**Steerable Versus Nonsteerable Sheath Technology in Atrial Fibrillation Ablation**

**A Prospective, Randomized Study**

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**Background**—Steerable sheath technology is designed to facilitate catheter access, stability, and tissue contact in target sites of atrial fibrillation (AF) catheter ablation. We hypothesized that rhythm control after interventional AF treatment is more successful using a steerable as compared with a nonsteerable sheath access.

**Methods and Results**—One hundred thirty patients with paroxysmal or persistent drug-refractory AF undergoing their first ablation procedure were prospectively included in a randomized fashion in 2 centers. Ablation was performed by 10 operators with different levels of clinical experience. Treatment outcome was measured with serial 7-day Holter ECGs and additional symptom-based arrhythmia documentation. Single procedure success (freedom from AF and/or atrial macroreentrant tachycardia) was significantly higher in patients ablated with a steerable sheath (78% versus 55% after 3 months, \( P = 0.005 \); 76% versus 53% after 6 months, \( P = 0.008 \)). Rate of pulmonary vein isolation, procedure duration, and radiofrequency application time did not differ significantly, whereas fluoroscopy time was lower in the steerable sheath group (33±14 minutes versus 45±17 minutes, \( P < 0.001 \)). Complication rates showed no significant difference (3.2% versus 5%, \( P = 0.608 \)). On multivariable analysis, steerable sheath usage remained the only powerful predictor for rhythm outcome after 6 months of follow-up (hazard ratio, 2.837 [1.197 to 6.723]).

**Conclusions**—AF catheter ablation using a manually controlled, steerable sheath for catheter navigation resulted in a significantly higher clinical success rate, with comparable complication rates and with a reduction in periprocedural fluoroscopy time.

**Clinical Trial Registration**—URL: http://clinicaltrials.gov. Unique identifier: NCT00469638.

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**Key Words:** atrial fibrillation ■ ablation ■ steerable sheaths ■ electrophysiology ■ clinical

**C**atheter ablation has evolved as a potentially curative treatment option for patients with paroxysmal and persistent atrial fibrillation (AF).

**Clinical Perspective on p 165**

During recent years, numerous technological developments in the field of catheter design, 3D anatomic orientation, catheter navigation, and catheter contact have been introduced to facilitate AF ablation procedures.\(^1\)\(^-\)\(^8\) Until today, for most of these technologies, evidence-based data analyzing the impact on clinical outcome parameters within prospective, randomized, multicenter trials are lacking.

We were the first to report on the usage of manually controlled, steerable sheath technology for catheter navigation during left atrial (LA) ablation procedures.\(^9\)\(^-\)\(^10\) With discontinuous and nontransmural ablation lines being one of the reasons for recurrences of AF and atrial macroreentrant tachycardia (MRT), steerable sheaths were designed to improve access to and contact with ablation target sites.\(^11\)\(^-\)\(^12\) To build up scientific evidence on the clinical use of that technology, we published data from a retrospectively matched case-control analysis indicating a significantly superior rhythm control compared with an ablation approach with a nonsteerable sheath access.\(^10\) On the basis of these
results, we have now planned and conducted a prospective randomized study to further strengthen scientific evidence on clinical outcome and safety to support usage of steerable sheath technology in clinical routine of AF catheter ablation (ClinicalTrials.gov Identifier: NCT00469638).

Methods
An investigator-initiated, randomized, controlled study aiming to compare AF catheter ablation using steerable sheath navigation against a conventional sheath access was conducted at 2 centers in Germany between August 2007 and October 2009. Ablation procedures were performed by 10 operators with different levels of clinical experience.

The institutional review board at each site approved the study, and participants provided written and verbal informed consent.

Patients
Participants were adults (18 to 75 years of age) who had (1) paroxysmal or persistent symptomatic AF (documented on ECG), (2) previously ineffective antiarrhythmic drug therapy (at least 1 antiarrhythmic drug) and (3) LA diameter \( \leq 60 \) mm (transthoracic echocardiography, parasternal). Patients with permanent AF, prior LA ablation procedure, AF due to reversible cause, known intracardiac or other thrombi, pregnancy, or contraindication for anticoagulation were excluded.

One hundred thirty patients underwent computerized random assignment (Figure 1). Seven patients had to be excluded because of a history of LA ablation (n=2), withdrawal of consent (n=3), and intracardiac thrombi recognized by preprocedural echocardiography (n=2). Of the 123 eligible patients, 63 (51%) were assigned to ablation using a steerable transseptal sheath (Agilis, St Jude Medical, St Paul, MN) and 60 (49%) to the use of a conventional nonsteerable sheath (Swartz SL0, St Jude Medical). Clinical characteristics of the study population are detailed in Table 1.

Study Design
After random assignment, patients underwent preprocedural transesophageal echocardiography and 3D cardiac imaging (CT or MRI). Ablation of paroxysmal and persistent AF was performed as detailed below. Follow-up with serial 7-day Holter started at the first postinterventional day and was continued for 6 months. ECG-documented episodes of AF and/or MRT lasting \( \geq 30 \) seconds as well as symptomatic arrhythmia episodes between the Holter recording periods were considered as arrhythmia recurrences. Data analysis was performed on the basis of intention-to-treat.

Ablation
Patients were studied under deep propofol sedation. In patients presenting with AF at the beginning of the procedure, electric cardioversion was applied to proceed in sinus rhythm. After transseptal puncture at a classic site in the oval fossa, mapping and ablation were performed under the guidance of 3D mapping systems (CARTO n=30, NavX n=93) supplemented by 3D image integration.\(^5,^{13,14}\) A temperature probe in the esophagus (Sensitherm, St Jude Medical) at the level of the LA tagged the esophageal location and provided intraesophageal temperature feedback during the procedure.\(^15\)

Radiofrequency alternating current was delivered in a unipolar mode between the irrigated tip electrode of the ablation catheter (F-Type, irrigated tip, Navi-Star Thermocool, Biosense Webster, Diamond Bar, CA; M-Curve IBI Therapy Cooled Path, St Jude Medical) and an external backplate electrode. The standard ablation setting consisted of an upper temperature limit of 50°C, a power of 40 W, and a flow rate of 30 mL/min. Near to the esophagus, power delivery was reduced to 25 W and 20 mL/min and further adapted according to the actual intraesophageal temperature increase.

Ablation Line Concept and Procedural End Point
In all patients, circumferential ablation around both ipsilateral pulmonary veins (PVs) was performed at the atrial side of the PV antrum. In addition, in patients with persistent AF a “box” lesion was created electrically, isolating the posterior LA by connecting both encircling lines at the roof and at the bottom of the posterior LA. Furthermore, a mitral isthmus line from the left lower PV to the mitral annulus was placed endocardially only. Ablation of the right atrial cavotricuspid isthmus was performed in patients with clinically documented, typical, isthmus-dependent right atrial flutter only.

The procedural end point was electrophysiologically proven bidirectional conduction block for the PV encircling ablation lines and the posterior “box” lesion. Gap detection and line verification was
performed using the “pace-and-ablate” approach as described previ-
ously.\textsuperscript{13} Results were confirmed by a circular mapping catheter
(Optima, St Jude Medical, Inc).

In the steerable sheath group, ablation followed the same lesion
line concept, using the same ablation catheters with identical catheter
settings. However, navigation of the catheter tip was achieved
through bending, stretching, and rotation of the bidirectional steer-
able sheath. The ablation catheter itself was handled passively and
allowing at the operator’s discretion in case the procedural end point
could not be achieved with the assigned sheath technology.

Periprocedural crossover between both randomization groups was
allowed at the operator’s discretion in case the procedural end point
could not be achieved with the assigned sheath technology.

Postprocedural Care and Follow-Up
Serial 7-day Holter ECGs (LifeCard CF, DelmarReynolds Medical
Inc, Irvine, CA) were recorded immediately after ablation and after
3 months and 6 months. The first month after ablation was defined
as the blanking period.

Reablations for symptomatic drug-refractory recurrences of AF
and MRT were scheduled after at least 3 months of follow-up. Pa-
patients undergoing reablation were handled as patients with arrhyth-
miic recurrences during follow-up and data analysis.

Antiarrhythmic medication was discontinued after ablation and
patients received a $\beta$-blocker. In the case of symptomatic arrhythmia recurrences, medication was allowed to be adapted according to the
investigator’s discretion.

Starting the day after the ablation procedure, patients received oral
antiocoagulation with an international normalized ratio of 2.0 to 3.0.
Anticoagulation was discontinued after the 6-month follow-up ac-
cording to the CHADS2 score.

Primary End Point
The primary end point of the study was the proportion of pa-
tients free from arrhythmia recurrences 6 months after ablation. Episodes
of AF and/or MRT qualified as arrhythmia recurrences if they were
documented on ECG and lasted longer than 30 seconds or if they
were reported by the patient, even in the absence of ECG document-
tation. Any such episode as well as the need for reablation was
considered as treatment failure.

Secondary End Points
Secondary end points measured freedom from arrhythmia 3 months
after ablation, achievement of PV conduction block, procedure
duration, fluoroscopy time, and the rate of adverse events.

Data Management and Statistical Analysis
The data were collected by the participating investigators and were
managed by the principal investigator. All authors had full access to
and take full responsibility for the integrity of the data. All authors
have read and agree to the manuscript as written.

Based on previous data from a retrospective case-control analysis
the sample size was calculated to detect a 15% difference of the primary
end point between both treatment groups, with a statistical
power of 80% and a 1-sided level of significance of 5%.\textsuperscript{10} Including
an 8% potential dropout rate, 130 patients had to be randomly
assigned for this study.

Statistical calculations were performed according to random
assignment as “intention-to-treat” analysis. The data were tested for
normal (gaussian) distribution using the Kolmogoroff-Smirnov test.

\begin{table}[htp]
\centering
\begin{tabular}{llll}
\hline
 & Total & \multicolumn{2}{c}{Steerable Sheath Group} & \multicolumn{2}{c}{Nonsteerable Sheath Group} \\
 & (n=123) & (n=63) & (n=60) & P Value \\
\hline
Age, y$^*$ & 59±9 & 57±9 & 62±9 & 0.002 \\
Male, n (%) & 79 (64) & 44 (70) & 35 (58) & NS (0.183) \\
Paroxysmal AF, n (%) & 79 (64) & 42 (67) & 37 (62) & NS (0.563) \\
AF history, mo$^\dagger$ & 47 (16 to 109) & 46 (14 to 117) & 55 (21 to 104) & NS (0.831) \\
Arterial hypertension, n (%) & 82 (67) & 42 (67) & 40 (67) & NS (0.100) \\
Coronary artery disease, n (%) & 24 (20) & 9 (14) & 15 (25) & NS (0.134) \\
Dilated cardiomyopathy, n (%) & 2 (2) & 0 (0) & 2 (3) & NS (0.236) \\
Valvular heart disease, n (%) & 10 (8) & 6 (10) & 4 (7) & NS (0.744) \\
Mitral valvuloplasty, n (%) & 1 (1) & 0 (0) & 1 (1) & NS (0.488) \\
Coronary bypass grafting, n (%) & 1 (1) & 1 (1) & 0 (0) & NS (1.000) \\
Lone AF, n (%)$^\ddagger$ & 28 (23) & 18 (29) & 10 (17) & NS (0.116) \\
LA diameter, mm$^\S$ & 44±6 & 43±6 & 45±6 & NS (0.156) \\
LVEF, %$^*$ & 61±7 & 61±8 & 60±8 & NS (0.675) \\
Prior isthmus ablation, n (%) & 2 (2) & 0 (0) & 2 (3) & NS (0.236) \\
\hline
\end{tabular}
\caption{Patient Characteristics}
\end{table}

LVEF indicates left ventricular ejection fraction.

$^*$Data are given as mean±SD.

$^\dagger$Data given as median and quartiles.

$^\ddagger$Lone AF is defined as absence of structural heart disease and arterial hypertension.

$^\S$LA diameter as measured by M-mode in long parasternal axis view.

\begin{footnotesize}
\begin{itemize}
\item LVEF indicates left ventricular ejection fraction.
\item Data are given as mean±SD.
\item Data given as median and quartiles.
\item Lone AF is defined as absence of structural heart disease and arterial hypertension.
\item LA diameter as measured by M-mode in long parasternal axis view.
\end{itemize}
\end{footnotesize}
experience was graded according to the number of previously performed AF ablation procedures (level 1, >300 procedures; level 2, >50 procedures; level 3, <50 procedures) and compared by Armitage trend test.

Univariable and multivariable linear logistic regression analyses were performed to identify predictors of ablation success (freedom from any arrhythmia at 6-month follow-up). Multivariable stepwise logistic regression analysis (bottom up approach) was performed using only variables significant at level $\alpha=0.1$ in univariable regression analyses. The studied parameters included age, sex, hypertension, duration of AF history, type of AF, diabetes, structural heart disease, LA diameter, and PV isolation, and early arrhythmia recurrences. All tests were performed with a 2-tailed significance level of $P\leq0.05$. The analyses were performed using SPSS for Windows, Release 15.0.

**Results**

A total of 123 patients, 79 men and 44 women (36%), mean age of 59±9 years, were randomly assigned and ablated. All patients completed the study to the end of the 6-month follow-up. Seven-day Holter ECG recordings were available for 109 of 123 (87%) patients after ablation, 103 of 123 (84%) patients at 3 months, and 122 of 123 (99%) at 6 months of follow-up. Patient demographics are shown in Table 1. Seventy-nine (64%) patients had paroxysmal AF and 44 (36%) had persistent AF. Structural heart disease was present in 36 (29%) patients, and 82 (67%) patients had a history of hypertension, 28 (23%) patients had so-called “lone AF.” Left ventricular ejection fraction and LA diameter measured $61\pm7\%$ and $44\pm6\%$, respectively. The median history of AF was 47 months (range, 16 months to 9 years). Baseline characteristics did not differ between both treatment groups apart from a higher mean age in the nonsteerable sheath group (62±9 versus 57±9; $P=0.002$) (Table 1).

**Clinical Outcome**

The primary end point of the study measured as freedom from AF and MRT at 6 months after a single ablation procedure was reached in 48 of 63 (76%) patients in the steerable sheath group and in 32 of 60 (53%) patients in the nonsteerable sheath group ($P=0.008$; Figure 2).

Clinical efficacy at 3 months of follow-up defined as one of the secondary end points provided comparable data with freedom from arrhythmia recurrences in 49 of 63 (78%) patients in the steerable sheath group versus 33 of 60 (55%) patients in the nonsteerable sheath group ($P=0.005$; Figure 2).

**Procedural Data**

In 8 of 60 (13%) patients randomly assigned to the nonsteerable sheath group, periprocedural crossover to a steerable sheath was performed at the discretion of the operator. No crossover occurred from the steerable to the nonsteerable sheath group.

For the secondary end points, mean procedure time did not differ significantly between both treatment groups ($163\pm53$ minutes with steerable sheath versus $174\pm47$ minutes with nonsteerable sheath, $P=0.234$). Fluoroscopy time, however, was significantly lower in the steerable sheath group ($33\pm14$ minutes versus $45\pm17$ minutes; $P<0.001$) (Table 2).

Postinterventional circular mapping catheter assessment of all 4 PVs was able to be performed in 59 of 63 (94%) patients in the steerable sheath group and in 55 of 60 (92%) patients in the nonsteerable sheath group. Among those patients, bidirectional block was confirmed in 52 of 59 (88%) and 43 of 55 (78%), respectively ($P=0.154$) (Table 2).

Operator experience did not differ significantly in both treatment groups (Table 2).

**Complications**

Procedure-related complications were observed in 2 of 63 (3.2%) patients in the steerable sheath navigation group and in 3 of 60 (5%) patients in the nonsteerable sheath group ($P=0.608$). In the steerable sheath group, 1 patient had peri-interventional stroke with minimal residuals during follow-up and 1 patient had a pseudoaneurysm at the femoral access site that had to be resolved surgically. In the nonsteerable sheath group, 2 patients had cardiac tamponade requiring pericardial puncture and 1 patient had a phrenic nerve palsy that resolved during follow-up. None of the patients had PV stenosis or esophageal perforation.

**Antiarrhythmic Medication**

Throughout the course of the study, the number of patients taking $\beta$-blockers significantly increased from 88 of 123 (72%) before ablation to 100 of 123 (81%) at the 6-month follow-up ($P=0.016$). The rate of class Ic and class III antiarrhythmic drug usage was significantly reduced from 44 of 123 (36%) before ablation to 22 of 123 (18%) at the 6-month follow-up ($P=0.002$). No significant difference in...
antiarrhythmic drug usage was detected between both treatment groups (Table 3).

Reablation Procedures
During study, follow-up reablation was performed in 3 of 63 (5%) patients in the steerable sheath group and in 2 of 60 (3%) patients in the nonsteerable sheath group ($P < 0.001$).

In the steerable sheath group, 2 patients were ablated for AF recurrences and 1 patient for a perimitral MRT. In the nonsteerable sheath group, 1 patient presented with AF recurrences and 1 patient presented with a peritricuspid MRT.

Predictors of Clinical Outcome
Univariable regression analysis revealed patient sex, duration of AF history, type of AF, type of sheath, completeness of PV isolation, and presence of early arrhythmia recurrences as significant or borderline predictors of the primary study end point (Table 4). Using stepwise multivariable logistic regression analysis, only the steerable sheath emerged as independent predictor of treatment success ($P = 0.018$).

Subgroup Analysis
Subgroup analysis for the occurrence of the primary study end point revealed a significant benefit of the steerable sheath in male patients, in patients with an LA diameter $\geq 45$ mm, in patients with an AF history $>18$ months, and in patients without structural heart disease (Table 5). No benefit was found in the subgroup of female patients, in patients with a LA diameter $<45$ mm, in patients with an AF history $\leq 18$ months, and in patients with structural heart disease (Table 5).

Discussion
Main Findings of the Study
This prospective, randomized, controlled study demonstrates that AF catheter ablation using a steerable transseptal sheath is associated with a significantly better rhythm control compared with an ablation with a nonsteerable sheath. Single procedure outcome improved $>20\%$. In multivariable analysis, the steerable sheath remained the only but powerful independent predictor for treatment success.

In addition, fluoroscopy duration was significantly reduced in patients ablated with a steerable sheath. Complication rates did not differ between both randomization groups.

Table 2. Procedural Data

<table>
<thead>
<tr>
<th></th>
<th>Steerable Sheath Group</th>
<th>Nonsteerable Sheath Group</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean procedure time, min*</td>
<td>163±53</td>
<td>174±47</td>
<td>NS (0.234)</td>
</tr>
<tr>
<td>Mean fluoroscopy time, min*</td>
<td>33±14</td>
<td>45±17</td>
<td>$P&lt;0.001$</td>
</tr>
<tr>
<td>RF application time, min*</td>
<td>52±17</td>
<td>50±18</td>
<td>NS (0.516)</td>
</tr>
<tr>
<td>No. of RF pulses†</td>
<td>43 (33 to 58)</td>
<td>46 (36 to 56)</td>
<td>NS (0.819)</td>
</tr>
<tr>
<td>Mean RF power delivery, W*</td>
<td>32±3.5</td>
<td>34±17</td>
<td>NS (0.352)</td>
</tr>
<tr>
<td>Mean catheter tip temperature, °C*</td>
<td>36.8±2.1</td>
<td>36.6±2.0</td>
<td>NS (0.783)</td>
</tr>
<tr>
<td>Max catheter tip temperature, °C*</td>
<td>40.1±3.0</td>
<td>40.0±2.9</td>
<td>NS (0.795)</td>
</tr>
<tr>
<td>Complete PVI proven by CMC‡</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left-sided veins, n (%)</td>
<td>51/59 (86%)</td>
<td>44/55 (80%)</td>
<td>NS (0.357)</td>
</tr>
<tr>
<td>Right-sided veins, n (%)</td>
<td>54/59 (92%)</td>
<td>47/55 (85%)</td>
<td>NS (0.291)</td>
</tr>
<tr>
<td>Left- and right-sided veins, n (%)</td>
<td>52/59 (88%)</td>
<td>43/55 (78%)</td>
<td>NS (0.154)</td>
</tr>
<tr>
<td>Operator experience§</td>
<td></td>
<td></td>
<td>0.400</td>
</tr>
<tr>
<td>Level 1 (n=43)</td>
<td>22/63 (35%)</td>
<td>21/60 (35%)</td>
<td></td>
</tr>
<tr>
<td>Level 2 (n=48)</td>
<td>21/63 (33%)</td>
<td>27/60 (45%)</td>
<td></td>
</tr>
<tr>
<td>Level 3 (n=32)</td>
<td>20/63 (32%)</td>
<td>12/60 (20%)</td>
<td></td>
</tr>
</tbody>
</table>

RF indicates radiofrequency; PVI, pulmonary vein isolation; and CMC, circular mapping catheter.
*Data given as mean±SD.
†Data are given as median and quartiles.
‡Proven bidirectional PV conduction block, confirmed by circumferential mapping catheter.
§Operator experience (n indicates number of operators) was graded by previous LA ablation procedures: level 1, $\geq$300 procedures; level 2, $>50$ procedures; and level 3, $<50$ procedures.

Table 3. Antiarrhythmic Drug Usage Before and 6 Months After Ablation

<table>
<thead>
<tr>
<th></th>
<th>Before Ablation</th>
<th>6-Month Follow-Up</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\beta$-Blocker</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steerable sheath group (n=63)</td>
<td>42 (67%)</td>
<td>52 (84%)</td>
<td>0.031</td>
</tr>
<tr>
<td>Nonsteerable sheath group (n=60)</td>
<td>46 (77%)</td>
<td>48 (80%)</td>
<td>NS (0.549)</td>
</tr>
<tr>
<td>Class Ic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steerable sheath group (n=63)</td>
<td>10 (16%)</td>
<td>5 (8%)</td>
<td>NS (0.267)</td>
</tr>
<tr>
<td>Nonsteerable sheath group (n=60)</td>
<td>11 (18%)</td>
<td>5 (9%)</td>
<td>NS (0.146)</td>
</tr>
<tr>
<td>Class III</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steerable sheath group (n=63)</td>
<td>10 (16%)</td>
<td>5 (8%)</td>
<td>NS (0.180)</td>
</tr>
<tr>
<td>Nonsteerable sheath group (n=60)</td>
<td>13 (22%)</td>
<td>7 (12%)</td>
<td>NS (0.180)</td>
</tr>
</tbody>
</table>

Class Ic indicates class Ic antiarrhythmic drugs; class III, class III antiarrhythmic drugs.
Table 4. Predictors for Occurrence of the Primary Study End Point

<table>
<thead>
<tr>
<th>Variable</th>
<th>Univariable Analysis</th>
<th>Multivariable Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hazard Ratio (CI)</td>
<td>P Value</td>
</tr>
<tr>
<td>Sex</td>
<td>2.029 (0.943 to 4.367)</td>
<td>0.070</td>
</tr>
<tr>
<td>AF history</td>
<td>1.004 (0.999 to 1.008)</td>
<td>0.091</td>
</tr>
<tr>
<td>Type of AF</td>
<td>2.366 (1.096 to 5.106)</td>
<td>0.028</td>
</tr>
<tr>
<td>Type of sheath</td>
<td>2.8 (1.296 to 6.049)</td>
<td>0.009†</td>
</tr>
<tr>
<td>Complete PVI</td>
<td>0.320 (0.116 to 0.877)</td>
<td>0.027</td>
</tr>
<tr>
<td>Early recurrence*</td>
<td>2.289 (1.029 to 5.091)</td>
<td>0.042</td>
</tr>
</tbody>
</table>

CI indicates confidence interval; PVI, pulmonary vein isolation.
*Early recurrence is defined as recurrence of any arrhythmia (AF and/or MRT) during 7 days.
†Type of sheath tightly misses significance after Bonferroni-Holm adjustment (P=0.054) but is the only remaining influence factor in multivariate analysis.

Role of Catheter Access and Catheter Contact for AF Ablation

Catheter ablation has been established as curative treatment for patients with AF. Circumferential ablation around the wide opening of the PV antrum is considered the basis of treatment for patients with paroxysmal and persistent AF. Similar to other long LA ablation lines, continuity and transmurality of these lesions is difficult to achieve. Clinically, that problem results in a significant number of AF/MRT recurrences caused by (1) primarily incomplete PV isolation, (2) too distally isolated PVs, and (3) the occurrence of PV reconnection.

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 3D ablation line concepts in a moving organ within a breathing patient. Steerable transseptal sheath technology has been developed to facilitate access and contact to ablation target sites to improve continuity, transmurality, and maintenance of radiofrequency lesion formation. Steerable transseptal sheaths are currently available as part of the robotic navigation system (Hansen Medical) and as a stand-alone technology to be used for manual ablation procedures.

To understand the clinical impact of steerable sheath catheter navigation, this prospective, randomized study evaluated the safety and efficacy of AF catheter ablation using similar lesion concepts and procedural end points but 2 different regimens of catheter handling: (1) conventional nonsteerable transseptal sheath access and (2) manually controlled steerable sheath technology.

Impact of Steerable Sheath Access on Procedural Parameters and Safety

Despite improved catheter access and tissue contact, steerable sheath navigation had no significant impact on procedural parameters such as procedure duration, radiofrequency application time, and number of radiofrequency pulses. Only the fluoroscopy time was significantly reduced from 45±17 minutes to 33±14 minutes (P<0.001). These observations must be discussed in the context of lack of hard electrophysiological end points for radiofrequency lesion deployment during the initial PV encircling lesion (before gap mapping and gap closure). As long as radiofrequency discontinuation is decided on a subjective judgment such as local electrogram reduction, the higher stability provided by a steerable sheath may lead operators to prolong radiofrequency application on a given ablation position, which in the end mimics potential reductions in procedural durations, but, on the other hand, could actually be beneficial for lesion formation, lesion maintenance, and clinical outcome.

As for the procedural end point, bidirectional PV conduction block was achieved more often within the steerable as compared with the nonsteerable sheath group (88% versus 78%; P=0.154). Even though the difference failed to reach statistical significance, together with the observed crossover in 13% of the nonsteerable sheath patients, these data show a trend toward a higher rate of complete PV isolation achieved with the steerable sheath.

Table 5. Treatment Effect Within Patient Subgroups

<table>
<thead>
<tr>
<th>Subgroups</th>
<th>Primary End Point</th>
<th>Steerable Sheath Group (n=63)</th>
<th>Nonsteerable Sheath Group (n=60)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male, n=79</td>
<td></td>
<td>36/44 (82%)</td>
<td>20/35 (57%)</td>
<td>0.016</td>
</tr>
<tr>
<td>Female, n=44</td>
<td></td>
<td>12/19 (63%)</td>
<td>12/25 (48%)</td>
<td>NS (0.317)</td>
</tr>
<tr>
<td>Type of AF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paroxysmal AF, n=79</td>
<td></td>
<td>34/42 (81%)</td>
<td>23/37 (62%)</td>
<td>NS (0.063)</td>
</tr>
<tr>
<td>Persistent AF, n=44</td>
<td></td>
<td>14/21 (67%)</td>
<td>9/23 (39%)</td>
<td>NS (0.068)</td>
</tr>
<tr>
<td>LA diameter*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥45 mm, n=54</td>
<td></td>
<td>19/26 (73%)</td>
<td>17/28 (61%)</td>
<td>NS (0.205)</td>
</tr>
<tr>
<td>&lt;45 mm, n=69</td>
<td></td>
<td>29/37 (79%)</td>
<td>15/32 (46%)</td>
<td>0.009</td>
</tr>
<tr>
<td>AF history</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥18 mo, n=89</td>
<td></td>
<td>35/45 (77%)</td>
<td>21/44 (46%)</td>
<td>0.004</td>
</tr>
<tr>
<td>&lt;18 mo, n=34</td>
<td></td>
<td>13/18 (71%)</td>
<td>11/16 (69%)</td>
<td>NS (0.822)</td>
</tr>
<tr>
<td>Structural heart disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, n=36</td>
<td></td>
<td>9/14 (64%)</td>
<td>13/22 (59%)</td>
<td>NS (0.755)</td>
</tr>
<tr>
<td>No, n=87</td>
<td></td>
<td>39/49 (80%)</td>
<td>19/38 (50%)</td>
<td>0.004</td>
</tr>
</tbody>
</table>

*LA diameter as measured by M-mode in long parasternal axis view.
Concerns exist on potential risks and side effects associated with an increased catheter-to-tissue contact as provided by the steerable sheath. In this prospective, randomized study, complication rates were similar in the steerable (3.2%) and nonsteerable (5%) sheath group \( (P=0.608) \), and they were comparable to previously published data from large clinical patient cohorts.\(^{10,17}\) In the steerable sheath group, no cardiac tamponade occurred. One patient had a thromboembolic event and 1 patient had a pseudoaneurysm at the vascular access site. In the nonsteerable sheath group, 2 cases of cardiac tamponade were observed together with 1 case of phrenic nerve palsy. Esophageal perforation was not observed in either treatment group; however, special care was taken using meticulous esophageal temperature monitoring in all patients.\(^{15}\) Nevertheless, given the rare occurrence of this complication, the number of patients included in this study is too low to fully judge that risk. Therefore, a potentially increased risk of esophageal injury caused by a higher tissue contact on the posterior wall must be kept in mind.

**Impact of Steerable Sheath Access on Clinical Outcome**

In our study, usage of the steerable sheath improved the primary end point defined as freedom from any ECG documented or other symptomatic AF/MRT recurrence after a single LA ablation procedure from 53% to 76%. Operator-initiated crossover in 8 of 60 (13%) patients randomly assigned to the nonsteerable sheath group strengthens the findings of the intention-to-treat analysis for the primary study end point.

Antiarrhythmic drug treatment was reduced for the entire study population from 36% before ablation to 18% after 6 months \( (P=0.002) \). For the individual randomization group, patients ablated with a steerable sheath had a nonsignificant trend toward less antiarrhythmic drug usage after 6 months of follow-up (16% versus 21%; \( P=0.519 \)).

Although beyond the goal and the design of this study, it is interesting to conceptualize on the causes for the observed improvement in clinical outcome. As discussed above, sufficient catheter-to-tissue contact in all intended ablation target sites is a common limitation during interventional AF ablation, which can be improved by steerable sheath technology. Objective contact assessment was not yet available at the time of the study but may have the potential to further analyze that concept in the future. Experimental data obtained with objective contact assessment technologies indicate a correlation between contact and lesion size.\(^{18}\) The improved outcome observed in our study may therefore be in part interpreted as the clinical result of improved lesion formation and lesion maintenance. Other factors contributing to clinical outcome are likely to be related to the stability of the catheter position over longer ablation periods and the ability to reliably access different ablation target sites.

**Predictors for Outcome and Subgroup Analysis**

Using stepwise multivariable logistic regression, the steerable sheath remained the only significant independent predictor of treatment success (hazard ratio, 2.837 [1.197 to 6.723]). Although completeness of PV isolation, type of AF, and presence of early AF recurrences also showed an association with clinical outcome, in multivariable analysis they failed to reach statistical significance and were outweighed by steerable sheath usage. The observed strong influence of steerable sheath navigation on ablation success independent from and on top of the achievement of complete PV isolation is interesting and concordant with previously published data.\(^{10}\) That observation implies that the steerable sheath treatment effect goes beyond better achievement of complete PV isolation and is at least in part attributable to a more effective substrate modification. Alternatively, less PV reconnection within the steerable sheath group may be discussed as a different mechanism leading to this observation. The lack of follow-up data on PV reconnection in our study population prevents a conclusive differentiation of the underlying pathophysiological mechanism.

Although random assignment was not prestratified for patient subgroups and despite a limited number of patients within individual subgroups preventing a final judgment on a potential treatment effect, the subgroup analysis indicates a predominant benefit of steerable sheath usage among male patients, in patients with a LA diameter <45 mm, in patients with an AF history >18 months, and in patients without structural heart disease. As a speculation, the benefit observed in male patients may relate to thicker LA myocardium necessitating more contact force for sustained transmural and continuous ablation lesions. The effect observed in patients with a longer AF history supports the discussion on a predominant treatment effect of steerable sheath handling on AF substrate modification. The benefit in patients with a LA diameter <45 mm must be discussed in the context of the curve of the steerable sheath used for the procedure. For the entire study, a small-curve steerable sheath was used. Practically, in a more dilated LA, the benefits of steerable sheath handling are being attenuated due to more difficult access conditions into individual PVs. Therefore, nowadays in clinical routine we have adopted usage of a medium-curve steerable sheath in patients with a LA diameter >45 to 50 mm.

**Previous Studies on Steerable Sheath Technology in AF Ablation**

The clinical benefit of steerable sheath navigation observed in our trial is comparable to previously published data from a retrospective study using a case-control design.\(^{10}\) In that study, safety and efficacy of AF ablation had been analyzed in 83 retrospectively matched patient pairs ablated with and without steerable sheath. Freedom from AF/MRT recurrences was increased from 56% to 77%, respectively.

Until now, prospective data comparing nonsteerable versus steerable sheath navigation in a randomized approach were only available from 1 further published single-center study.\(^{19}\) In that study, Rajappan et al\(^{19}\) did not find a significant improvement in clinical outcome using steerable sheath navigation (41% versus 48%). The data by Rajappan et al may be interpreted as being inconsistent with the findings of our trial. However, this may at least in part be due to significant differences in the study protocols. The most important differences relate to the single-center design, the
ablation concept, and the ablation end point. In the protocol by Rajappan et al, isolation of the PVs was performed with 20 to 30 W as a distal segmental PV disconnection. Entrance block was the only procedural end point. The large proximal PV antrum was not electrically isolated. Considering these aspects, the discrepant results obtained in both studies can be interpreted as differences between segmental PV disconnection and wide circumferential PV antrum isolation in itself rather than a treatment effect of the steerable sheath. Overall, the discrepant results obtained in both studies underline the need for additional detailed analysis to further clarify the relevance of steerable sheath navigation for AF catheter ablation procedures.

Study Limitations

Follow-up was based on serial 7-day Holter recording, together with additional symptom-based detection of arrhythmia recurrences. We are aware that even with such a close follow-up, additional asymptomatic arrhythmia recurrences may be overlooked. Furthermore, for symptomatic arrhythmia recurrences without ECG-documentation, AF and MRT cannot be differentiated reliably. Nevertheless, shortcomings in follow-up affect both randomly assigned groups and are therefore unlikely to influence the overall outcome difference observed between both treatment groups.

The significantly higher age of patients ablated within the nonsteerable sheath group might have led to a bias in favor of steerable sheath navigation. However, age failed to be a significant predictor of rhythm outcome in univariable analysis.

Random assignment was not prestratified for patient subgroups. Additionally, the number of patients within the individual subgroups may be too low to provide sufficient statistical power to reliably detect differences in treatment effect between both randomization groups.

The findings of this study are limited to the specific ablation approach and the specific energy settings used in our protocol.

Conclusions

This prospective, randomized study compared rhythm outcome, procedural data, and safety in patients undergoing AF catheter ablation using a steerable sheath versus a conventional nonsteerable sheath. Rhythm outcome after a single LA ablation procedure, defined as freedom from any atrial arrhythmia (AF/MRT) at 6 months of follow-up, significantly improved from 53% to 76%. Fluoroscopy time was reduced, and the complication rates did not differ. 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.

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References

Catheter ablation has been established as a curative treatment for patients with atrial fibrillation (AF). Access to ablation target sites and catheter-to-tissue contact are increasingly recognized as determinants for effective lesion formation and subsequent ablation success. Apart from magnetic and robotic catheter navigation systems, manually controlled steerable sheath technology has been developed as a rather simple tool to improve the amount of contact, the stability of contact, and reliable access to different ablation target sites. To understand the clinical impact, this study evaluated the efficacy and safety of steerable sheath catheter navigation in a prospective randomized study design in 2 centers in Germany. Usage of the steerable sheath improved clinical outcome, defined as freedom from AF and macroreentrant tachycardia 6 months after ablation, by 23%. Importantly, that benefit was not associated with an increased complication risk. As a caveat, this study is too small to fully judge the risk of esophageal perforation, and all patients were treated with intraesophageal temperature monitoring. The presented data, however, are relevant for 2 reasons. First, the improvement in ablation outcome was achieved with a rather simple technological tool easily incorporated into the clinical workflow of manual point-by-point radiofrequency ablation. Second, unlike numerous other technological developments within the field of AF catheter ablation, the present study provides solid scientific evidence for outcome improvement that can be expected on clinical application.
Steerable Versus Nonsteerable Sheath Technology in Atrial Fibrillation Ablation: A Prospective, Randomized Study

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