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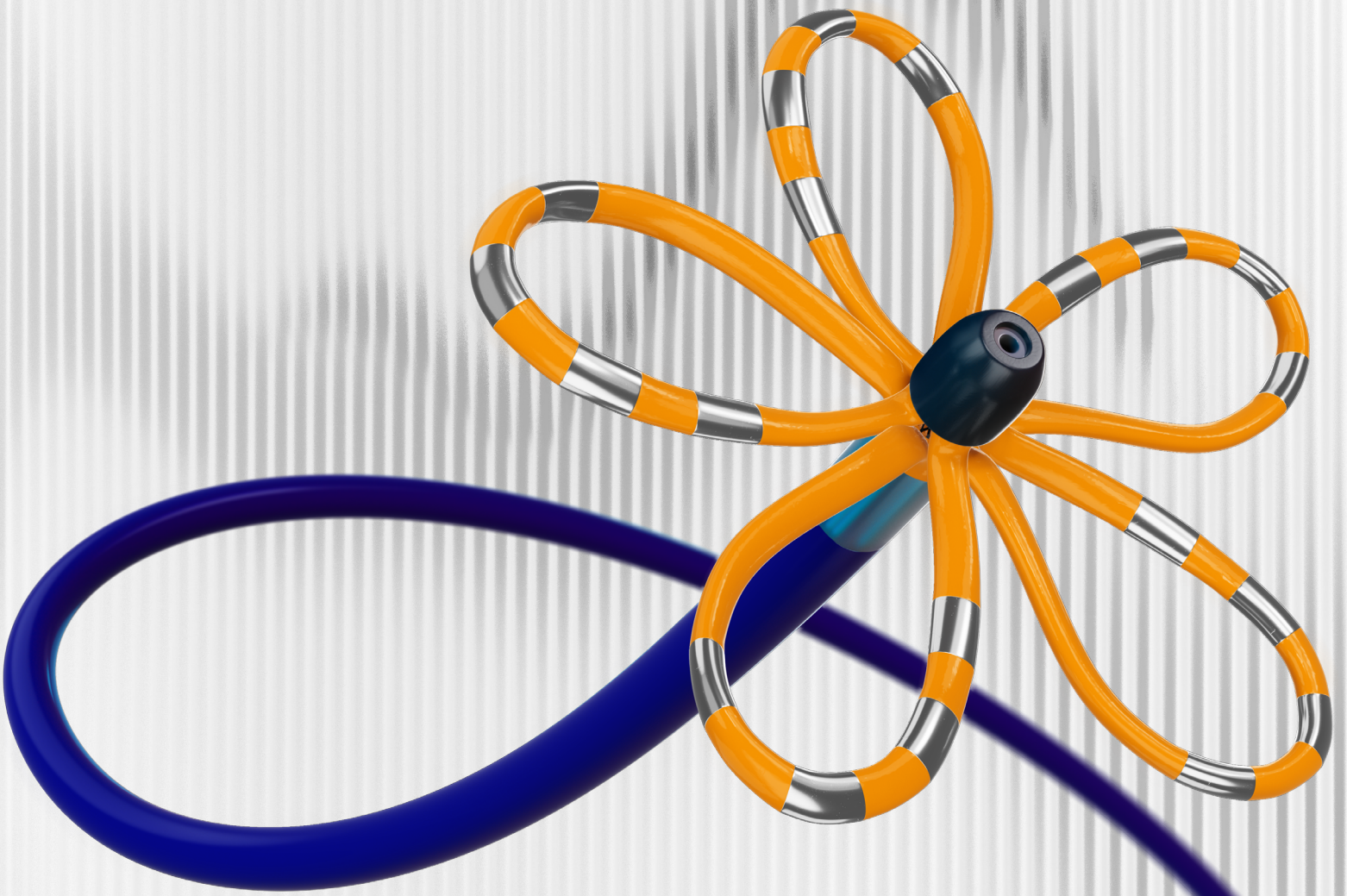
ADVENT
PIVOTAL TRIAL

Recurrent Atrial Arrhythmia Burden



FARAPULSE™
Pulsed Field Ablation System

ADVENT US IDE Clinical Trial Results

Recurrent Atrial Arrhythmia Burden

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OBJECTIVE

- The ADVENT Pivotal Trial compared FARAPULSE™ Pulsed Field Ablation (PFA) to standard-of-care thermal ablation devices (force-sensing radiofrequency (RFA) or cryoballoon ablation (CBA)) and found no significant difference in 1-year freedom from atrial arrhythmias (AA) between groups.
- There is recent evidence that indicated post-ablation AA burden is a better predictor of clinical outcomes than the standard 30-second definition, so the recurrent AA burden was assessed to determine if it[1,2]:
  - Impacted quality of life
  - Impacted healthcare utilization
  - Differed between ablation modalities

METHODS

- During ADVENT, post-ablation transtelephonic ECG monitoring (TTM) was collected weekly and for symptomatic episodes and 72-hour Holters were collected at 6- and 12-months.
- The TTM and Holter data was used to calculate the AA burden. Total AA burden was estimated by the greater of 2 values:
  1) % AA over total duration of Holter data or
  2) % of weeks of TTM with AA over total # of weeks with TTMs recorded
- Quality of life was assessed at baseline and 12-months.
- This sub-analysis included 593 (97.7%) patients.

ATRIAL ARRHYTHMIA BURDEN SUMMARY

- There was good overall compliance for weekly TTMs (67.5%) and 72-hour Holter monitoring (81.3%)[1].
- There was an average of 27 weeks of TTM from 589 patients and 61,841 hours of Holter recordings from 539 patients (average of 114.7 hours/patient).
- Most patients (465 (78.4%)) had an AA burden of <0.1%, which averaged to <1.4 minutes of AA/day.
- The aggregate patients with residual AA burden exceeding 10% was 47 (7.9%).

ATRIAL ARRHYTHMIA BURDEN, QUALITY OF LIFE

- Quality-of-life (QoL) AFEQT assessments were available from 287 PFA and 282 thermal patients.
- The aggregate data of both PFA and thermal patients was grouped by <0.1%, 0.1-9.9% and ≥10% post-ablation AA burden.
- There was a significant ($p < 0.035$) improvement in QoL, post-ablation, regardless of AA burden.
- **There was a significantly ($p < 0.001$) greater QoL improvement in patients with AA burden <0.1% versus ≥10%.**

ATRIAL ARRHYTHMIA BURDEN, CLINICAL INTERVENTIONS

- Clinical interventions were classified as redo ablations, cardioversions or hospitalizations.
- There was a low number of clinical interventions in the <0.1% AA burden patient cohort with a significant ($p < 0.001$) increase in frequency as AA burden increased.
- **There was a significantly ($p < 0.001$) lower risk for redo ablation, cardioversion and hospitalization with AA burden <0.1% vs. ≥0.1% (Table 1).**
- This data is consistent with other studies[3,4] that patients with AA burden above 0.1% can expect significantly worse QoL and an increased need for clinical interventions.

Table 1	AA Burden		
	<0.1%	0.1-9.9%	≥10%
Redo Ablations	0.86%	11.1%	38.3%
Cardioversions	0.65%	9.9%	17.0%
Hospitalizations	1.72%	14.8%	42.6%

Recurrent Atrial Arrhythmia Burden

ATRIAL ARRHYTHMIA BURDEN, ABLATION MODALITY

- To assess the difference in ablation modality a threshold of 0.1% AA burden was used.
- **There was a significant (p=0.04) difference in AA burden between PFA, RFA and CBA with patients treated with PFA being more likely to have an AA burden <0.1% than patients treated with RFA or CBA (Figure 1).**
- When AA burden between PFA and thermal was evaluated based on patient demographics, the only variable to show a significant (p=0.002) difference in AA burden <0.1% was type of prior failed AAD(s).
- Patients with prior failed Class I/III AADs pre-ablation were more likely to have an AA burden <0.1% with PFA compared to thermal ablation. Class II/IV failed patients had no significant difference between ablation groups.

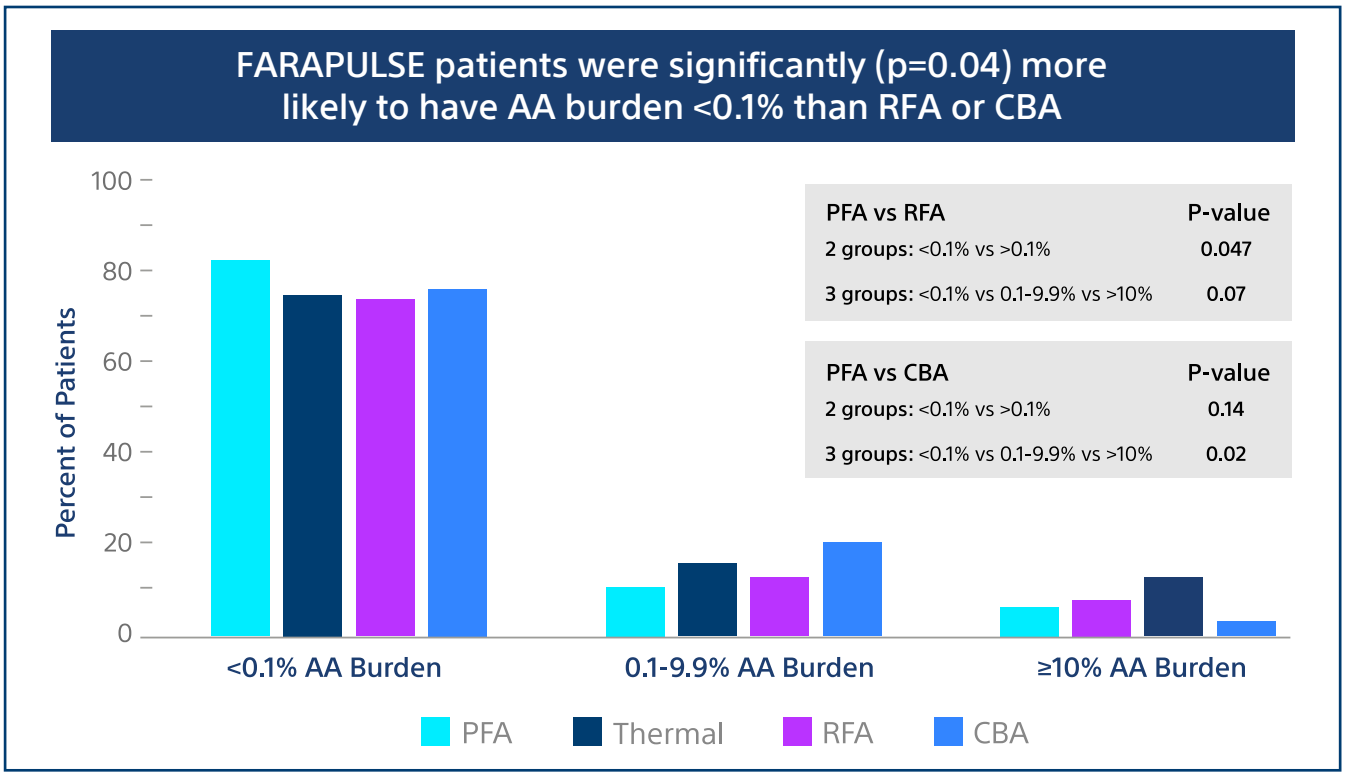

Figure 1. Post-Ablation Atrial Arrhythmia Burden Threshold of 0.1% by Ablation Modality.

CONCLUSIONS

- There was a significantly greater QoL improvement in patients with AA burden <0.1% (p=0.04) and an increased risk for redo ablation, cardioversion and hospitalization in patients with >0.1% AA burden ($p < 0.001$).
- Patients treated with FARAPULSE had a significantly (p=0.04) greater reduction in AA burden (<0.1%) than patients treated with RFA or CBA which was found to be a clinically meaningful threshold in regards to patient-oriented clinical outcomes such as quality of life and healthcare utilization.[3]

1. Reddy VY, Gerstenfeld EP, Natale A, et al., Pulsed field or conventional thermal ablation for paroxysmal atrial fibrillation. *New England Journal of Medicine*. 2023;Nov2;389(18):1660-1671. doi:10.1056/NEJMoa2307291
2. Reddy V, Mansour M, Calkins H. et al., Pulsed Field vs Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation: Recurrent Atrial Arrhythmia Burden. *J Am Coll Cardiol*. null2024, 0 (0). https://doi.org/10.1016/j.jacc.2024.05.001
3. Andrade JG, Deyell MW, Macle L, et al. Healthcare utilization and quality of life for atrial fibrillation burden: the CIRCA-DOSE study. Eur Heart J. 2023;44:765-776. doi: 10.1093/eurheartj/ehac692
4. Verma A, Haines DE, Boersma LV, et al. Influence of monitoring and atrial arrhythmia burden on quality of life and health care utilization in patients undergoing pulsed field ablation: A secondary analysis of the PULSED AF trial. Heart Rhythm. 2023;20:1238-1245. doi: 10.1016/j.hrthm.2023.05.018

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