter ablation procedure. Furthermore, due to serious consequences of these complications, some of the participating centers performed a transthoracic echocardiogram before discharge. These additional precautions may safeguard against undetected pericardial complications in the SDD population.

Economic Impact of SDD

The one-way economic sensitivity analysis demonstrated potential cost savings for each hospital, which increased as more patients were discharged home the same day. Procedural costs (*e.g.* lab time, lab staff, equipment cost) are the same for SDD and ONS groups; therefore, the difference in hospital costs between the groups was dependent on utilization of hospital resources post ablation. Patients observed overnight increased the hospital costs independent of the procedure. Since the West Coast hospital had the highest inpatient costs, they would benefit the most from SDD. Discharging patients the same day may also improve hospital throughput via increased availability of cardiac telemetry beds that could be occupied by additional patients. SDD protocols may also contribute to increased hospital capacity. From a patient's perspective, outpatient procedures contribute to early ambulation, increased patient comfort, and early return to work, which may also improve patient satisfaction.

Clinical Implications

Catheter ablation has emerged as an important tool for the management of AF, and the number of AF ablation procedures continues to rise, while complication rates are steadily decreasing.¹ To date, there is no recommendation regarding discharge time after a catheter ablation.¹ Hence, the majority of centers admit patient for at least an overnight stay. This practice has obvious cost implications. A SDD strategy can alleviate some of the financial strain on healthcare systems, which is of extreme importance in the current climate. The recent COVID-19 pandemic reminds us that patient choice, hospital economics, and hospital resource would support a SDD approach. As the world-wide hospital systems recover, options like SDD should be considered for the physical/mental health of our patients and the strength of our healthcare system. Ultimately, SDD could improve the patient experience and reduce healthcare cost burdens on hospital resources that are already strained to meet the needs of the growing AF patient population.^{1, 14}

Limitations

Before considering the broad applicability of the results of our study, certain important limitations should be noted. These include: the retrospective non-randomized nature of the study; the study was performed at high-volume ablation centers; and the possibility that there was under-reporting of minor self-limiting complications such as small groin hematoma in the SDD group. Follow-up transthoracic echocardiogram which may missed asymptomatic pericardial effusions were not performed. The study was solely based on cryoballoon ablation techniques for AF and may not be applicable to other modalities of ablation. Lastly, the selection of patients deemed appropriate to be discharged by the operators was based on their skills, comfort level, and hospital-specific discharge standards, therefore these results should be cautiously generalized.

Conclusions

Same day discharge after an uncomplicated cryoballoon ablation for AF in carefully selected patients appears to be safe. This strategy has obvious benefits to both the patients and healthcare providers. The implications of SDD on financial benefits, throughput, and resource utilization may be of great importance in our current clinical climate.

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Figure Legends

Figure 1. The event specific 30-day complication rates for patients either discharged the same day (SDD in blue) or observed during an overnight hospital stay (ONS in orange) following cryoballoon ablation for the treatment of atrial fibrillation are displayed. The ONS and SDD cohorts had similar event specific and overall 30-day complication rates ($p=0.136$).

Abbreviations: CHF=chronic heart failure; PNP=phrenic nerve palsy; and TIA=transient ischemic attack.

Figure 2. One-way sensitivity analysis of yearly cost savings per 100 cryoballoon ablation procedures as a function of percent of SDD per year is depicted for the East Coast (blue), West Coast (orange) and Midwest (grey) hospitals. As the percent of every 100 patients to undergo cryoballoon ablation for the treatment of AF who are discharged the same day as the procedure increased the hospital cost savings also increased.

Table 1. List of patient eligibility criteria for SDD at each hospital/region.

East Coast (Staten Island University Hospital, Northwell Health System, Staten Island, NY)	West Coast (Mercy General Hospital, Dignity Health Heart and Vascular Institute, Sacramento, CA)	Midwest (Spectrum Health Medical, Grand Rapids, MI)
Monitor for 6 hours after procedure Systolic BP >100; HR <100	Monitor for 6 hours after procedure Systolic BP >90 (or asymptomatic if lower); HR <100	Monitor for 6 hours after procedure Systolic BP>90; HR<100
O ₂ Saturation >95% on room air Normal mental status Residence <30 min from hospital Ambulatory status unchanged from baseline	O ₂ Saturation >90% on room air Normal mental status No specific criteria used Ambulatory status unchanged from baseline	O ₂ Saturation >95% on room air Normal mental status Residence <75 miles from hospital Ambulatory status unchanged from baseline, off bedrest >60 min, ambulating by 20:00
Echocardiogram to evaluate for pericardial effusion prior to discharge	Pericardial effusion ruled out at the end of procedure by intracardiac echocardiography	Absence of hemodynamic instability; echocardiogram only performed in patients with unstable vitals or chest pain refractory to medical therapy
Follow-up appointment with cardiac electrophysiologist within 4 weeks. A phone call to patient the next day by a staff.	Follow-up appointment with cardiac electrophysiologist in 6 weeks	Follow-up with cardiac electrophysiologist in 3 months

Abbreviations: BP=blood pressure and HR=heart rate.

Table 2. Demographics of SSD versus ONS patients.

	SDD (n=1,194)	ONS (n=1,180)	p-value
Age, mean±SD	64±11 years	66 ±10 years	< 0.0001
BMI, mean±SD	30±6	31±6	< 0.0001
Baseline LVEF, mean±SD	56±9 %	55±10 %	< 0.0001
CHA ₂ DS ₂ -VAsC Score, mean±SD	1.4±1.0	2.2±1.4	< 0.0002
Male, n (%)	825 (69%)	793 (67%)	0.322
Hypertension, n (%)	757 (72%)	855 (72%)	< 0.0001
Diabetes, n (%)	226 (18%)	246 (21%)	0.241
Hyperlipidemia, n (%)	610 (51%)	555 (47%)	0.048
OSA, n (%)	306 (25%)	314 (27%)	0.586
Cardiac Device, n (%)	146 (12%)	176 (15%)	0.056
History of MI, n (%)	81 (7%)	67 (6%)	0.265
PCI, n (%)	108 (9%)	154 (13%)	0.002
History of CHF, n (%)	119 (10%)	191 (16%)	< 0.0001
History of COPD, n (%)	176 (14%)	222 (19%)	0.008
History of CVA or TIA, n (%)	56 (5%)	65 (6%)	0.365
Age >75, n (%)	200 (17%)	240 (20%)	0.024
BB, n (%)	723 (61%)	457 (38%)	0.002
CCB, n (%)	481 (40%)	578 (48%)	< 0.0001
Digoxin, n (%)	41 (3%)	98 (8%)	< 0.0001
ASA, n (%)	353 (30%)	355 (30%)	0.782
Plavix, n (%)	43 (3%)	201 (17%)	< 0.0001

Abbreviations: ASA=Aspirin; BB=beta-blocker; BMI=body mass index; CCB=calcium channel blocker; CHF= chronic heart failure; COPD=chronic obstructive pulmonary disease; CVA=cerebrovascular accident; LVEF=left ventricular ejection fraction; MI=myocardial infarct; OSA=obstructive sleep apnea; PCI=percutaneous coronary intervention; and TIA=transient ischemic attack.

Table 3 . Individual complications in SDD and ONS cohorts.

Complications	SDD (n=1,194)	ONS (n=1,180)	p value
Hematomas	8 (0.7%)	11 (0.9%)	0.46
PNP, n (%)	0 (0%)	6 (0.5%)	0.01
TIA, n (%)	3 (0.3%)	2 (0.2%)	0.66
CHF, n (%)	0 (0%)	1 (0.1%)	0.31
Pericardial effusion, n (%)	0 (0%)	3 (0.3%)	0.08
Pericarditis, n (%)	3 (0.3%)	1 (0.3%)	0.32
Death, n (%)	0 (0%)	0 (0%)	NA
Other, n (%)	1 (0.1%)	0 (0%)	0.32
Total, n (%)	15 (1.3%)	24 (2.0%)	0.13

Abbreviations: CHF=chronic heart failure; PNP=phrenic nerve palsy; and TIA=transient ischemic attack.

Table 4. Annual cost saving by hospital per percent of every 100 patients who followed a SDD protocol.

% SDD / 100 Patients	East Coast Yearly Cost Savings	West Coast Yearly Cost Savings	Midwest Yearly Cost Savings
5%	\$4,582.50	\$8,381.25	\$7,185.00
10%	\$9,165.00	\$16,762.50	\$14,370.00
15%	\$13,747.50	\$25,143.75	\$21,555.00
20%	\$18,330.00	\$33,525.00	\$28,740.00
25%	\$22,912.50	\$41,906.25	\$35,925.00
30%	\$27,495.00	\$50,287.50	\$43,110.00
35%	\$32,077.50	\$58,668.75	\$50,295.00
40%	\$36,660.00	\$67,050.00	\$57,480.00
45%	\$41,242.50	\$75,431.25	\$64,665.00
50%	\$45,825.00	\$83,812.50	\$71,850.00

Figure 1. Complication rates in ONS and SDD cohorts.

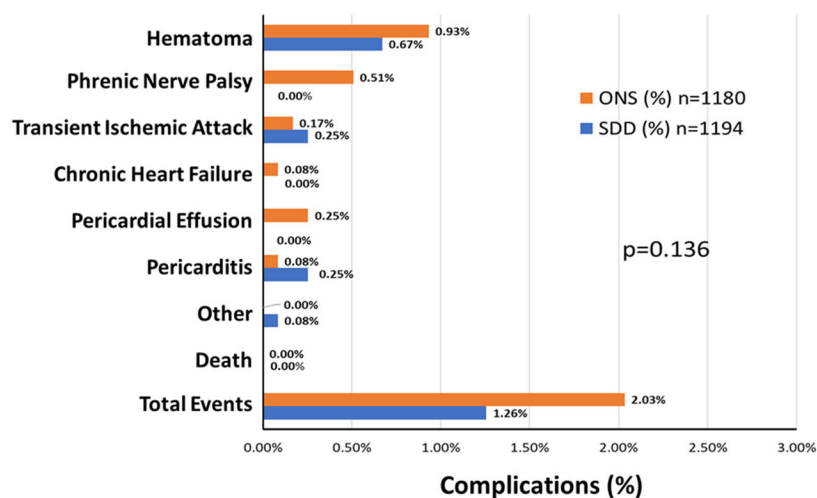


Figure 2 . Annual hospital cost savings as a function of percent of SDD patients.

