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ORIGINAL PAPER

Remote vs. conventional navigation for catheter ablation of atrial fibrillation: insights from prospective registry data

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Abstract

Background Robotic (RNS) or magnetic navigation systems (MNS) are available for remotely performed catheter ablation for atrial fibrillation (AF).

Objective The present study compares remotely assisted catheter navigation (RAN) to standard manual navigation (SMN) and both systems amongst each other.

Methods The analysis is based on a sub-cohort enrolled by five hospitals from the multicenter German ablation Registry.

Results Out of 2442 patients receiving catheter ablation of AF, 267 (age 61.4 ± 10.4, 69.7% male) were treated using RAN (RNS $n = 187$, 7.7% vs. MNS $n = 80$, 3.3%). Fluoroscopy time [RNS median 17 (IQR 12–25) min vs. MNS 22 (16–32) min; $p < 0.001$] and procedure duration [RNS 180 (145–220) min vs. MNS 265 (210–305) min; $p < 0.001$] were significantly different. Comparing RAN (11%) to SMN (89%) fluoroscopy time (RAN 19 (13–27) min, vs. SMN 25 (16–40) min; $p < 0.001$), energy delivery (RAN 3168 (2280–3840) s vs. SMN 2640 (IQR 1799–3900) s; $p = 0.008$) and procedure duration [RAN 195 (150–255) min vs. SMN 150 (120–150) min; $p = 0.001$] differed significantly. In terms of acute and 12 months outcome, no differences were seen between the two systems or in comparison to SMN.

Conclusion AF ablation can be performed safely, with high acute success rates using RAN. RNS results in less fluoroscopy burden and shorter procedure durations. Compared to SMN, a reduced fluoroscopy burden, prolonged procedure and ablation duration were observed using RAN. Overall, the number of RAN procedures is small suggesting low impact on clinical routine of AF ablation.

Keywords Catheter ablation of AF · Remote navigation systems · AF ablation registry

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Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia [1] representing the most frequent heart rhythm disorder leading to emergency room admission and hospitalization [2, 3]. While pharmacological treatment is often limited, radiofrequency (RF) catheter ablation aiming for pulmonary vein isolation (PVI) has emerged as the standard of care once an invasive treatment is indicated [4–6]. Nonetheless, AF ablation strategies based on RF current are complex, technically challenging, require high manual skills, physical effort and are associated with a high fluoroscopy burden of the operator [7]. Thus, remote catheter navigation and ablation systems have been developed to minimize the operator's fluoroscopy exposure and physical exhaustion performing several procedures a day, just as to improve catheter stability, procedural success rates and to warrant safety potentially lowering the rate of serious complications.

Currently, two navigation systems are available to remotely perform catheter ablation for AF. The more recently released robotic navigation system (RNS) consists of an electromechanical steerable sheath connected to a robot arm enabling catheter navigation apart from the source of radiation (Hansen Medical®). The magnetic navigation system (MNS) provides direct steering via a magnetic field (Niobe, Stereotaxis®).

Both systems have proven to be safe and feasible to achieve PVI in different single center studies, especially since irrigated ablation has become available for the MNS. Comparing both systems, the existing single center data suggests a difference regarding procedural parameters such as fluoroscopy time and procedure duration [8–10].

But nevertheless, nearly 10 years after introduction of both systems, there is still a paucity of data comparing procedural characteristics, complications and outcomes. Consequently, the present analysis aims to answer these questions providing first prospective registry data gathered from the German Ablation Registry, not only comparing both remote navigation systems but also comparing remotely assisted catheter navigation (RAN) to standard manual catheter navigation (SMN). Moreover, the analysis of the proportion of remotely performed PVI relative to the overall number of AF procedures provides new insights into the impact of RAN on clinical routine PVI.

Methods

Recruiting sites

Altogether, in the German ablation registry, 55 centers collected patient-specific and procedural data on their patients undergoing catheter ablation procedures. The study was approved by the ethics committee of the Landesärztekammer Rheinland-Pfalz in 2007. The present analysis is based on data from five German electrophysiological centers performing RAN PVI, which agreed to participate in this prospective multicenter registry.

Patients' characteristics/population

All patients, age ≥ 18 years, who underwent catheter ablation of AF between July 2008 and May 2011 were registered after written and informed consent was obtained. Patients who received multiple ablation procedures during the hospital stay were excluded. A total cohort of 2442 patients undergoing catheter ablation of AF was divided into two whether SMN or RAN was applied. Furthermore, the RAN group (267 patients) was divided into two groups depending on whether RNS or MNS was utilized.

Procedures

All patients underwent circumferential PVI guided by a circular mapping catheter with the confirmed endpoint of entrance block and thereby electrical isolation of all pulmonary veins [3, 11–14]. If AF persisted after PVI, ablation of fractionated electrograms and application of complete lines was performed at the operator's discretion. In the vast majority, a 3.5-mm irrigated tip radiofrequency catheter without contact force sensor and a 3D mapping system (CARTO®, Biosense Webster and Ensite NavX®, St. Jude Medical) were used. Procedure duration was defined as the time from puncture to removal of last catheter sheath and fluoroscopy time was the duration of fluoroscopy used during the entire procedure.

The Sensei® robotic navigation system

The characteristics of the RNS have been previously described in detail [15–17]. In brief, it is an electromechanical system, which attains remote control of conventional ablation catheters. It consists of a steerable outer (14F) and inner (10.5F) sheath directed via a pull-wire mechanism connected to a robot arm. The robot arm on his part is navigated by a "3D" Joystick positioned in the control room. The force applied by the ablation catheter (g/cm^2) is continuously being monitored (IntelliSense™, Hansen Medical™) to avoid excessive tissue pressure [9].

The NIOBE™ magnetic navigation system

The technological details have been described previously [18, 19]. In brief, two external magnets positioned on either side of the patient generate a low intensity magnetic field (0.08 or 0.1 T). A specially developed magnetic enabled irrigated tip catheter is remotely steered by changing the orientation of the magnetic field.

Definition of complications

The term complication includes all adverse events requiring treatment, prolonged hospital stay or result in fatality in the context of invasive treatment of AF. Two categories of complications were defined: (1) minor complications, those resolving spontaneously, without sequelae and did not prolong the hospital stay. (2) A major complication was defined as an adverse event resulting in permanent injury, death or requiring medical intervention for treatment or prolonged hospitalization for more than 48 h [20, 21]. A fatal complication was defined as a procedure-related complication leading to death [22, 23].

Registry management

The Foundation Institut für Herzinfarktforschung (IHF, Ludwigshafen, Germany) as the central contract research organization for this study was responsible for project management, data management and clinical monitoring. The respective physician or study nurse in the participating center performed the data acquisition of patient characteristics, procedural data and complication monitoring. Documentation and data management was handled paperless as an internet-based case report form system; all obtained information was confidential and the transmitted data from the participating center was encrypted with a secure socket layer. The final data management, description of the biometric model and statistical analysis was carried out by the IHF [22].

Follow up

A predefined 12-month follow up (FU) was executed by the IHF. Just as baseline, procedural data and complication monitoring the respective ablation center transferred the existing FU data as an internet-based case report form system to the IHF. Performance of a 24 h Holter ECG at 12 months post PVI was a prerequisite for data entry. Furthermore, in 5.6% of patients, a Holter of an implanted cardiac device (pacemaker, ICD, CRT) was available. Moreover, IHF performed a telephone-based FU interview assessing symptomatic AF and quality of life. All symptomatic episodes whether documented or not were considered as AF recurrence.

Statistical analysis

Data are shown as absolute values, percentages, means with standard deviation or medians with quartiles (interquartile range, IQR). For statistical comparison, the Mann–Whitney–Wilcoxon test for continuous variables and Fisher's exact test for binary variables were performed. All statistical comparisons were two sided with p values < 0.05 considered as statistically significant. Differences in procedural quantities were adjusted for age, paroxysmal AF, first ablation, linear lesions and CFAE ablation by gamma regression. All computations were performed using the Statistical Analysis System (SAS, version 9.23, SAS Institute Inc., Cary, NC, USA).

Results

Within 35 months of registration initially an increasing number of remote procedures ($n = 267$, 11.0%) was noted with a maximum in 2009 for MNS ($n = 42$) and in 2010 for RNS ($n = 104$). Afterwards, especially the portion of magnetic-guided AF ablation procedures markedly decreased (Fig. 1).

A total number of 187 patients (7.7%) with a mean age of 60.0 ± 11.3 years (68.4% male) underwent RNS PVI and in 80 patients (3.3%) with a mean age of 62.6 ± 11.3 years (62.5% male) MNS was applied. The majority of 2175 patients (89%) with a mean age of 61.5 ± 10.2 years (70.1% male) received PVI using

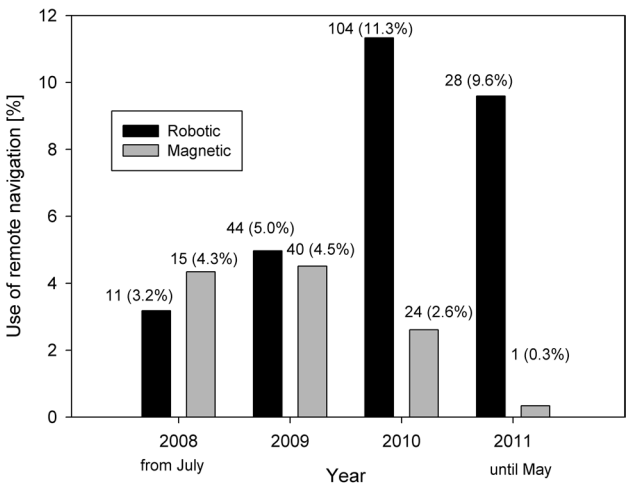

Fig. 1 Development of application of remote controlled catheter navigation between 07/2008 and 05/2011

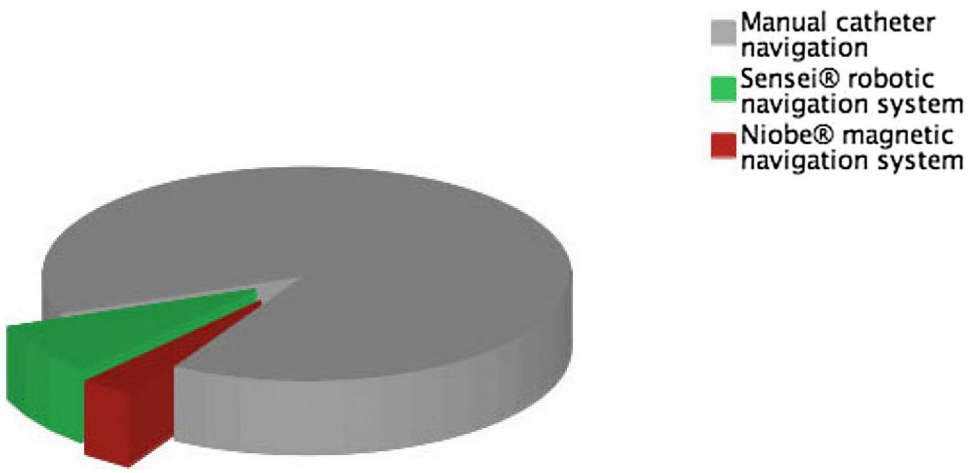

Fig. 2 2442 AF Ablation procedures performed in five German electrophysiology centers between 07/2008 and 05/2011

SMN (Fig. 2). The majority of patients (SMN 91%, RNS 87 and 94.9% in MNS group) had a preserved ejection fraction (> 50%). In the SMN group, in 39.6% an underlying heart disease was present as opposed to 37.4% in RNS and 40.0% in MNS group (Table 1). Nearly, all patients (97.1% in SMN, 95.7% in RNS group and 97.5% in MNS group) suffered from at least one symptomatic AF episode every month. A majority of both RAN groups (95.2% in RNS and 82.5% in MNS group) were naïve to catheter ablation with significantly more first procedures in the RNS group ($p < 0.001$). Fewer patients receiving SMN PVI were naïve to interventional treatment of AF (SMN 77.3% vs. RAN 91.4%; $p = 0.001$). Furthermore, persistent AF was more frequent in the SMN group (SMN $n = 836$ (38.4%) vs. RAN $n = 84$ (31.5%); $p = 0.027$). Baseline characteristics are shown in Table 1.

FU data were available for 1227 patients (56.4%) in SMN and for 204 patients (76.4%) in RNS group. Median FU in MNS group was 468 (413; 535) and 502 (418; 2503) days in RNS group.

Robotic vs. magnetic navigation

Procedural characteristics

In all registered RAN procedures, an open irrigated tip catheter for ablation was used. For all MNS PVI, the NIOBE II® system was used.

In most procedures, three-dimensional mapping was utilized (RNS 99.5% vs. MNS 95.0%). While in RNS procedures predominantly EnSite™ NavX™ and Velocity™ was applied, 93% of MNS procedures were assisted by the CARTO® 3D mapping system. No statistically significant difference was revealed with regard to proportion of patients receiving linear lesions (RNS $n = 61$ vs. MNS $n = 25$; $p = 0.89$) or ablation of fractionated electrograms (RNS $n = 8$ vs. MNS $n = 2$; $p = 0.73$).

The amount of overall energy delivered was comparable between both RAN groups (RNS $n = 3060$s. (IQR 2280–3840) vs. MNS $n = 3180$s. [IQR 2160–3872); $p = 0.91$]. Comparing the fluoroscopy time [RNS 17 (IQR

Table 1 Patients' baseline characteristics

	Manual navigation	Remote navigation		*p* value
		Hansen robotic	Stereotaxis magnetic navigation	
Number of patients *n* (%)	2175 (89.0%)	187 (7.7%)	80 (3.3%)	
Male gender % (*n*)	70.1% (1524/2175)	68.4% (128/187)	62.5% (50/80)	0.26
Age (years ± SD)	61.5 ± 10.2	60.0 ± 11.3	62.6 ± 11.3	0.54
Age > 75% (*n*)	3.9% (85/2175)	4.3% (8/187)	10.0% (8/80)	0.11
CHA_2DS_2Vasc score	1.8 ± 1.3	1.8 ± 1.4	2.4 ± 1.6	0.51
Diabetes % (*n*)	7.1% (155/2175)	7.5% (14/187)	3.8% (3/80)	0.80
Cardiac disease % (*n*)	39.6% (862/2175)	37.4% (70/187)	40.0% (32/80)	0.69
CAD % (*n*)	18.0% (391/2175)	17.1% (32/187)	16.3% (13/80)	0.73
LV function > 50% % (*n*)	91.0% (1825/2006)	87.0% (160/184)	94.9% (75/79)	1.0
Pacemaker/ICD/CRT % (*n*)	5.9% (129/2175)	4.3% (8/187)	0% (0/80)	0.048
Cardiomyopathy	3.8% (82/2175)	4.3% (8/187)	0% (0/80)	0.61

Table 2 Robotic vs. magnetic catheter navigation

	Hansen robotic navigation	Stereotaxis magnetic navigation	*p* value
Number of procedures	187 (70.0%)	80 (30.0)	
Naïve to catheter ablation *n* (%)	178/187 (95.2%)	66/80 (82.5%)	< 0.001
Paroxysmal AF	117/187 (62.6%)	39/80 (48.8%)	0.042
Persistent AF	59/187 (31.6%)	25/80 (31.3%)	1.00
Long-standing persistent AF	11/187 (5.9%)	16/80 (20.0%)	0.001
Linear lesion *n* (%)	61/187 (32.6%)	25/80 (31.3%)	0.89
Fractionated electrograms	8/187 (4.3%)	2/80 (2.5%)	0.73
Acute success *n* (%)	183/186 (98.4%)	76/80 (95.0%)	0.20
Fluoroscopy time (min)	17 (12; 25)	22 ± (16; 32)	< 0.001
Area dose product (cGy*cm^2)	2154 (1297; 3490)	2706 (1681; 4338)	0.020
Procedure duration (min)	180 (145; 220)	265 (210; 305)	< 0.001
RF delivery (s)	3060 (2280; 3840)	3180 (2160; 3872)	0.91

Table 3 Comparison of procedural quantities adjusted by gamma regression

Adjusted percent change (95% confidence interval)[a]	Remote vs. manual navigation	Hansen robotic vs. stereotaxis magnetic navigation
Fluoroscopy time (min)	− 12.1 (− 18.3, − 5.4)	− 25.4 (− 35.9, − 13.1)
Area dose product (cGy*cm^2)	− 11.9 (− 20.6, − 2.3)	− 17.1 (− 32.9, + 2.4)
Procedure duration (min)	+ 25.8 (+ 20.3, + 31.6)	− 30.7 (− 35.9, − 25.1)
RF delivery (s)	+ 19.1 (+ 8.6, + 30.5)	+ 1.1 (− 15.6, + 21.2)

[a]Adjusted for age, paroxysmal AF, first ablation, linear lesions, CFAE ablation

12–25) min vs. MNS 22 (IQR 16–32) min; $p < 0.001$] and the area dose product [RNS 2154 cGy*cm^2 (IQR 1297–3490) vs. MNS 2706cGy*cm^2 (IQR 1681–4338); $p = 0.02$], both were found to be significantly reduced in the RNS group, resulting in a lower fluoroscopy burden within the RNS collective. Furthermore, the procedure duration (RNS 180 (IQR 145–220) min vs. MNS 265 (IQR 210–305) min; $p < 0.001$) was significantly shorter in the RNS group (Tables 2, 3).

In terms of procedure-associated complications (mild, moderate and severe non-fatal), there were no statistically significant differences between both systems (Table 4).

Outcome

Although there was no difference comparing the acute success rates between both groups [RNS $n = 183$ (98.4%) vs. MNS $n = 79$ (95%); $p = 0.20$], we observed a tendency towards a higher number of early in-hospital relapses within the MNS collective [RNS $n = 12$ (6.4%) vs. MNS $n = 11$ (13.8%); $p = 0.059$]. At hospital discharge, significantly more patients in MNS group had accompanying antiarrhythmic drug (AAD) medication (RNS 57.2% vs. MNS 72.5%; $p = 0.02$) and among them significantly more patients (RNS 25.7% vs. MNS 43.8%) received class III AAD treatment as relapse prophylaxis (Table 4). But at 12-month FU in the majority of patients, antiarrhythmic drug treatment was already discontinued without a statistically significant difference between groups (RNS 22.6% vs. MNS 36.2%; $p = 0.11$). At 12-month FU 46.2% of patients in RNS and 44.8% in MNS group were free from AF with no difference between groups ($p = 0.88$). AF recurrence adjusted for age, sex, type of AF (paroxysmal, persistent, long-standing persistent), complexity of ablation and concomitant disease (Fig. 3) did not show any difference between both systems either (OR 1.29; 0.88–1.89). In terms of symptom based FU 91.4% in RNS and 82.5% in MNS stated an improvement of AF symptoms and an improvement in quality of life after AF ablation.

Remote controlled catheter navigation vs. standard manual navigation

Procedural characteristics

Comparing not only the two RAN systems amongst each other but the entire group of patients receiving remote controlled PVI ($n = 267$) to patients treated with SMN ($n = 2175$) nearly all procedures were assisted by a 3D mapping system. In the SMN group predominantly (77.4%), the CARTO® system was applied.

Ablation of fractionated electrograms was more often performed within the SMN group [SMN $n = 471$ (21.7%) vs. RAN $n = 10$ (3.7%); $p < 0.001$].

No significant difference was found comparing the application of linear lesions [SMN $n = 582$ (26.8%) vs. RAN $n = 86$ (32.2%); $p = 0.069$].

Table 4 In-hospital outcome of robotic vs. magnetic catheter navigation

	Hansen robotic navigation	Stereotaxis magnetic navigation	*p* value[a]
Number of patients *n* (%)	187 (70.0%)	80 (30.0%)	
Severe, non-fatal complications n (%)	2/187 (1.1%)	1/80 (1.3%)	1.00
Myocardial infarction	0/187 (0%)	0/80 (0%)	
Stroke	0/187 (0%)	1/80 (1.3%)	0.30
Major bleeding, with medical intervention	2/187 (1.1%)	0/80 (0%)	1.00
Moderate, non-fatal complications n (%)	10/186 (5.4%)	5/80 (6.3%)	0.78
TIA	1/187 (0.5%)	0/80 (0%)	1.00
Aneurysma spurium/AV fistula	3/187 (1.6%)	4/80 (5.0%)	0.20
Relevant pericardial effusion	3/186 (1.6%)	0/80 (0%)	0.56
Pneumothorax	1/186 (0.5%)	1/80 (1.3%)	0.51
Hemathorax	1/186 (0.5%)	0/80 (0%)	1.00
Mild, non-fatal complications n (%)	6/186 (3.2%)	4/80 (5.0%)	0.49
Minor bleeding, without medical Intervention	6/187 (3.2%)	5/80 (5.0%)	0.49
Fatal complications *n* (%)	0 (0%)	0 (0%)	
Early, in-hospital relapse	12/187 (6.4%)	11/80 (13.6%)	0.059
AAD treatment at discharge n (%)	107/187 (57.2%)	58/80 (72.5%)	0.02
Class I antiarrhythmic drugs *n* (%)	59/187 (31.7%)	24/80 (30.0%)	0.89
Class III antiarrhythmic drugs *n* (%)	48/187 (25.7%)	35/80 (43.8%)	0.006
Amiodarone *n* (%)	21/48 (43.8%)	25/35 (74.3%)	0.007
Dronedarone *n* (%)	20/48 (41.7%)	17.1% (6/35)	0.03

[a]Fisher's exact test

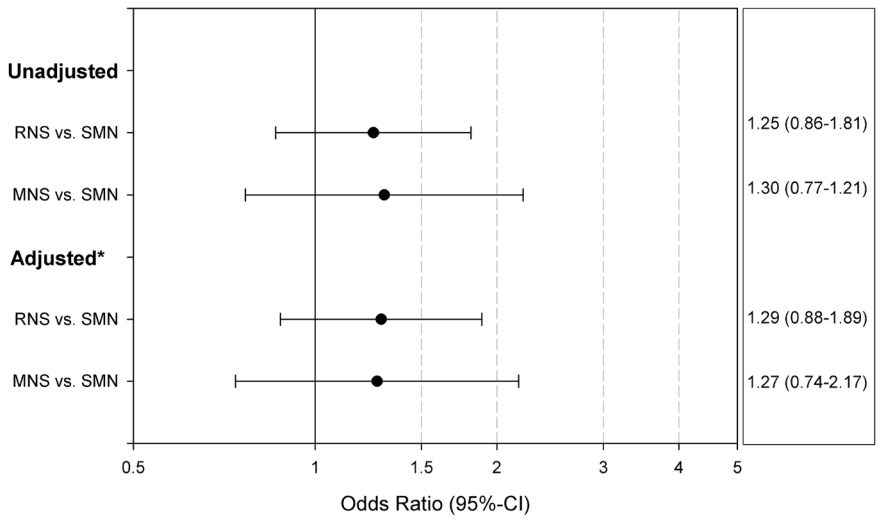

Fig. 3 AF recurrence at 12-month follow up adjusted for complexity

* adjusted for age (linear), sex, type of AF (paroxysmal / persistent / long-standing), chronic renal failure, valvular heart disease, NYHA II+ in organic heart disease, (pre)syncope, first ablation, linear lesions, presence of secondary arrhythmia

Fluoroscopy time [SMN 25 (IQR 16–40) min vs. RAN 19 (IQR 13–27) min; $p < 0.001$] and area dose product [SMN 2798 cGy*cm^2 (IQR 1600–4952) vs. RAN 2316 cGy*cm^2 (IQR 1376–3628); $p < 0.001$] were significantly reduced in the RAN group while RAN procedures were significantly longer [SMN 150 (IQR 120–200) min vs. RAN 195 (IQR 150–255) min; $p < 0.001$] with a need for higher overall energy deliveries [SMN 2640 s. (IQR 1799–3900) vs. RAN 3168 s. (IQR 2280–3840); $p = 0.008$] (Tables 3, 5).

Severe non-fatal [SMN $n = 23$ (1.1%) vs. RAN $n = 3$ (1.1%); $p = 0.76$] and mild non-fatal [SMN $n = 112$ (5.2%) vs. RAN $n = 10$ (3.8%); $p = 0.37$] did not differ, but more moderate non-fatal complications [SMN $n = 61$ (2.8%) vs. RAN $n = 15$ (5.6%); $p = 0.023$] were seen in the RAN group (Table 6).

Outcome

Acute procedural success [SMN $n = 2129$ (98.1%) vs. RAN $n = 259$ (97.4%); $p = 0.48$] or early in-hospital relapse rates [SMN $n = 181$ (8.3%) vs. RAN $n = 23$ (8.6%); $p = 0.82$] did not differ significantly.

At hospital discharge, 61.5% in SMN group and 61.8% in RAN group had accompanying antiarrhythmic drug treatment, with no significant difference between the varying antiarrhythmic agents either (Table 6), which was already discontinued at 12-month FU in the majority of both groups (SMN 33.8% vs. RAN 29.2%; $p = 0.36$). Furthermore, there was no difference in terms of FU: after 12 months, 51.9% in SMN group and 45.7% in RAN group ($p = 0.13$) were free from AF. AF recurrence rates adjusted for complexity (Fig. 3) did not show any difference between remote assisted and manual catheter navigation either (OR 1.27; 0.74–2.17). Interestingly, symptom-based FU revealed an improvement in AF symptoms and quality of life in 79.3% of SMN and 87% of RAN patients.

Discussion

Since the introduction of the MNS in 2003, supplemented 2008 by a second system, when RNS became available, both demonstrated in various studies that PVI can safely and effectively be performed using a remote controlled catheter steering technique [13, 18]. Two meta-analyses by Shurrab et al. and Proietti et al. even showed a lower peri-procedural complication rate comparing the new remote assisted catheter navigation techniques to the established standard manual navigation. Our data does not show significant differences in terms of pericardial complications but a higher rate of moderate non-fatal complications due to groin complications using the large diameter RAN sheaths. Regarding procedural outcome both RAN systems have proven their equality in comparison to SMN but failed to demonstrate superiority [10, 23–28] which is supported by our present data showing nearly identical acute and FU success rates comparing RAN procedures to SMN PVIs performed in the same electrophysiological centers. Although in the SMN group significantly more patients with persistent AF received ablation of fractionated electrograms, at 12-month FU, the outcome did not differ from RAN patients. These differences are unlikely due to an influence of the underlying catheter navigation technique but may be interpreted in the context of the findings of Verma et al. [29] showing that more extended ablation did not lead to additional benefit over PVI alone. Despite the rather high recurrence rate at 12-month FU in both groups, potentially due to high percentage of persistent AF patients, lack of advanced technology just as contact force measurement or Surround Flow technique [30] as well as lacking loss of pace capture evaluation of the ablation lines, the majority of patients stated an improvement in AF symptoms and quality of life after AF ablation irrespective of catheter steering technique.

Table 5 Manual vs. remote catheter navigation

	Manual navigation	Remote navigation	*p* value
Number of procedures	2175 (89.1%)	267 (10.9%)	
Naïve to catheter ablation *n* (%)	1681/2174 (77.3%)	244/267 (91.4%)	< 0.001
Paroxysmal AF	1122/2175 (51.6%)	156/267 (58.4%)	0.038
Persistent AF	836/2175 (38.4%)	84/267 (31.5%)	0.027
Long-standing persistent AF	217/2175 (10.0%)	27/267 (10.1%)	0.91
Linear lesion *n* (%)	582/2174 (26.8%)	86/267 (32.2%)	0.069
Fractionated electrograms	471/2173 (21.7%)	10/267 (3.7%)	< 0.001
Acute success *n* (%)	2129/2171 (98.1%)	259/266 (97.4%)	0.48
Fluoroscopy time (min)	25 (16; 40)	19 (13; 27)	< 0.001
Area dose product (cGy*cm^2)	2798 (1600; 4952)	2316 (1376; 3628)	< 0.001
Procedure duration (min)	150 (120; 200)	195 (150; 255)	< 0.001
RF delivery (s)	2640 (1799; 3900)	3168 (2280; 3840)	0.008

Table 6 In-hospital outcome of manual vs. remote catheter navigation

	Manual navigation	Remote navigation	*p* value
Number of patients	2175 (89.0%)	267 (11%)	
Severe, non-fatal complications n (%)	23/2175 (1.1%)	3/267 (1.1%)	0.76
Myocardial infarction	0/2174 (0%)	0/267 (0%)	
Stroke	4/2174 (0.2%)	1/267 (0.4%)	0.44
Major bleeding, with medical intervention	19/2174 (0.9%)	2/267 (0.7%)	1.00
Moderate, non-fatal complications n (%)	61/2157 (2.8%)	15/266 (5.6%)	0.023
TIA	2/2174 (0.1%)	1/267 (0.4%)	0.29
Aneurysma spurium/AV fistula	31/2174 (1.4%)	7/267 (2.6%)	0.18
Relevant pericardial effusion	16/2157 (0.7%)	3/266 (1.1%)	0.46
Pneumothorax	5/2157 (0.2%)	2/266 (0.8%)	0.17
Hematothorax	3/2157 (0.1%)	1/266 (0.4%)	0.37
Mild, non-fatal complications n (%)	112/2158 (5.2%)	10/266 (3.8%)	0.37
Minor bleeding, without medical intervention	110/2174 (5.1%)	10/267 (3.7%)	0.45
Fatal complications *n* (%)	0	0	1
Early, in-hospital relapse	181/2175 (8.3%)	23/267 (8.6%)	0.82
AAD treatment at discharge n (%)	1336/2174 (61.5%)	165/267 (61.8%)	0.95
Class I antiarrhythmic drugs *n* (%)	589/2174 (27.1%)	83/267 (31.1%)	0.17
Class III antiarrhythmic drugs *n* (%)	721/2174 (33.2%)	83/267 (31.1%)	0.53
Amiodarone *n* (%)	446/721 (61.9%)	47/83 (56.6%)	0.40
Dronedarone *n* (%)	198/721 (27.5%)	26/83 (31.3%)	0.44

In terms of procedure characteristics, existing data showed a reduced fluoroscopy burden but also a tendency towards longer procedure and ablation duration using RAN systems [10, 24, 25, 31]. These findings can be underlined by our prospective registry data demonstrating a reduced fluoroscopy burden at the cost of longer procedure duration due to complex technical setup and catheter positioning using RAN. Interestingly, in direct comparison, RNS procedures were significantly shorter allowing even less fluoroscopy burden than MNS using NIOBE II®. This lower fluoroscopy burden and shorter procedure durations using RNS in comparison to MNS is surprising since almost all procedures in both groups were performed using three-dimensional mapping and there was no difference with regard to procedure extent (comparable RF delivery time) or lines and defragmentation. The longer MNS procedure durations are probably due to the time-consuming catheter positioning and position reassessment within the magnetic field. Furthermore, this overall prolonged procedure time in the MNS group consequently may have contributed to the increased fluoroscopy time using MNS, considering a certain fluoroscopy time relative to procedure duration. These assumptions are supported by recently published data comparing the NIOBE II® to the new generation NIOBE ES® system resulting in significantly improved procedure durations and fluoroscopy time due to improved catheter steering and mapping features [32, 33]. Other reasons may be related to the different technical ways, in which three-dimensional mapping is communicating with remote navigation in respective systems. While NIOBE II® uses standard 3D mapping RNS enables, via additional software interface (Hansen Medical®, CoHesion®), catheter movements in direct relation to 3D geometry, connecting steering unit and mapping system. Thus, this link helps to reassess catheter position relying on 3D mapping system only, which results in reduced fluoroscopy application [10].

The potentially most relevant difference between RAN and SMN just as between both systems inherits tissue contact and risk of perforation. In this context, it was always thought that MNS is less likely to cause left atrial perforation, but on the other hand, may be inferior regarding contact force and lesion quality [9, 25]. Interestingly, we found comparable ablation durations comparing both RAN systems but when comparing RAN procedures to SMN significantly more RF energy was needed to produce equal lesions. These findings are in line with existing data indicating that the use of more flexible catheter tips in MNS results in longer ablation times potentially due to reduced contact force exerted [18, 31, 34]. Surprisingly, RNS showed similar long RF delivery times while Dello Russo and colleagues observed less overall energy delivery, similar to SMN [35].

This difference may be related to the catheter used. While Dello Russo and colleagues combined RNS with contact force measurement catheter (Thermocool Smart Touch®, Biosense Webster) achieving similar lesions as SMN, the 201 RNS PVIs entering in our registry were performed without contact force measurement, which once again underlines

the utility of contact force measurement in the creation of effective ablation lesions.

This aspect of lesion quality may also explain the early in-hospital relapse rates. Although there were no differences in overall energy delivery and comparable success rates, the reduced force exerted by the magnetic navigation catheter tip could have led to the higher number of early in-hospital relapses which consequently may have been the reason for an increased use of concomitant AAD therapy in the MNS group.

Beyond comparison of both remotely controlled catheter steering techniques among each other and to SMN, another important finding is related to the relative proportion of procedures being performed using RAN systems. This allows insights into the importance of these techniques in the actual electrophysiological practice. Our registry data show that only a limited number of AF ablation procedures (10.9%) were performed with remote navigation support. Over time, the application of remote systems initially increased as far as the present data can reflect this course. However, especially the use of MNS decreased clearly during the registry period (Fig. 1).

It is likely that the complex setup process, especially using MNS, the necessity of manual steering of additional diagnostic catheters as well as longer procedure duration along with increased cost while lacking superiority regarding success rates with respect to long-term arrhythmia freedom have contributed to this development [24, 36]. This leads to the conclusion that RAN for AF ablation procedures at present did not seem to prevail as a standard alternative to SMN, limiting the use of RAN to special indications.

Limitations

The present data have been generated from a prospective, internet-based registry and are therefore non-randomized and non-controlled. As in all prospective registries, the quality of these data may be limited since consistency cannot be guaranteed and was not monitored during the entry process. The overall number of patients included in this registry is high but the collective presents some heterogeneity in terms of baseline characteristics, AF episode duration and total number of procedures performed with only a limited number of patients treated by remote navigation systems. Although these heterogeneities make data interpretation more complex, statistical procedures (gamma regression, adaption for complexity) were performed to ensure a meaningful interpretation of data. However, prospective multicenter registry data do provide insights to routine clinical practice with respect to patients' and procedural characteristics.

Conclusion

Catheter ablation for atrial fibrillation can safely and effectively be performed using both RAN systems. In direct comparison procedure, duration and fluoroscopy burden seem to favor RNS rather than MNS for this indication. Compared to SMN, remote steering techniques without contact force measurement catheter enable a reduced fluoroscopy burden with a necessity for longer procedure durations and energy delivery. However, the use of both systems with regard to the overall number of AF ablation procedures remained low and over the course of time remote navigation did not prevail as a standard alternative to SMN in clinical routine of AF ablation.

Compliance with ethical standards

Conflict of interest There are no conflicts of interest for this article.

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