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Feasibility and performance of catheter ablation with zero-fluoroscopy approach for regular supraventricular tachycardia in patients with structural and/or congenital heart disease

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Abstract

Patients with structural heart disease (SHD) are more difficult to ablate than those with a structurally healthy heart. The reason may be technical problems. We compared periprocedural data in unselected patients (including SHD group) recruited for zero-fluoroscopy catheter ablation (ZF-CA) of supraventricular arrhythmias (SVTs).

Consecutive adult patients with atrioventricular nodal reentry tachycardia (AVNRT), accessory pathways (AP), atrial flutter (AFL), and atrial tachycardia (AT) were recruited. A 3-dimensional electroanatomical mapping system (Ensite Velocity, NavX, St Jude Medical, Lake Bluff, Illinois) was used to create electroanatomical maps and navigate catheters. Fluoroscopy was used on the decision of the first operator after 5 minutes of unresolved problems.

Of the 1280 patients ablated with the intention to be treated with ZF approach, 174 (13.6%) patients with SHD (age: 58.2 ± 13.6; AVNRT: 23.9%; AP: 8.5%; AFL: 61.4%; and AT: 6.2%) were recruited. These patients were compared with the 1106 patients with nonstructural heart disease (NSHD) (age: 51.4 ± 16.4; AVNRT: 58.0%; AP: 17.6%; AFL: 20.7%; and AT: 3.7% $P \leq .001$). Procedural time (49.9 ± 24.6 vs 49.1 ± 23.9 minutes, $P = .55$) and number of applications were similar between groups ($P = 0.08$). The rate of conversion from ZF-CA to fluoroscopy was slightly higher in SHD as compared to NSHD (13.2% vs 7.8%, $P = .02$) while the total time of fluoroscopy and radiation doses were comparable in the group of SHD and NSHD ($P = .55$; $P = .48$).

ZF-CA is feasible and safe in majority of patients with SHD and should be incorporated into a standard approach for SHD; however, the procedure requires sufficient experience.

Abbreviations: AFL = atrial flutter, AVNRT = atrioventricular nodal reentry tachycardia, CS = coronary sinus, EPS = electrophisiology study, GUCH = grown-up congenital disease, NSHD = nonstructural heart defects or disease, SHD = structural heart defects or diseases, SVT = supraventricular arrhythmia, ZF-CA = zero-fluoroscopy catheter ablation.

Keywords: adult congenital heart disease, radiation exposure, radiofrequency catheter ablation, structural heart disease, supraventricular tachyarrhythmia

1. Introduction

Significant progress has been made in percutaneous catheter ablation (CA) for supraventricular arrhythmias (SVTs) over the last 3 decades, with significant reductions in complications and improvements in efficacy.[1–5] However, the use of fluoroscopy for catheter navigation and monitoring during most interventional cardiovascular procedures and CAs exposes patients and medical staff to potentially dangerous, cumulative doses of ionizing radiation.[6–13]

Although several techniques, approaches, and regulations have been recommended for limiting radiation exposure, the medical staff is working with a substantial risk of irradiation associated

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with cumulative exposure.[5–8] Reducing or eliminating exposure is highly recommended for patients in several cases, such as pregnancy, young age, cancer, skin disorders, and obesity, and for those undergoing repetitive procedures especially for cardiac, cardiothoracic, or vertebral columns anomalies.[9–11]

Considerable development has been made given that 3D-electroanatomical mapping (3D-EAM) systems have been implemented that precisely enable the creation of a 3D cardiac anatomy and the real-time navigation of catheters without the need of fluoroscopy.[14–16]

In recent years, many scientific studies have been published on the experience of implementing procedures with significantly reduced fluoroscopy (near-ZF) or zero-fluoroscopy (ZF) approach.[13–20]

The literature reviews so far indicate that most authors report their experience with ZF in patients without a structural heart disease (SHD). Patients with any SHD, including subgroups, that is: organic heart diseases; ischemic/nonischemic dilated cardiomyopathy and other cardiomyopathies; anatomical defects; grown-up congenital heart disease or adult congenital heart disease (GUCH/ACHD); and hypertrophic cardiomyopathy, and those with previous cardiac surgery for valvular heart disease or past coronary artery bypass grafting or severe thoracic anomalies seem to pose a real challenge for electrophysiologists.[21]

Moreover, in some of randomized trials on ZF or near-ZF approach, patients with abovementioned conditions were routinely excluded.[22]

The purpose of this study was compared periprocedural data in consecutive patients recruited from a prospective registry including cases of ZF for CA of SVTs. Further, periprocedural data of patients with SHDs were compared with those of patients with nonstructural heart diseases (NSHDs).

2. Patients and methods

Data were obtained from a prospective standardized multicenter CA registry from January 2012 to February 2017. Seven centers were included. In all, 1280 consecutive unselected adult patients (mean age, 52.3 ± 16.2 years) with a final diagnosis of SVT or supraventricular substrate were recruited. The conditions included atrioventricular nodal reentry tachycardia (AVNRT), accessory pathway, atrial flutter (AFL), and atrial tachycardia. The only contraindications for ZF were cardiac implantable electronic devices, planned pulmonary vein isolation (PVI) procedure, and post-PVI arrhythmias. SHD was not the primary contraindication for following the ZF approach. The data of 174 patients with SHD were compared with those of 1106 patients with NSHD. All patients underwent routine blood tests, electrocardiography, detailed echocardiography, and standardized history taking (basic clinical symptoms) prior to the procedure. For the assessment of the frequency of basic clinical symptoms or their intensity, a scale in the range of 1 to 10 was created.

In all cases, the 3D-EAM system (Ensite Velocity, NavX, St Jude Medical, Lake Bluff, Illinois) was used to create the electroanatomical maps and navigate catheters. Routinely, no other detailed imaging technique was used before ablation apart from transthoracic or transesophageal echocardiography (if needed). Two femoral vein introducers were used for catheter insertion; when these failed, the left femoral, subclavian, or jugular internal vein was used. The procedures were performed under light sedation, while the catheters were routinely introduced under local anesthesia.

This study was performed with the consent of the Bioethics Committee in accordance with the Declaration of Helsinki as well as approved by the Bioethics Committee of the University of Rzeszów No.5/4/2017.

Data were collected from the ELEKTRA registry and RARE-A-CAREgistry. All patients or their corresponding representatives gave informed consent before the procedure. All authors had full access to the data and take full responsibility of the integrity of the data. Further, all authors have read and agreed to the manuscript as written.

The study was conducted in EP Labs equipped for immediate use of fluoroscopy. None of the intervention team used lead-protective aprons during the procedure, although such equipment was always available in case of need for fluoroscopy. No intracardiac or transesophageal echocardiography was performed during the procedure.

Procedures were performed only by a highly experienced team of 3 advanced electrophysiologists and 3 middle-advanced fellows. All procedures including early implementation period of ZF approach by 3 advanced electrophysiologists were included into analysis.

2.1. Standard electrophisiology study (EPS) and zero-fluoroscopy catheter ablation (ZF-CA) approach

The protocols for the simplified approach and ZF have been reported earlier.[13,23]

The simplified 2-catheter femoral access approach included the following: the use of 2 catheters, an ablation catheter, and a nonsteerable decapolar diagnostic catheter (APT Medical Inc., Shenzen, China, St. Jude Medical, St. Paul, MN or Biotronik, Berlin, Germany); standardized catheter positioning during the procedure (decapolar catheter in the coronary sinus [CS] and mapping/ablation catheter in the right atrium, His region, and right ventricle); and standardized ventricular and atrial EPS before and after ablation with a 10 to 15-minute observation period. If CS cannulation was not achieved within 5 minutes, the decapolar catheter was positioned on the lateral site of the tricuspid annulus or in the superior vena cava. An electrophysiological recording system (EP-Tracer, Cardio-Tek, Maastricht, The Netherlands) was used during procedures with standard filters. Standard settings (max. 60–65 °C and 50 [in AVNRT] –65 W [in AFL]) of the RF generator (Stockert, Biosense-Webster, Diamond Bar, CA) were used. Mapping was performed by creating a simplified map with the 3D-EAM system (Ensite Velocity NavX, St. Jude Medical, Lake Bluff, Illinois). The 3D map was projected at 30° left anterior oblique and 30° right anterior oblique positions.[13,23]

If the arrhythmia originated from the left atrium or mitral annulus, the ablation catheter was inserted through the patent foramen ovale or retrogradely via the femoral artery.

By definition, the ZF approach was followed as an intention-to-perform procedure; therefore, the medical staff was not using lead-protective aprons until fluoroscopy was needed. If necessary, the fluoroscopy was performed, and the decision was made by the main operator after 5 minutes of unresolved navigational issues observed via catheter monitoring, for safety reasons or the need for a transseptal puncture. No intracardiac echocardiography was available in this group. A clear explanation concerning the reasons for using fluoroscopy was prespecified in the computer database and registry protocol, and this should be written in the medical reports and stored in the database. The procedural definitions, end-points, and complications were based on standard clinical definition.[8] Patient status was reported in the medical reports and stored in the database immediately after ablation, after 1 day, and before hospital discharge. Only in-hospital complications were recorded.

2.2. Data collection

All preoperational data were collected prospectively in a computer database and saved. The data were also collected during ablation and supplemented with the results of treatment.

2.3. Statistical analysis

The data of patients with SHD were compared with those of patients with NSHD. All results were subjected to a statistical analysis. Data were presented as mean (SD) and percentages (%). The Student *t* test was used to compare differences between groups. All analyses were made using the licensed Statistica 13.1 package. All tests were statistically significant when "*P*" was <.05.

3. Results

The study population consisted of 1280 consecutive patients with SVT; of which, 174 patients had SHD. The baseline characteristics of the study groups are presented in Table 1.

On studying the scores for clinical symptoms, we noted that SHD patients presented with significantly higher exercise intolerance ($P<.001$) and more frequent palpitations ($P=.008$) than NSHD patients, while other symptom intensities (such as those for dyspnea, chest pain, and dizziness) were similar in both groups ($P>.05$). Moreover, the incidence for syncope was similar. SHD patients had significantly worse heart failure parameters than NSHD patients ($P<.001$).

A detailed analysis of 174 SHD patients (Table 2) showed that the organic heart diseases group was most commonly studied (58.6%) and consisted of patients with various types of cardiomyopathies, mitral or aortic valve anomalies, aortic aneurysms, Ebstein anomaly, or dextroversion and patients who had previously undergone percutaneous coronary interventions due to acute coronary syndromes. The next group was of postsurgery patients (17.8%) including those who had undergone coronary artery bypass grafting and mitral or aortic valvuloplasty (or replacement). Another group consisted of patients with significant thorax anomalies (13.7%), and the last group comprised GUCH patients (9.7%). In this group, there were individuals after atrial septal defect (ASD 2) and ventricular septal defect (VSD) closure. Some of the patients had at least 2 or more SHDs but the most advanced type was considered during classification.

Analysis of different types of SVT suggested that in SHD patients, AFL (61.3%) was the most common, while in NSHD patients, AVNRT (57.7%) was the most common. In both groups, atrial tachycardia was the least likely to be observed. Only in NSHD group frequent symptomatic premature ventricular contraction/ventricular tachycardia (1.3%) were additionally ablated during the same session. The remaining results are shown in Table 3.

Next, several basic parameters during EPS and ablation in SHD and NSHD patients were compared (Table 4). Procedural time was similar between patients with SHD and NSHD (49.9 ± 24.6 vs 49.1 ± 23.9 minutes, $P=.55$).

The rate of conversion from ZF-CA to fluoroscopy and failed procedure were slightly higher in SHD as compared to NSHD (13.2% vs 7.8% $P=.02$). The number of applications as well as total procedural time for CA, total time of fluoroscopy, and radiation exposure were similar in both groups, and differences

Table 1

General characteristic patients with structural heart disease and nonstructural heart disease.

	Total cohort n=1280	SHD n=174	NSHD n=1106	*P* value
General characteristics				
Mean age, yr	52.3±16.2	58.2±13.6	51.4±16.4	<.001
Range	(18–91)	(18–84)	(18–91)	
Height, cm	169.2±8.8	171.7±11.8	168.9±10.9	<.001
Range	(149–200)	(149–197)	(149–200)	
Weight, kg	77.9±16.7	84.8±18.7	76.9±16.1	<.001
Range	(34–155)	(43–155)	(34–150)	
BMI		28.2±5.8	26.0±5.4	<.001
Male patients	591 (45.3%)	118 (70.2%)	473 (41.6%)	<.001
Basic clinical symptoms (score 1–10)				
Exercise intolerance	5.3±3.8	6.1±3.8	5.1±3.9	<.001
Dyspnea	4.5±3.1	4.7±3.1	4.5±3.2	.31
Chest pain	1.6±2.9	1.7±3.1	1.6±2.9	.54
Palpitations	7.3±3.8	6.6±4.0	7.4±3.8	.01
Fatigue	3.7±3.8	4.0±4.0	3.6±3.8	.16
Dizziness	3.8±3.2	3.9±3.3	3.8±3.2	.59
Presyncope	3.3±3.3	3.2±3.2	3.3±3.3	.76
Syncope	0.7±2.1	0.5±1.8	0.7±2.1	.34
Echocardiographic findings				
EF, %	60.6±8.9	48.9±13.2	62.7±5.7	<.001
LVIDD, mm	48.9±6.1	53.3±7.6	48.2±5.5	<.001
LVIDS, mm	32.3±6.4	38.1±8.8	31.2±5.3	<.001
LA, mm	38.2±6.8	42.5±6.9	37.3±6.4	<.001

BMI=body mass index, EF=ejection fraction, LA=left atrium, LVIDD=left ventricle diameter in diastole, LVIDS=left ventricle diameter in systole, NSHD=nonstructural heart disease, SHD=structural heart disease.

Table 2

Types of structural heart disease referred for zero-fluoroscopy catheter ablation.

Primary SHD	n=174	(100%)
OHD	n=102	(58.6%)
MV and AoV anomaly	32	
PCI	25	
HCM	14	
CMP dilated	12	
RVH (PH)	6	
CMP tachyarrhythmic	6	
Ao aneurysm	3	
Ebstein anomaly	2	
NCC	1	
Dextroversion	1	
Postsurgery	n=31	(17.8%)
CABG	20	
AoV repl.	8	
MV plasty	3	
TA	n=24	(13.8%)
ACHD/GUCH	n=17	(9.8%)
ASD 2: surgery	12	
ASD 2: Amplatzer Septal Occluder	3	
ASD 2 & PAPVR	1	
VSD: surgery	1	

ACHD=adult congenital heart disease, AoV repl.=aortic valve replacement, ASD=2-ostium secundum atrial septal defect, CABG=coronary artery bypass grafting, CMP=cardiomyopathy, GUCH=grown-up congenital heart disease, HCM=hypertrophic cardiomyopathy, MV plasty=mitral valve repair and mitral valve replacement, NCC=noncompaction cardiomyopathy, OHD=organic heart disease, PAPVR=partial anomalous pulmonary venous return, PCI=percutaneous coronary intervention, RVH=right ventricular hypertrophy, SHD=structural heart diseases, TA=thorax anomaly, VSD=ventricular septal defect.

were not statistically significant ($P>.05$). However, there were significantly higher values in the SHD patients with regard to the duration of measurement and maximum values for energy and temperature in RF settings. This difference may be associated with differences in ablated substrates because in AFL, higher energy settings were required.

ZF approach was completed in 91.4% of 1280 subjects with SVT. There was significant increase in conversion to fluoroscopy in SHD ($P=.02$) and the indications for fluoroscopy in SHD group were: difficulty in cannulation of CS and instability of decapolar catheter (n=7), atypical anatomy (n=5), need for angiographically guided transseptal puncture (n=3), peripheral vessel puncture with fluoroscopy control (n=3), navigation problems (n=3), and stabilizing sheath introduction (n=2). In NSHD, the most 5 frequent indications for fluoroscopy were: difficulty in cannulation of CS and instability of decapolar catheter (n=17), instability of ablation catheter (n=12), monitoring of retrograde approach with aortic valve crossing and mapping of mitral annulus (n=9), need for angiographically guided transseptal puncture (n=8), and navigation problems close to His area (n=7).

After conversion to fluoroscopy, SHD (n=23) and NSHD (n=87) did not show significant changes in the total time of fluoroscopy (5.05 ± 5.13 vs 5.59 ± 7.45 minutes, respectively [$P=0.75$]) as well as radiation doses were comparable in the both groups.

Major complications were very rarely observed during in-hospital follow-up: surgically managed groin hematoma (n=1) in SHD, AV fistula (n=1), surgically managed groin hematoma (n=1), and prolonged hospital stay for symptomatic pericardial effusion without tamponade (n=2) in NSHD diagnosed immediately after successful procedure, but symptoms appeared during procedure (Table 4).

4. Discussion

To the best of our knowledge, this is the largest registry of ZF approach as well as the first study comparing SHD and NSHD patients who underwent ZF-CA for regular SVT and supraventricular substrates.[12,21]

The study showed that the minimally invasive ZF approach without the use of intracardiac echocardiography (ICE) enabled treatment without fluoroscopy in majority of patients (>90%) with a short treatment duration and very high safety profile, comparable to that reported in previous meta-analysis.[18] Moreover, the study reports information on differences in CA of SVT between SHD and NSHD.

SHD patients and medical staff are usually exposed to radiation several times in the current medical settings.[4–6] Therefore, efforts to minimize the risk of irradiation should be validated while developing technologies (eg, 3D-EAM systems) and progressing in electrophysiology. There are several additional techniques and devices that facilitate the use of ZF approach during electrophysiological procedures (ICE, TEE, Carto UNIVU, contact force, imaging integration, and MediGuide). However, their additional costs and complexity of management should be taken into account for universal use of these approaches in EP lab worldwide.

We have been applying the ZF approach during ablation for several years.[13,23,24] In this study, we present an analysis of a large group of patients with SHD including adolescent GUCH/ACHD patients in whom ablation was performed without the use of fluoroscopy. Other authors are also increasingly reducing the use of fluoroscopy for ablation; however, SHD is rare and the incidence of SHD is low in their described groups.[14,15,17]

Table 3

Types and numbers of supraventricular tachycardia in subgroups.

	SHD n=174	NSHD n=1106	*P* value	Total cohort n=1280
Types of SVT				
AVNRT, %	42 (23.9)	656 (58.0)	<.001	698 (53.4)
AP, %	15 (8.5)	199 (17.6)	.001	214 (16.4)
AFL, %	108 (61.4)	234 (20.7)	<.001	342 (26.2)
AT, %	11 (6.2)	42 (3.7)	.001	53 (4.0)
PVC/VT, %	0 (0.0)	14 (1.3)	–	14 (1.1)

AFL=atrial flutter and interatrial reentry tachycardia, AP=accessory pathways, AT=atrial tachycardia, AVNRT=atrioventricular nodal reentry tachycardia, NSHD=nonstructural heart disease, PVC=premature ventricular contractions, SHD=structural heart disease, SVT=supraventricular tachycardia, VT=ventricular tachycardia.

Table 4

Electrophisiology study and ablation parameters.

	SHD n=174	NSHD n=1106	*P* value	Total cohort n=1280
Total procedure's time, min	51.2±26.9	49.9±25.2	.55	50.0±25.4
Number of applications	17.6±13.2	20.2±17.9	.08	19.8±17.5
Time of applications, sec	457.5±356.3	369.2±286.3	<.001	380.5±297.5
Max Watt for applications, W	50.4±11.2	44.1±11.1	<.001	44.9±11.3
Max temp. of applications, °C	58.4±7.1	54.9±7.4	<.001	55.3±7.4
Power settings – Watt, W	57.6±928	52.0±8.1	<.001	52.7±8.4
Temperature settings, °C	62.1±4.1	60.1±4.2	<.001	60.4±4.2
ZF completed	n=151 (86.8%)	n=1019 (92.1%)	.02	1170 (91.4%)
Conversion to X-ray	n=23 (13.2%)	n=87 (7.8%)	.02	110 (8.8%)
Time of X-ray in fluoroscopy group, min	5.05±5.13 range 1–17	5.59±7.45 range 1–46	.75	5.49±7.08 range 1–46
DAP, cGy × cm^2	1620.6±2472.3	1152.4±1650.1	.48	1261.3±1850.5
mGy	97.3±133.9	81.5±89.2	.63	83.7±95.5
*Major complications, %	1 (0.5)	4 (0.4)		5 (0.4)

DAP=dose area, mGy=milligray, NSHD=nonstructural heart disease, SHD=structural heart disease.
* Major complications: groin hematoma (n=1) in SHD and AV fistula (n=1), groin hematoma (n=1) and pericardial effusion without tamponade (n=2) in NSHD.

Casella et al[14] demonstrated that patients' lifetime risks of cancer incidence and mortality from ZF procedures were reduced by 96% compared with those from conventional fluoroscopic procedures. Moreover, the genetic study revealed a substantial increase in the incidence of mutations associated with an increasing radiation dose.

The differences in clinical parameters might affect the prognosis after an ablative approach and these relationships were described by Sardu et al.[25,26] Cardiac arrhythmias are a common occurrence after cardiac surgery because a new arrhythmogenic substrate appears, which is sometimes difficult to identify.[3] Further, deformities of the spine move the heart inside the chest, resulting in an atypical anatomy of the heart in thoracic anomalies and advance scoliosis. This could be a real challenge for electrophysiologists. In this study, longer ablation time and parameters of CA were expected for SHD patients than those for patients with a normal heart anatomy; however, ZF were successfully and safely incorporated into daily practice in this group too.

Giaccardi et al[15] in their meta-analysis compared a group of 145 patients treated only under fluoroscopic guidance with 297 patients treated using a nonfluoroscopic electroanatomic mapping system (EnSite Velocity). They concluded that the conventional fluoroscopic technique and the near-zero radiation (RX) approach provide similar outcomes and may significantly reduce or eliminate ionizing radiation exposure in radiofrequency CA. Similar results were presented by Yang et al,[18] although the results are mainly for patients without SHD.

Further, Mah et al[16] conducted a study in patients aged ≥10 years, weighing ≥35 kg, and having a normal cardiac anatomy or trivial structural heart defects such as bicuspid aortic valve or a persistent left superior vena cava. Patients were excluded if they had more than trivial congenital heart disease prior to ablation or prior to cardiac surgery. However, even with a combination of 3D-EAM and ICE, complete ZF approach was followed only in a minority of patients.[27–30] In contrast, our study showed ZF approach feasibility wherein even in the SHD group, procedural time could be reduced significantly, probably because of lesser time spent on detailed contour mapping and multichamber 3D mapping.

In our study group, 174 individuals with SHD were compared with 1106 patients without SHD. In SHD the most frequent SVT is AFL, but in NSHD majority of SVTs are AVNRTs. We showed that SHD patients have worse exercise capacity and heart function than NSHD patients. Despite this, the ablation time was not longer and the number of applications was similar compared with those for NSHD patients.

Comparison of our previous data on implementation of ZF approach and current study shows encouraging constant value of ZF approach performance with very safe, effective, and fast procedures.[13,31] There are, however, needs for new ZF dedicated catheters, selective use of ICE (for crossing aortic valve or need for transeptal puncture), CS catheter stability, and approach modification (patient preselection or magnetic resonance preprocedural imaging) to decrease number of cross-over to fluoroscopy.

4.1. Limitations

The present study had few limitations. Firstly, this is not randomized trial and not all severe SHD or GUCH were treated, but the study showed routine incorporation of ZF approach in regular conditions and practice of nonuniversity hospitals. Furthermore, the conversion to fluoroscopy could be decreased if the steerable decapolar catheter were used for CS cannulation. The learning curve of each individual or ZF approaches and EPS protocol could be different and had potential impact on procedural data. We did not make a detailed analysis of the clinical course in the studied groups while Sardu et al[32–34] showed that ventricular failure as a pump may result in worse results in patients with metabolic syndrome, diabetes mellitus, and other diseases that have been ablated. In our study, echocardiographic parameters were worse in the SHD group compared to NSHD. We did not study clinical differences or follow-up because we focused on assessing whether SHD patients are a more difficult group for ablation or not. The results showed that SHD patients are not an obstacle to ZF ablation. Finally, long-term follow-up should be performed (planned) to confirm the early encouraging results of this registry and cost-effectiveness. The results of this study and this ZF approach or its modification is not validated during CA in patients with cardiac implantable electronic devices.

5. Conclusions

The minimally invasive ZF approach was successfully and safely implemented in majority of ablation procedures of regular SVT in SHD and NSHD patients although this method requires sufficient experience. Strict ZF approach even in patients with SHD should be routinely performed but additional imaging modalities or new devices dedicated for ZF procedures may decrease the rate of conversion to fluoroscopy and risk of complications and failures.

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