Steerable Versus Non-Steerable Sheath Technology in Atrial Fibrillation Ablation: A Prospective Randomized Study

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Overview

Researchers at two centers in Germany performed a prospective, randomized, controlled study comparing the outcomes of atrial fibrillation (AF) ablation using a conventional, non-steerable transseptal guiding sheath and a bi-directional steerable transseptal guiding sheath (Agilis NxT™ Steerable Introducer, St. Jude Medical).

Sixty patients were randomized to the non-steerable group and 63 were randomized to the steerable group. At 6-month follow-up, those procedures with treatment facilitated by the Agilis NxT steerable introducer resulted in:

- Significantly higher single-procedure success
- Significantly lower fluoroscopy time
- Similar procedure and RF application times
- Similar complication rates
- Trend toward a higher rate of complete pulmonary vein (PV) isolation
- Similar reduction in antiarrhythmic drugs

Study Background and Purpose

Background

Circumferential ablation around the opening of the PV antrum has been established as a curative treatment for patients with paroxysmal and persistent AF. The Agilis NxT steerable introducer is designed to improve catheter agility, stability and tissue contact, which may facilitate the placement of continuous and transmural lesions, thereby improving primary outcomes.

"Sufficient and stable catheter-to-tissue contact in all intended ablation target sites is one of the challenges interventionalists are facing while trying to place complex three-dimensional ablation line concepts in a moving organ within a breathing patient." (Piorkowski, 2011)

Purpose

The study was performed to compare the curative success rate of AF ablation procedures performed with a conventional non-steerable transseptal guiding sheath and those performed with a bi-directional steerable guiding sheath.

Research Methods

Ablation Procedure

For all patients, ablation was performed using a 3-D mapping system supplemented with 3-D image integration. Radiofrequency (RF) energy was delivered using an irrigated tip catheter. Ablation was performed using the following standard settings: upper temperature limit of 50 °C, power of 40W and a flow rate of 30 ml/min. The SensiTherm™ esophageal temperature monitoring system was used in all patients to provide intraesophageal temperature feedback.

Circumferential ablation was performed around both ipsilateral PVs at the atrial side of the PV antrum. Additional ablation lines were placed in patients with persistent AF and with clinically documented isthmus-dependent right atrial flutter. Details can be found in the published article. Gap detection and line verification were performed using the "Pace-and-Ablate" approach.

In the steerable sheath group, navigation of the catheter tip was achieved through deflection and rotation of the bi-directional steerable sheath. The ablation catheter itself was handled passively and only advanced or retracted in order to achieve optimal wall contact.

Technical details of the Agilis NxT steerable introducer were as follows:

- Inner diameter: 8.5 F
- Outer diameter: 11 F
- Total length: 91 cm
- Working length: 72 cm
- Bi-directional deflection (90°/180°)
- Small curve

Follow-up

Serial 7-day Holter ECGs were recorded immediately after ablation and after 3 and 6 months. The first-month post-procedure was defined as a blanking period.

Patient Population

A total of 123 patients were randomized (63 in the steerable group and 60 in the non-steerable group). All patients completed the study through the 6-month follow-up. Baseline characteristics did not differ between both treatment groups with the exception of a higher mean age in the non-steerable group (Table 1).

Table 1. Patient Characteristics*

	Total (n=123)	Agilis NxT Steerable Introducer (n=63)	Non-Steerable Sheath (n=60)	P value
Age (years)	59 ± 9	57 ± 9	62 ± 9	0.002
Male, n (%)	79 (64)	44 (70)	35 (58)	NS
Paroxysmal AF, n (%)	79 (64)	42 (67)	37 (62)	NS
Lone AF, n (%)	28 (23)	18 (29)	10 (17)	NS
AF history (months)	47	46	55	NS
Prior isthmus ablation, n (%)	2 (2)	0 (0)	2 (3)	NS
Arterial hypertension, n (%)	82 (67)	42 (67)	40 (67)	NS
Valvular heart disease, n (%)	10 (8)	6 (10)	4 (7)	NS
Coronary artery disease, n (%)	24 (20)	9 (14)	15 (25)	NS
Left ventricular ejection fraction (%)	61 ± 7	61 ± 8	60 ± 8	NS

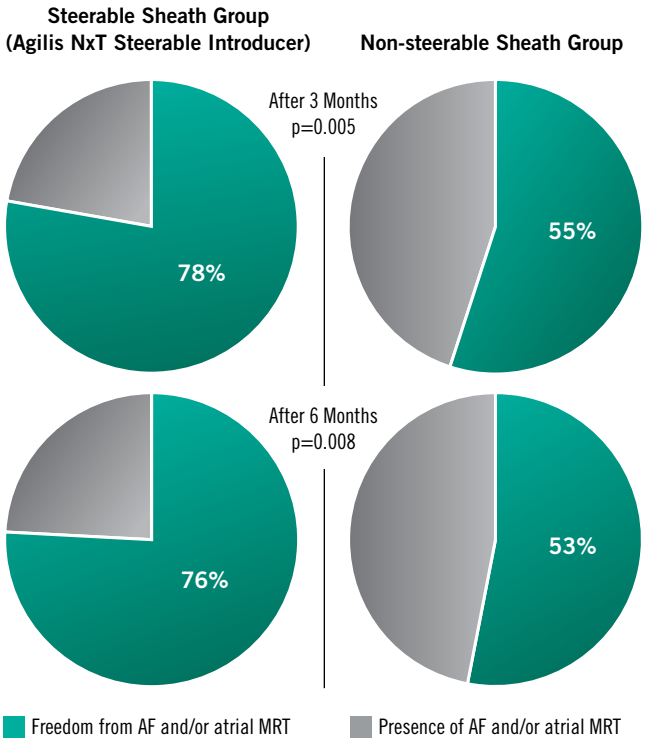
* The complete list of patient characteristics can be found in the publication.

Results

Procedural Success

Use of the bi-directional steerable guiding sheath significantly improved clinical success, which was defined as single-procedure freedom from AF and/or atrial macroreentrant tachycardia (MRT) after both 3 and 6 months: 78% versus 55%, p=0.005 at 3 months and 76% versus 53%, p=0.008 at 6 months (Figure 1).

Figure 1. Procedural Success by Sheath Type



Predictors of Clinical Success

The use of a steerable sheath is the only variable that is a significant predictor of treatment success in both univariable and multivariable analysis (Table 2).

Table 2. Univariable Analysis

Variable	Hazard Ratio (CI)	P-value
Gender	2.029 (0.943; 4.367)	0.070
AF history	1.004 (0.999; 1.008)	0.091
Type of AF	2.366 (1.096; 5.106)	0.028
Type of sheath	2.8 (1.296; 6.049)	0.009†
Complete PVI	0.320 (0.116; 0.877)	0.027
Early recurrence*	2.289 (1.029; 5.091)	0.042

Multivariable Analysis

Variable	Hazard Ratio (CI)	P-value
Gender	—	—
AF history	—	—
Type of AF	—	—
Type of sheath	2.837(1.197; 6.723)	0.018†
Complete PVI	—	—
Early recurrence*	—	—

* Early recurrence defined as recurrence of any arrhythmia (AF and/or macroreentrant tachycardia) during 7-day Holter immediately after AF ablation.

† Type of sheath tightly misses significance after Bonferroni-Holm adjustment (p=0.054) but is the only remaining influence factor in multivariate analysis.

Predictors of Clinical Success

Fluoroscopy time was significantly lower in the steerable sheath group, while procedure and RF application times were similar in both groups (Table 3).

Table 3. Fluoro, RF Ablation and Procedure Times by Group

	Agilis NxT Steerable Introducer	Non-Steerable Sheath	P-value
Fluoroscopy time (min)	33 ± 14	45 ± 17	p<0.001
RF ablation time (min)	52 ± 17	50 ± 18	NS
Procedure time (min)	163 ± 53	174 ± 47	NS

Complications

There were no differences in the rate of procedural complications by treatment group (Table 4).

Table 4. Complications

	Agilis NxT Steerable Introducer (n=63)	Non-Steerable Sheath (n=60)
Total procedure-related complications:	2 (3.2%)	3 (5%)
Peri-interventional stroke	1 (1.6%)	0
Pseudoaneurysm	1 (1.6%)	0
Cardiac tamponade	0	2 (3.3%)
Phrenic nerve palsy	0	1 (1.7%)

Post-Ablation Antiarrhythmic Drugs

The number of patients taking beta blockers significantly increased for both groups of patients from baseline to 6-month follow-up, while the rate of class Ic and class III antiarrhythmic drug usage decreased significantly for both groups during the same time period. There was no significant difference in antiarrhythmic drug usage between the groups during the study time period.

"The data add to the thesis that improved catheter stability and better catheter-to-tissue contact provided by a steerable sheath results in higher clinical treatment success in the setting of AF catheter ablation." (Piorkowski, 2011)

St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.

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