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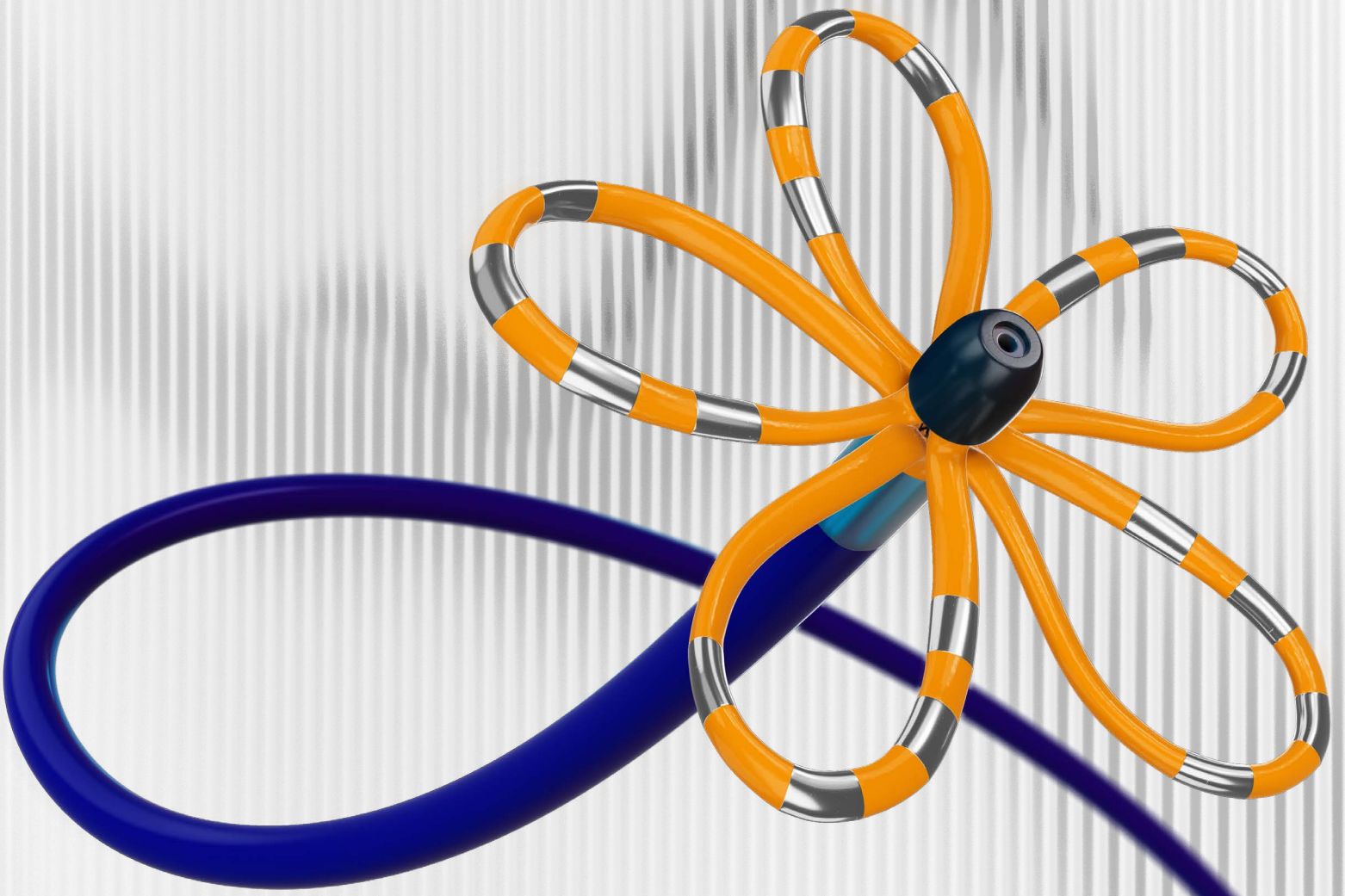
ADVENT
PIVOTAL TRIAL

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 improvement in QoL, post-ablation, regardless of AA burden.
- **There was a significantly 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 increase in frequency as AA burden increased.
- **There was a significantly 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 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 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 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.

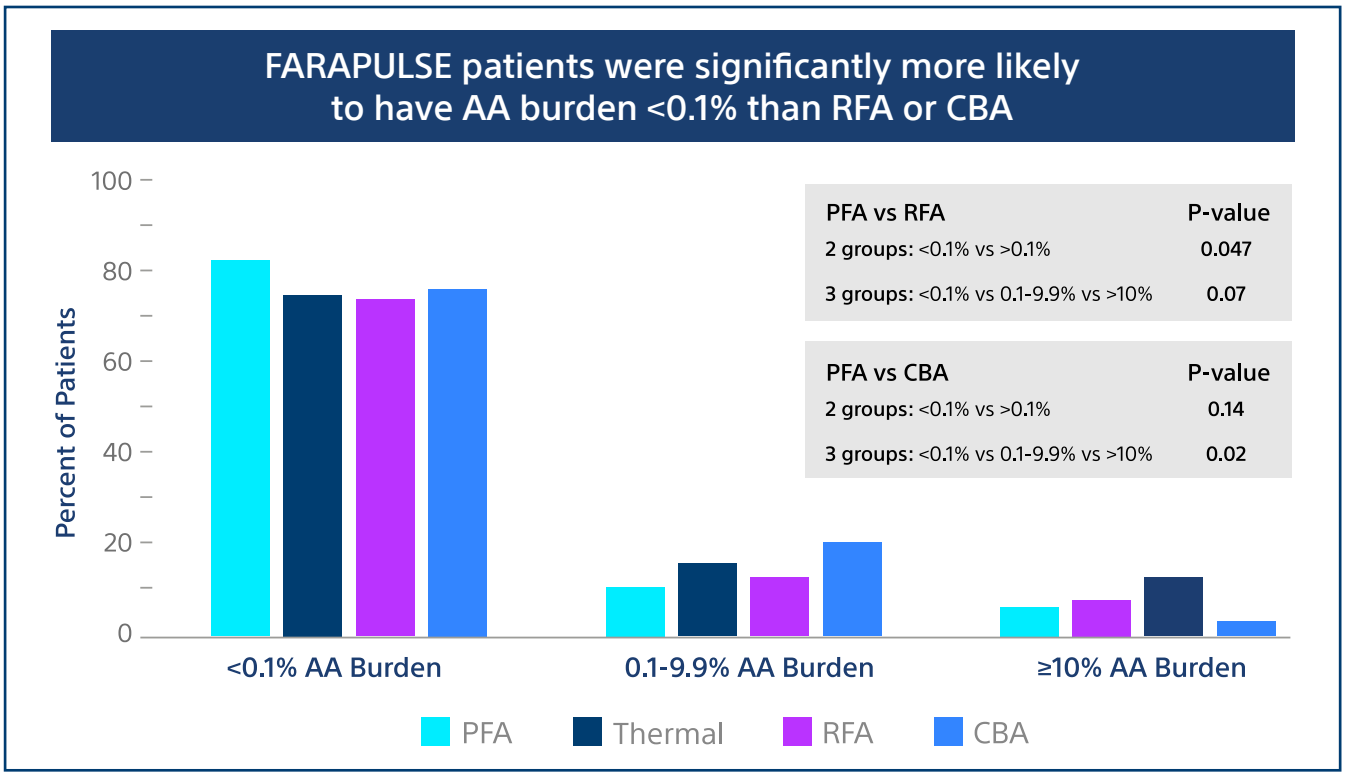

Figure 1. Post-Ablation Atrial Arrhythmia Burden Threshold of 0.1% by Ablation Modality.

CONCLUSIONS

- There was a significantly greater QoL improvement in patients with AA burden <0.1% and an increased risk for redo ablation, cardioversion and hospitalization in patients with >0.1% AA burden.
- Patients treated with FARAPULSE had a significantly greater reduction in AA burden (<0.1%) than patients treated with RFA or CBA which was found to be a clinically meaningful threshold.

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

FARAPULSE™ Pulsed Field Ablation
Indications, Safety, and Warnings

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