Research Article

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QDOT MICRO™ versus THERMOCOOL® SMARTTOUCH™ and THERMOCOOL SMARTTOUCH® Surround Flow in radiofrequency ablation of paroxysmal atrial fibrillation

Jose Osorio*,[1], Sonia Maccioni[2], Reecha Sharma[3], Leena Patel[4], Paul Spin[4] & Andrea Natale[5]

[1]Medical Director Electrophysiology, Electrophysiology - Cardiovascular Group, HCA Florida Miami, Miami, FL 33133, USA
[2]Johnson & Johnson Medical Devices, Franchise Health Economics and Market Access, Irvine, CA 92618, USA
[3]Johnson & Johnson Medical Devices, Clinical Research, Irvine, CA 92618, USA
[4]EVERSANA™, Burlington, ON, L7N 3H8, Canada
[5]Executive Medical Director, Texas Cardiac Arrhythmia Research, St. David's Medical Center, Austin, TX 78705, USA
*Author for correspondence: Tel.: +1 205 971 7566; jose.osorio@hcahealthcare.com

Aim: The objective of this study was to indirectly compare QDOT MICRO™ (QDOT), Thermocool® SmartTouch™ (ST) and Thermocool® SmartTouch® Surround Flow (STSF) to treat paroxysmal atrial fibrillation. **Methods:** Differences in baseline characteristics between study cohorts were reduced by reweighting patients using inverse probability of treatment weighting. The primary outcome was procedure time. Secondary outcomes were fluoroscopy time, clinical success at 12 months, and rhythm monitoring-adjusted recurrence. **Results:** QDOT was associated with significantly faster mean procedure and fluoroscopy time, and significant improvement in the rate of recurrence compared with pooled ST/STSF. No difference was observed for clinical success at 12 months. **Conclusion:** QDOT was associated with greater efficiency, greater effectiveness in rhythm monitoring-adjusted recurrence and similar effectiveness in clinical success at 12 months compared with pooled ST/STSF.

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Atrial fibrillation (AF) is the most common type of cardiac arrhythmia, affecting up to 2–4% of adults worldwide [1]. AF is associated with considerable morbidity, mortality and burden on the healthcare system [1]. As an alternative treatment option to antiarrhythmic drugs (AADs), catheter ablation for pulmonary vein isolation (PVI) is safe and effective in patients with symptomatic paroxysmal AF (PAF) [2]. The Thermocool® SmartTouch™ (ST) and Thermocool® SmartTouch® Surround Flow (STSF) catheters, with contact force sensing technology, are the latest generation irrigated radiofrequency (RF) ablation catheters used in the treatment of AF. In patients with PAF who were ablated with ST/STSF, up to 94% were free from AF recurrence and off AADs at 12 months [3,4].

The QDOT MICRO™ (QDOT) catheter is a next-generation of contact force sensing, irrigated, RF catheter that is designed to facilitate temperature-controlled and very high-powered short-duration ablation [5,6]. Findings from early prospective, multicenter, single-arm studies showed that QDOT had rapid total procedure (55.0–105.2 minutes) and fluoroscopy (6.6–7.0 minutes) times, and low rates of adverse events (3.8–7.0%) in the treatment of patients with symptomatic PAF indicated for catheter-based PVI [5,6]. More recently, the efficiency, effectiveness and safety of QDOT was assessed in the Q-FFICIENCY trial (NCT03775512), a prospective, multicenter, single-arm US FDA investigational device exemption (IDE) trial of patients with symptomatic PAF who have experienced prior AAD failure [7].

Comparison of QDOT with ST and STSF suggest that QDOT may provide similar reductions in arrhythmia recurrence with shorter procedure durations. However, no studies directly evaluate the comparative effectiveness of QDOT to other available RF technologies, including ST and STSF. In the absence of direct, head-to-head comparative studies, indirect treatment comparison methods that adjust for differences in study patient cohorts, such as inverse probability treatment weighting (IPTW), can be used. Thus, the objective of this study was to evaluate the comparative effectiveness of QDOT to ST and STSF for the treatment of patients with PAF.

Methods

Data sources

Individual patient data for QDOT, ST and STSF were available from their respective prospective, multicenter, single-arm FDA IDE clinical trials (i.e., Q-FFICIENCY [NCT03775512], SMART-AF [NCT01385202] and SMART-SF [NCT02359890] trials). These trials have been previously published [7–9]. Briefly, all three trials enrolled adult patients with symptomatic PAF that were refractory to AADs, were followed for 12 months and were conducted in multiple centers in USA.

Q-FFICIENCY

The Q-FFICIENCY trial was a prospective, multi-center, non-randomized, pre-market IDE trial. The trial was conducted in 22 locations in USA, with a duration of 12 months [7]. Key inclusion criteria were patients aged ≥18 years and have symptomatic PAF with at least one electrocardiographically documented AF episode within 6 months prior to enrollment, as well as a physician's note indicating recurrent, self-terminating AF within 7 days. Additionally, they have experienced prior AAD failure, as evidenced by recurrent symptomatic AF or intolerability/contraindication to AADs. Main exclusion criteria were prior surgical or catheter ablation for AF, left atrial (LA) thrombus and/or contraindication to anticoagulation.

SMART-AF

The SMART-AF trial was a prospective, multi-center, non-randomized, single-arm IDE trial. The trial was conducted in 21 locations in USA, with a duration of 12 months [8]. Patients were included in the trial if they met key inclusion criteria that is, aged ≥18 years and have experienced at least three AF episodes within 6 months of the study and one documented AF episode within 12 months of the study. Moreover, prior AADs failure also needed to be shown by repeated AF episodes. Patients were excluded from the study if they had a previous ablation for AF, amiodarone within 6 months of the study, cardiac surgery within the last 2 months, or history of blood clotting or bleeding abnormalities among others.

SMART-SF

The SMART-SF trial was a prospective, multi-center, non-randomized, single-arm IDE trial. The trial was conducted in 17 locations in USA, with a duration of 12 months for the extended effectiveness study [9]. Patients were included in the SMART-SF trial if they were ≥18 years of age and had symptomatic PAF with at least one documented AF episode within 1 year prior to enrollment, as well as a physician's note indicating recurrent, self-terminating AF among others. In addition, prior AAD failure was required, as evidenced by symptomatic AF or intolerability to AADs. Main exclusion criteria included previous surgical or catheter ablation for AF, amiodarone at any time in the 3 months of the study, any percutaneous coronary intervention, cardiac surgery or valvular cardiac surgical or percutaneous procedure within the past 2 months and contraindication to anticoagulation.

Outcomes

The primary outcome of interest for this analysis was total procedure time. Secondary outcomes included total fluoroscopy time, clinical success at 12 months and rhythm monitoring-adjusted recurrence. Outcomes were defined as follows:

Procedure time

Total time (in minutes) between the procedure start (first femoral puncture for Q-FFICIENCY trial, and first catheter insertion for SMART-AF and SMART-SF trials) and procedure end (last catheter removal).

Fluoroscopy time

Total duration (in minutes) for those who underwent fluoroscopy.

Clinical success at 12 months

Composite definition of AF/atrial flutter (AFL)/atrial tachyarrhythmias (AT) recurrence, defined as acute procedural failure, symptomatic AF/AFL/AT recurrence after the 3-month blanking period or one repeat ablation after the 3-month blanking period.

Rhythm monitoring-adjusted recurrence

Rate of symptomatic recurrence of AF, AFL, AT or atypical flutter after the 3-month blanking period. This was designed to address changes in recurrence rates due to variations in the frequency of monitoring in each trial (Appendix 1).

For Holter and transtelephonic monitor (TTM), all recurrence durations were ≥30 seconds and recurrence events had to be at least 24 hours apart (i.e., no multiple records in a single day).

Statistical analyses

QDOT was compared with the pooled ST/STSF population for the following outcomes: procedure time, fluoroscopy time, clinical success at 12 months and rhythm monitoring-adjusted recurrence. The per-protocol population from the Q-FFICIENCY trial (n = 166) and the primary effectiveness population from the SMART-AF trial (n = 114) were used to analyze all outcomes. For the SMART-SF trial, the modified intention-to-treat (mITT) population (n = 155) was used for procedure and fluoroscopy time analyses and the effectiveness population (n = 78) was used to analyze clinical success at 12 months and rhythm monitoring-adjusted recurrence.

To mitigate bias when comparing patients from the QFFICIENCY, SMART-AF and SMART-SF trials, differences in baseline characteristics between study cohorts were reduced by reweighting patients using IPTW [10]. That is, patients in the SMART-AF and SMART-SF trials with similar characteristics as patients in the Q-FFICIENCY trial were assigned larger weights, thereby aligning the pooled SMART-AF and SMART-SF population to the population of the Q-FFICIENCY trial. The impact of patient reweighting on the sample size was expressed as an effective sample size (ESS), where an ESS lower than the original sample size reflects large differences in the study cohorts before reweighting [11]. The baseline characteristics that were used for this adjustment were identified and ranked using a rigorous process that considered both prognostic strength and cross-trial differences. Details on the IPTW and factor ranking processes are provided in Appendix 1 & 2.

Detailed methods for calculating comparative estimates are presented in Appendix 1. Results for procedure time and fluoroscopy time are reported as ratios of means (RoM) and 95% confidence intervals (CI), clinical success at 12 months is reported as a hazard ratio (HR) and 95% CI, and rhythm monitoring-adjusted recurrence is reported as a rate ratio (RR) and 95% CI. Details on monitoring techniques for each study and the strategies used to reduce the impact of the differences are provided in Appendix 1.

Scenario, sensitivity & subgroup analyses

For each outcome, scenario analyses were conducted to assess the impact of adjusting for fewer factors in the analyses on the comparative effectiveness estimates and the ESS. This process involved dropping factors from adjustment one at a time in the order of least to most important, as identified during the ranking procedure.

Sensitivity analyses comparing QDOT to ST and to STSF independently were conducted. Subgroup analyses were performed to examine the influence of modes of delivery, very high power for very short durations (QMODE+) and more standard delivery mode (QMODE) on outcomes. For comparative effectiveness and efficiency, patients who received QMODE+ only for PVI (n = 91) were investigated in subgroup analyses. For procedure time, an additional subgroup analysis was done including patients who received QMODE+ only (n = 59) and those who used QMODE+ and QMODE combined (n = 107). The selection of patients for subgroup analysis is presented in Appendix 3.

Results

Patient population & population adjustment

A total of 166 patients from the Q-FFICIENCY trial were included in analyses for procedure time, clinical success at 12 months and rhythm monitoring-adjusted recurrence. A total of 269 patients from the pooled SMART-

AF/SMART-SF trials were included in the procedure time analysis, and 192 patients in clinical success and rhythm monitoring-adjusted recurrence analyses. For the fluoroscopy time analyses, 30 patients (18%) from the Q-FFICIENCY trial, 0 patients from the SMART-AF trial and 6 patients (4%) from the SMART-SF trial were excluded because they underwent ablation without fluoroscopy, resulting in 136 patients from the Q-FFICIENCY trial and 263 patients from the pooled SMART-AF/SMART-SF trials.

Before IPTW was performed for the efficiency analyses, differences between the Q-FFICIENCY trial and pooled SMART-AF/SMART-SF trials were observed for the following baseline characteristics: race, thromboembolic event, other arrhythmia, hypertension, ethnicity, diabetes, sex and ablation procedure (Table 1, Appendix 4–6). After IPTW, these characteristics showed improved balance between trials. Similarly, for the effectiveness analyses, differences observed in race, other arrhythmia, hypertension, ethnicity, diabetes and sex before IPTW showed improvements in balance after IPTW. After adjusting for all considered prognostic factors, the ESS for the pooled SMART-AF/SMART-SF cohort was not substantially reduced.

Comparative efficiency & effectiveness results

Procedure time

Results from the main analysis showed that QDOT was associated with a significantly shorter mean procedure time (144.26 minutes) than pooled ST/STSF before and after IPTW (197.47 minutes and 200.89 minutes, respectively). Before IPTW, QDOT showed a 27% reduction in procedure time compared with pooled ST/STSF (RoM: 0.73, 95% CI: 0.68–0.79) (Table 2). Similarly, after IPTW, QDOT showed a 28% reduction in procedure time compared with pooled ST/STSF (RoM: 0.72, 95% CI: 0.66–0.78) (Table 2). Results were consistent in scenario (Appendix 7) and sensitivity analyses (Table 2). QDOT was also associated with a significantly shorter procedure time than pooled ST/STSF in the subgroup analyses of QMODE+ for PVI (RoM: 0.62, 95% CI: 0.56–0.69), combined QMODE+ and QMODE (RoM: 0.79, 95% CI: 0.72–0.86), and QMODE+ Only (RoM: 0.59, 95% CI: 0.52–0.66) (Table 2).

Fluoroscopy time

Results from the main analysis showed that QDOT was associated with a significantly shorter mean fluoroscopy time (13.11 minutes) than pooled ST/STSF before and after IPTW (28.59 minutes and 28.84 minutes, respectively). Before IPTW, QDOT showed a 54% reduction in fluoroscopy time compared with pooled ST/STSF (RoM: 0.46, 95% CI: 0.39–0.54) (Table 2). Similarly, after IPTW, QDOT showed a 55% reduction in fluoroscopy time compared with pooled ST/STSF (RoM: 0.45, 95% CI: 0.38–0.54) (Table 2). Results were consistent in the scenario (Appendix 8) and sensitivity analyses (Table 2). QDOT was also associated with a significantly shorter fluoroscopy time than pooled ST/STSF in the subgroup analysis of QMODE+ for PVI (RoM: 0.34, 95% CI: 0.27–0.43) (Table 2).

Clinical success at 12 months

Results from the main analysis showed that QDOT demonstrated similar clinical success at 12 months as pooled ST/STSF before and after IPTW. Before IPTW, QDOT showed a 34% higher clinical success rate at 12 months, but this result was not statistically significant (HR: 1.34, 95% CI: 0.84–2.14) (Table 3). Similar results were observed after IPTW (HR: 1.34, 95% CI: 0.82–2.19) (Table 3, Appendix 9). Results were consistent in scenario analyses (Appendix 10) and subgroup analyses for QMODE+ for PVI (HR: 1.74, 95% CI: 0.91–3.33) (Table 3). Since the results were not statistically significant and the proportional hazards assumption was not met ($P = 0.028$ from the Grambsch–Therneau test), the sensitivity analyses comparing them independently were not conducted.

Rhythm monitoring-adjusted recurrence

Results from the main analysis showed that QDOT was associated with a significant improvement in rhythm monitoring-adjusted recurrence compared with pooled ST/STSF before and after IPTW. Before IPTW, pooled ST/STF showed a 144% higher rate of recurrence than QDOT (RR: 2.44, 95% CI: 1.22–4.89) (Table 3). Similar results were observed after IPTW (RR: 2.44, 95% CI: 1.20–4.94) (Table 3). Results were consistent in the scenario (Appendix 11) and sensitivity analyses (Table 3). QDOT was also associated with a significant improvement in rhythm monitoring-adjusted recurrence compared with pooled ST/STSF in the subgroup analysis of QMODE+ for PVI (RR: 3.70, 95% CI: 1.33–10.28) (Table 3). Findings from all scenario and subgroup analyses were consistent with main analysis.

Table 1. Overview of baseline characteristics before and after IPTW by efficiency and effectiveness outcomes.

Characteristic	Categories	Procedure time			Fluoroscopy time			Clinical success at 12 months and rhythm monitoring-adjusted recurrence		
		Q-FFICIENCY	Pooled SMART-AF + SMART-SF		Q-FFICIENCY	Pooled SMART-AF + SMART-SF		Q-FFICIENCY	Pooled SMART-AF + SMART-SF	
			Before IPTW	After IPTW[¶]		Before IPTW	After IPTW[¶]		Before IPTW	After IPTW[¶]
		n = 166	n = 269	ESS = 169	n = 136	n = 263	ESS = 180	n = 166	n = 192	ESS = 142
Race, n (%)	Non-white White	18 (10.8) 148 (89.2)	10 (3.7) 259 (96.3)	20 (12.0) 149 (88.0)	14 (10.3) 122 (89.7)	10 (3.8) 253 (96.2)	20 (11.1) 160 (88.9)	18 (10.8) 148 (89.2)	9 (4.7) 183 (95.3)	15 (10.5) 127 (89.5)
Age in years, mean (SD)	–	63.16 (11.03)	60.68 (10.72)	62.55 (10.53)	63.17 (11.37)	60.57 (10.75)	62.72 (10.47)	63.16 (11.03)	60.77 (10.95)	62.60 (10.86)
Thromboembolic event - composite[†], n (%)	Yes No	18 (10.8) 148 (89.2)	16 (5.9) 253 (94.1)	18 (10.6) 151 (89.4)	15 (11.0) 121 (89.0)	16 (6.1) 247 (93.9)	19 (10.5) 161 (89.5)	18 (10.8) 148 (89.2)	13 (6.8) 179 (93.2)	13 (8.9) 129 (91.1)
Other arrhythmia - composite[‡], n (%)	Yes No	44 (26.5) 122 (73.5)	94 (34.9) 175 (65.1)	40 (23.7) 129 (76.3)	38 (27.9) 98 (72.1)	92 (35.0) 171 (65.0)	46 (25.3) 134 (74.7)	44 (26.5) 122 (73.5)	69 (35.9) 123 (64.1)	34 (24.1) 108 (75.9)
Hypertension, n (%)	Yes No	115 (69.3) 51 (30.7)	158 (58.7) 111 (41.3)	117 (69.4) 52 (30.6)	93 (68.4) 43 (31.6)	154 (58.6) 109 (41.4)	123 (68.5) 57 (31.5)	115 (69.3) 51 (30.7)	116 (60.4) 76 (39.6)	99 (69.5) 43 (30.5)
Ethnicity, n (%)	Hispanic/Latino Not Hispanic/Latino; NR	6 (3.6) 160 (96.4)	4 (1.5) 265 (98.5)	7 (3.9) 162 (96.1)	3 (2.2) 133 (97.8)	4 (1.5) 259 (98.5)	4 (2.3) 176 (97.7)	6 (3.6) 160 (96.4)	4 (2.1) 188 (97.9)	5 (3.8) 137 (96.2)
LA diameter, mean (SD)	–	38.19 (5.93)	38.66 (5.76)	38.23 (5.81)	38.36 (6.18)	38.60 (5.77)	38.31 (5.78)	38.19 (5.93)	38.40 (5.84)	38.16 (5.89)
Diabetes, n (%)	Yes No	33 (19.9) 133 (80.1)	35 (13.0) 234 (87.0)	34 (20.4) 135 (79.6)	26 (19.1) 110 (80.9)	33 (12.5) 230 (87.5)	35 (19.3) 145 (80.7)	33 (19.9) 133 (80.1)	25 (13.0) 167 (87.0)	30 (20.8) 112 (79.2)
Sex, n (%)	Female Male	65 (39.2) 101 (60.8)	93 (34.6) 176 (65.4)	66 (39.1) 103 (60.9)	53 (39.0) 83 (61.0)	90 (34.2) 173 (65.8)	72 (40.1) 108 (59.9)	65 (39.2) 101 (60.8)	68 (35.4) 124 (64.6)	54 (38.0) 88 (62.0)
Heart disease - composite[§], n (%)	Yes No	15 (9.0) 151 (91.0)	20 (7.4) 249 (92.6)	12 (7.1) 157 (92.9)	12 (8.8) 124 (91.2)	19 (7.2) 244 (92.8)	14 (8.0) 166 (92.0)	15 (9.0) 151 (91.0)	14 (7.3) 178 (92.7)	11 (7.4) 131 (92.6)
Left ventricular ejection fraction, mean (SD)	–	59.69 (7.00)	59.69 (7.00)	59.53 (7.17)	60.39 (7.27)	59.97 (7.32)	60.24 (7.28)	59.69 (7.00)	59.76 (7.39)	59.62 (7.32)
Ablation procedure within 1 year prior to enrollment, n (%)	Yes No	3 (1.8) 163 (98.2)	10 (3.7) 259 (96.3)	3 (1.7) 166 (98.3)	3 (2.2) 133 (97.8)	10 (3.8) 253 (96.2)	4 (2.0) 176 (98.0)	3 (1.8) 163 (98.2)	7 (3.6) 185 (96.4)	2 (1.7) 140 (98.3)
Duration of symptomatic AF in months, mean (SD)	–	51.94 (77.11)	54.45 (65.02)	55.06 (62.78)	49.15 (72.95)	55.39 (65.44)	52.66 (59.30)	51.94 (77.11)	55.93 (60.92)	54.42 (59.50)

[†]Thromboembolic event – composite included the following: transient ischemic attack, stroke/cerebrovascular event secondary to thromboembolism, deep vein thrombosis, pulmonary embolus and other.
[‡]Other arrhythmia – composite included the following: left/right atrial tachycardia, AV node re-entry tachycardia, ventricular tachycardia and atrial flutter/atypical atrial flutter.
[§]Heart disease – composite included the following: congestive heart failure, left ventricular hypertrophy, non-ischemic cardiomyopathy and significant valve disease.
[¶]Adjusted for all available ranked factors; race (non-white), age, thromboembolic event (composite), other arrhythmia (composite), hypertension, ethnicity (Hispanic/Latino), left atria diameter, diabetes, sex (female), heart disease (composite), left ventricular ejection fraction, ablation procedure within 1 year prior to enrollment and duration of symptomatic AF in months.
AF: Atrial fibrillation; AV: Atrioventricular; ESS: Effective sample size; LA: Left atrial; SD: Standard deviation.

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Table 2. Procedure time and fluoroscopy time before and after IPTW.

	Before IPTW			After IPTW		
	Average time (minutes)		Ratio of means (95% CI)	Average time (minutes)		Ratio of means (95% CI)
	QDOT	Comparator		QDOT	Comparator	
Procedure time						
QDOT vs Pooled ST/STSF	144.26	197.47	0.73 (0.68, 0.79)	144.26	200.89	0.72 (0.66, 0.78)
Sensitivity:						
QDOT vs ST	144.26	218.79	0.66 (0.60, 0.72)	144.26	214.30	0.67 (0.59, 0.77)
QDOT vs STSF	144.26	181.79	0.79 (0.73, 0.86)	144.26	191.27	0.75 (0.67, 0.85)
Subgroup:						
QMODE+ for PVI vs Pooled ST/STSF	126.18	197.47	0.64 (0.59, 0.70)	126.18	204.13	0.62 (0.56, 0.69)
QMODE+ and QMODE vs Pooled ST/STSF	156.38	197.97	0.79 (0.73, 0.86)	156.38	197.97	0.79 (0.72, 0.86)
QMODE+ Only vs Pooled ST/STSF	122.27	197.26	0.62 (0.57, 0.67)	122.27	207.29	0.59 (0.52, 0.66)
Fluoroscopy time						
QDOT vs Pooled ST/STSF	13.11	28.59	0.46 (0.39, 0.54)	13.11	28.84	0.45 (0.38, 0.54)
Sensitivity:						
QDOT vs ST	13.11	40.28	0.33 (0.27, 0.39)	13.11	41.35	0.32 (0.26, 0.39)
QDOT vs STSF	13.11	19.65	0.67 (0.56, 0.79)	13.11	21.02	0.62 (0.51, 0.77)
Subgroup:						
QMODE+ for PVI vs Pooled ST/STSF	10.30	28.59	0.35 (0.28, 0.43)	10.30	29.24	0.34 (0.27, 0.43)

Ratio of means <1 indicates shorter time for QDOT.
CI: Confidence interval; IPTW: Inverse probability treatment weighting; PVI: Pulmonary vein isolation; ST: SmartTouch™; STSF: SmartTouch® Surround Flow.

Table 3. Clinical success at 12 months and rhythm monitoring-adjusted recurrence before and after IPTW.

	Before IPTW	After IPTW
Clinical success at 12 months	**Hazard ratio (95% CI)**	**Hazard ratio (95% CI)**
QDOT vs pooled ST/STSF	1.34 (0.84, 2.14)	1.34 (0.82, 2.19)
Subgroup:		
QMODE+ for PVI vs Pooled ST/STSF	1.66 (0.90, 3.04)	1.74 (0.91, 3.33)
Rhythm monitoring-adjusted recurrence	**Rate ratio (95% CI)**	**Rate ratio (95% CI)**
Pooled ST/STSF	2.44 (1.22, 4.89)	2.44 (1.20, 4.94)
Sensitivity:		
QDOT vs ST	2.24 (1.07, 4.67)	1.95 (1.00, 3.79)
QDOT vs STSF	3.17 (1.18, 8.54)	2.37 (1.07, 5.27)
Subgroup:		
QMODE+ for PVI vs Pooled ST/STSF	3.83 (1.51, 9.70)	3.70 (1.33, 10.28)

Hazard/rate ratio >1 indicates increased success / decrease in rhythm monitoring-adjusted recurrence for QDOT.
CI: Confidence interval; IPTW: Inverse probability treatment weighting; PVI: Pulmonary vein isolation; ST: SmartTouch™; STSF: SmartTouch® Surround Flow.

Discussion

QDOT MICRO, a novel contact force sensing, irrigated, RF catheter, demonstrated improved efficiency, improved rhythm monitoring-adjusted recurrence, and similar effectiveness in clinical success at 12 months compared with pooled ST/STSF. QDOT was associated with a significantly shorter mean procedure and fluoroscopy times compared with pooled ST/STSF. Although clinical success at 12 months did not show a statistical difference between QDOT and pooled ST/STSF, QDOT was associated with a significant improvement in rhythm monitoring-adjusted recurrence compared with pooled ST/STSF. The scenario and sensitivity analyses supported these findings. Similar results were observed in the subgroup analyses of QMODE+ patients. The current study adds to the growing body of evidence that high-power, short-duration ablation is associated with improved efficiency and effectiveness of AF ablation [12–15]. Notably, QDOT's two ablation modes, QMODE and QMODE+, provide the option of toggling between a conventional power/temperature controlled setting and very high-power setting of 90 W during the procedure. This versatility of the QDOT catheter gives operators the flexibility to adapt the RF application to specific cardiac anatomies to improve outcomes while optimizing their workflows [7].

QDOT data used in this study represents the initial results for investigators who had no previous experience with the new QDOT catheter [7]. The learning curves of operators improve over time, and procedural efficiencies and effectiveness may further improve once the catheter is widely used in routine clinical practice. A recent QDOT study reported 89% first-pass isolation with no complications using the very high-power short-duration ablation mode [7]. This lends support to our study.

The clinical trials used to inform the current analysis varied in the failure modes used to define clinical success at 12 months. Specifically, acute procedural failure, AF/AFL/AT symptomatic recurrence within 91–365 days post-index procedure, and repeat ablation after the three-month blanking period were common in all three trials, whereas initiation of AADs after the blanking period was included in the Q-FFICIENCY and SMART-AF trials but not SMART-SF. Because variation in the outcome definition makes it difficult to compare trials and interpret findings, the composite end point of clinical success at 12 months in this study was defined as acute procedural failure, symptomatic recurrence event after the 3-month blanking period or repeat ablation after the 3-month blanking period. Failure modes not included in all three clinical trials were excluded in the current study's composite clinical success end point.

Several PAF ablation trials use different study designs, including thoroughness of AF detection protocols. Comparing success rates of AF ablation technologies and devices that are derived from such studies should be done with caution and after careful review of the differences in study design [16]. Evidence suggests that an increase in either frequency or intensity of monitoring results in increased detection of arrhythmia [17–21]. Thus, to address differences in monitoring encounters that may have missed atrial arrhythmia recurrence events, analyses were conducted to predict observed atrial arrhythmia recurrence events in the SMART-AF and SMART-SF studies through standardizing the number of monitoring encounters to those in Q-FFICIENCY, using well established methods [22]. To our knowledge, this is the first study to minimize the differences in rhythm monitoring frequency between studies to assess recurrence post-ablation.

The use of QDOT to treat AF showed improvement in efficiency and effectiveness compared with ST and STSF. QDOT allows delivery of very high-power short-duration ablation (90 W over 4 seconds) to achieve optimal lesion, thereby reducing procedure time and PV reconnections [23,24]. The shorter ablation time using QDOT can potentially lead to reduced healthcare utilization with lower use of anesthesia, radiation, nursing and facility time [25,26]. These time savings may facilitate more procedures being done and lead to overall efficiency in delivery of care [25].

This study was conducted using rigorous methods based on guidance from UK National Institute for Health and Care Excellence [22]. A major strength of the study was that prognostic factors were identified *a priori* and rank ordered using a data-driven approach. The use of individual patient data permitted reweighting of patients to minimize differences in patient baseline characteristics across trials and rederivation the clinical success at 12 months end point to reduce bias. Furthermore, differences in monitoring frequency across trials were adjusted to minimize confounding when examining atrial arrhythmia recurrence. However, the validity of relative treatment effects from unanchored ITCs depends on the balance of all observable and unobservable clinically relevant prognostic factors and treatment effect modifiers; an assumption that is generally considered difficult to meet [11]. Despite a wide range of prognostic variables adjusted for in the comparative analysis, as in any unanchored ITC, residual confounding cannot be excluded, representing a notable limitation of this analysis.

Conclusion

The current study demonstrates that temperature-controlled ablation with QDOT was associated with greater efficiency, greater effectiveness in rhythm monitoring-adjusted recurrence, and similar effectiveness in clinical success at 12 months compared with pooled ST/STSF, with significant reductions in procedure time, fluoroscopy time and rhythm monitoring-adjusted recurrence. These benefits were observed with use of both of QDOT's ablation modes, highlighting the versatility of the QDOT catheter and the flexibility it gives operators to adapt the RF application to specific cardiac anatomies to improve outcomes while optimizing their workflows.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: https://bpl-prod.literatumonline.com/doi/10.57264/cer-2023-0005

Author contributions

All authors were responsible for study conception and design. P Spin was responsible for acquisition, analysis, and interpretation of data. L Patel was responsible for drafting the manuscript, and all authors were responsible for revising the manuscript critically. All authors agree to be held accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part are appropriately investigated and resolved.

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Data sharing statement

The authors certify that this manuscript reports the secondary analysis of clinical trial data that have been shared with them, and that the use of this shared data is in accordance with the terms agreed upon their receipt. Data were provided by Biosense Webster.

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Summary points

- Atrial fibrillation (AF) is the most common type of cardiac arrhythmia.
- The Thermocool® SmartTouch™ (ST) and Thermocool® SmartTouch® Surround Flow (STSF) catheters are the latest generation irrigated radiofrequency (RF) ablation catheters used in the treatment of AF.
- The QDOT MICRO™ (QDOT) catheter is a next-generation of contact force sensing, irrigated, RF catheter that is designed to facilitate temperature-controlled and very high-powered short-duration ablation.
- In the absence of direct, head-to-head comparative studies, indirect treatment comparison methods that adjust for differences in study patient cohorts, such as inverse probability treatment weighting (IPTW), can be used.
- Individual patient data for QDOT, ST, and STSF were available from their respective prospective, multicenter, single-arm US FDA investigational device exemption (IDE) clinical trials.
- QDOT was compared with the pooled ST/STSF population for the following outcomes: procedure time, fluoroscopy time, clinical success at 12 months and rhythm monitoring-adjusted recurrence.
- To mitigate bias when comparing patients from the Q-FFICIENCY, SMART-AF, and SMART-SF trials, differences in baseline characteristics between study cohorts were reduced by reweighting patients using IPTW.
- This study demonstrates that temperature-controlled ablation with QDOT was associated with greater efficiency, greater effectiveness in rhythm monitoring-adjusted recurrence and similar effectiveness in clinical success at 12 months compared with pooled ST/STSF, with significant reductions in procedure time (ratio of means [RoM]: 0.72, 95% CI: 0.66–0.78), fluoroscopy time (RoM: 0.45, 95% CI: 0.38–0.54), and rhythm monitoring-adjusted recurrence (rate ratio [RR]: 2.44, 95% CI: 1.20–4.94).

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