Journal of Medical Economics

ISSN: 1369-6998 (Print) 1941-837X (Online) Journal homepage: www.tandfonline.com/journals/ijme20

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To cite this article: Petr Neužil, Angel Ferrero de Loma-Osorio, Ángel Martínez Brotons, Lourdes Bondanza Saavedra, Davide A. Mei, Petr Moučka, Steffen Uffenorde, Jaime Vieira Ruiz & Giuseppe Boriani (2025) Cost-consequence analysis of three cardiac ablation technologies in paroxysmal atrial fibrillation, Journal of Medical Economics, 28:1, 1826-1839, DOI: 10.1080/13696998.2025.2575460

To link to this article: https://doi.org/10.1080/13696998.2025.2575460

JOURNAL OF MEDICAL ECONOMICS
2025, VOL. 28, NO. 1, 1826–1839
https://doi.org/10.1080/13696998.2025.2575460
Article /2575460

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Cost-consequence analysis of three cardiac ablation technologies in paroxysmal atrial fibrillation

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ABSTRACT

Background and aim: The rapid evolution of catheter ablation technologies has introduced variability in clinical outcomes, procedural efficiency, and costs. This study aimed to evaluate the economic costs and clinical outcomes associated with radiofrequency ablation (RFA), cryoablation (CRYO), and pulsed field ablation (PFA) for the treatment of paroxysmal atrial fibrillation (AF).

Methods: A cost-consequence analytical model was developed to assess the economic impact and clinical outcomes of three treatment alternatives for adult patients with paroxysmal AF, from the hospital's perspective, in the short (index hospitalization) and medium-term (1 year). Real-world data were collected across three European specialty centers (Czech Republic, Italy, and Spain). The collected data captured procedural durations (including pre-procedural, skin-to-skin, and post-procedural phases), resource consumption, and staff workload. Costs were retrieved from institutional economic databases and published cost repositories. Costs were expressed in Euro (2025). Medium-term outcomes (complications, reinterventions, hospitalizations, cardioversions) were sourced from literature.

Results: A total of $N = 270$ patients were included in the analysis. PFA was associated with consistency and predictable procedure duration compared to the other treatment alternatives. This efficiency may support increased capacity within the healthcare systems. PFA demonstrated cost saving of 10% compared to CRYO and 22% compared to RFA procedures, primarily driven by procedure time. Additionally, PFA showed a cost per responder of €2,406, versus €2,873 for CRYO (+19%) and €3,436 for RFA (+43%), reflecting both lower procedural costs and superior clinical outcomes.

Conclusion: These findings suggest that PFA technology may offer economic and operational advantages, including more efficient resource utilization, reduced procedural complexity and consumables use, compared to traditional ablation modalities. However, variations in hospital clinical practices may limit the generalizability of results.

ARTICLE HISTORY
Received 29 August 2025
Revised 25 September 2025
Accepted 6 October 2025

KEYWORDS
Atrial fibrillation; pulsed field ablation; cryoablation; radiofrequency ablation; economic evaluation

Introduction

Paroxysmal atrial fibrillation (AF) is a common subtype of AF, characterized by self-terminating episodes that typically last less than seven days. AF is the most common cardiac arrhythmia, affecting 1.5–2% of European adults, with an anticipated surge to 9.5% in individuals aged over 65 by 2060[1]. Epidemiological studies show that globally in 2021 there were 4.48 million incident cases of atrial fibrillation[2]. Among 9,816 eligible patients from 831 sites in 26 countries, 26.5% had paroxysmal, 23.8% had

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Supplemental data for this article is available online at https://doi.org/10.1080/13696998.2025.2575460.

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persistent, and 49.6% had permanent AF[3]. As a primary contributor to stroke, dementia, heart failure, and premature mortality, AF constitutes a significant threat to the expanding elderly demographic and healthcare systems and carries important use of economic resources[1,4]. This growing burden underscores the need for effective and sustainable treatment strategies[5].

Catheter ablation has become a cornerstone in the rhythm control strategy for AF, preventing AF recurrences, reducing AF burden, and improving quality of life in symptomatic paroxysmal or persistent AF where the patient is intolerant or does not respond to antiarrhythmic drugs (AAD)[6–8]. However, the rapid evolution of ablation technologies—ranging from radiofrequency (RFA) and cryoballoon (CRYO) to pulsed field ablation (PFA)—has introduced variability in clinical outcomes, procedural efficiency, and healthcare costs[9].

In a previous study, we explored the procedural characteristics and costs associated with the three widely adopted ablation modalities across three European cohorts[10]. Model estimates indicate that these time savings result in cost savings for hospitals and reduce outlay on redo procedures[10]. Building upon those findings, the present study aims to provide a comprehensive evaluation of both economic implications and clinical outcomes associated with RFA, CRYO, and PFA in the treatment of paroxysmal AF in three additional European centers, with an expanded patient cohort (more than 250 vs 91 in the previous study).

This second part of this investigation aims to support clinical decision-making and healthcare policy by providing a cost-consequence analysis. It will report clinical effectiveness and associated costs over a 1-year time horizon for adult patients diagnosed with paroxysmal AF who have undergone pulmonary vein isolation (PVI) ablation, from the hospital's perspective. As ablation strategies continue to evolve, such data are important for optimizing patient care and ensuring sustainable healthcare delivery in a perspective of appropriate use of available resources and value-based health care[11,12].

Methods

Data collection and statistical analysis

Real-world data on procedural times and resource use for PVI in patients with paroxysmal AF were collected from three European medical centers. The procedures evaluated included use of PFA (FaraWave; Farapulse - Boston Scientific Inc, Marlborough, MA.), CRYO, and RFA. The participating centers were Na Homolce Hospital (Prague, Czech Republic), Azienda Ospedaliero-Universitaria Policlinico di Modena (Modena, Italy), and Hospital Clínico Universitario de Valencia (Valencia, Spain).

Eligible participants were adults ($\geq$18 years) diagnosed with paroxysmal AF and treated with PVI ablation. Specific inclusion and exclusion criteria are detailed in Supplementary Table 1. Each center selected the most recent patients who met the criteria, targeting a total of $N = 90$ patients per site (30 patients per ablation technique). The data provided by the three centers were collected on patients treated consecutively over a period from January 2024 to February 2025. Since CRYO is no longer used in Czech and Spanish centers, the data collected refer to the most recent prior of use (up to 2019). Only for Czech Republic, RFA data specifically pertain to treatments performed in 2021 (most recent period). Historical data was included to ensure a comprehensive analysis despite the current procedural practices. The collected data are listed in Supplementary Table 2, including general information, procedural time, staff workload, and other resource use. A total of $N = 270$ patients were included in the analysis, a sample size considered adequate to ensure statistical robustness and meaningful interpretation of results, while remaining feasible within the operational scope of the study. Data was drawn from the most recent period of use to enable a comprehensive comparison across treatment strategies, despite evolving clinical practices. In every center use of PFA, CRYO or RFA was left to usual practice and occurred before data collection. The protocols of the three ablation methods are described in the previous analysis[10]. The local ethics committees approved data collection for scientific purposes.

The primary objective of the statistical analysis was to evaluate potential differences in patient demographics and clinical characteristics across treatment groups. For continuous, normally distributed variables, one-way analysis of variance (ANOVA) was applied. When significant differences were detected,

Bonferroni-adjusted pairwise post-hoc comparisons were conducted to identify specific group differences. Categorical variables were analyzed using the chi-square test.

Sample size

Sample size calculations were conducted to determine the number of cases required to detect differences in procedure time between PFA and comparator technologies (CRYO and RFA). The primary endpoint guiding the sample size estimation was the mean difference in procedure time between PFA and the comparator arms. A mean difference of approximately 30 min was assumed for the PFA vs. CRYO comparison. For the PFA vs RFA comparison, the expected difference ranged from 40 to 100 min, resulting in substantially smaller required sample sizes.

Calculations were based on a one-sided significance level (α) of 0.025 and a power ($1-\beta$) of 0.90, assuming equal allocation between groups (1:1). Under these assumptions, a sample size of 79 cases was deemed sufficient to detect the expected difference in procedure time between PFA and CRYO. This sample size also provides adequate power for detecting differences in the PFA vs. RFA comparison.

Economic model

A cost-consequence model was designed to compare the resource use and associated costs of each of the three therapeutic options to treat paroxysmal AF: PFA, CRYO and RFA. The model adopts the hospital perspective, incorporating only those costs directly incurred by the healthcare facility. The analysis was conducted over a 1-year time horizon, capturing costs from the initial hospitalization through discharge, as well as any subsequent expenses related to complications, hospitalizations, or reinterventions. The study was conducted in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS 2022)[13].

Model structure and data sources

The model structure and data sources were thoroughly detailed in a previous analysis[10]. A decision-tree model was developed in Microsoft Excel, grounded in real-world procedural data. Patients entered the model upon undergoing one of the three ablation techniques: RFA, CRYO, or PFA. Following the procedure (short-term), patients were categorized based on the occurrence of complications within the following year (medium-term). Subsequently, in the medium-term analysis, they were further divided into those requiring a repeat ablation due to recurrent paroxysmal AF and those who did not. Patients undergoing reintervention were assumed to face an additional risk of complications.

Input values were derived from real-world data on procedural times, resource utilization, and unit costs provided by the three participating European centers. Collected data included patient demographics, detailed procedural timing (pre-procedure, skin-to-skin, and post-procedure phases), staff involvement (physicians, nurses, technicians), medications used for anesthesia and pain management, diagnostic tests performed (e.g. X-ray, CT), and length of stay (LOS).

Clinical effectiveness, after the index hospitalization, was evaluated as the proportion of patients undergoing a redo ablation, cardioversion procedure, hospitalization, and incidence of major adverse events over the year following the index procedure. The clinical inputs considered in the model were extracted from the ADVENT trial, a prospective, multicenter, randomized, blinded, noninferiority safety and effectiveness pivotal study comparing PFA with standard-of-care ablation using either RFA or CRYO for the treatment of paroxysmal AF[14,15]. The ADVENT trial is considered a rigorous and high-level evidence study for pulsed field ablation (PFA) in the treatment of paroxysmal atrial fibrillation (AF) and therefore was adopted as a reference for our analysis[14]. Repeat ablation was performed for clinical recurrence in 4% of patients who initially underwent PFA and 7% of patients who underwent thermal ablation[14]. Similarly, according to the study mentioned above[14], PFA was associated with a low rate of complications, such as cardiac tamponade (0.7%), transient ischemic attack (0.3%), pulmonary edema (0.3%) or vascular access complications (0.3%; Supplementary Table 3). In the ADVENT trial, the single procedure-related clinical stroke occurred in a patient who underwent RFA[14]. Overall, the complications rate was similar between the three procedures.

A secondary analysis from the ADVENT study[15] examined how residual atrial arrhythmia (AA) burden following ablation influenced the need for clinical interventions—including electrical cardioversion and hospitalization—throughout the subsequent 12-month period. During this follow-up interval, participants who maintained $\geq$0.1% AA burden demonstrated substantially elevated risks for repeat ablation procedures (relative risk [RR]: 24.5; 95% CI: 8.7–68.8), cardioversion interventions (RR: 19.4; 95% CI: 5.7–65.5), and hospital admissions (RR: 14.5; 95% CI: 6.90–30.8) when compared to those with $<$0.1% AA burden. These correlations between AA burden and clinical intervention requirements were consistently observed across both PFA and thermal ablation modalities (CRYO and RFA). Collectively, these findings align with previous research and establish that residual post-ablation AA burden exceeding 0.1% during the first year represents a clinically meaningful threshold beyond which patients face significantly diminished quality of life and substantially increased likelihood of requiring clinical interventions including repeat ablation, cardioversion, and hospitalization. This is in line with the merging role of AF burden as a reference for clinical decision-making, beyond the usual classification based on AF subtypes[16]. The rates on repeat procedures, cardioversions, and hospital admissions from the ADVENT sub-analysis were considered into the model for the medium-term analysis[15].

A scenario analysis was conducted incorporating complication and redo rates derived from real-world clinical registries. Specifically, all complication rates and PFA redo procedures were sourced from the multicenter EUropean Real World Outcomes with Pulsed Field AblatiOn in Patients with Symptomatic AtRIAl Fibrillation (EU-PORIA) registry[17]. EU-PORIA is a multicenter, observational study designed to capture procedural characteristics and follow-up outcomes of PFA in routine clinical practice across Europe[17]. As the EU-PORIA registry does not report redo rates for CRYO or RFA, these data were extracted from Della Rocca et al.[18], a multicenter, real-world study on paroxysmal AF ablation conducted across four European centers.

Costs

All costs were assessed from the hospital perspective, meaning that only direct hospital expenses related to the treatment of paroxysmal AF were considered.

To estimate procedural costs, a micro-costing methodology was adopted. This included detailed data on procedure duration, healthcare personnel involvement (e.g. time spent by physicians, nurses, and technicians), hospital LOS, medications administered (such as anaesthetics), and diagnostic tests performed during the procedure.

Beyond the initial procedure, additional costs related to complications, events (cardioversion and redo ablations) were incorporated, based on values sourced from published literature. Unit costs and their respective sources are listed in Supplementary Table 3. Hourly staff costs were provided directly by the participating centers. Inpatient costs were calculated by multiplying the daily hospitalization rate by the length of stay. Drug and diagnostic test costs were derived from national healthcare tariffs in each country.

All costs were expressed in or adjusted to 2025 Euros. The total cost per patient was calculated for each treatment option. To capture the full economic impact over the 1-year time horizon, it was assumed that any redo procedure would require a separate hospital admission.

To further assess the economic efficiency of each ablation modality from a value-based healthcare perspective, the cost per responder was also calculated, as the ratio of total costs (including index procedure and hospitalization expenses) to the percentage of patients achieving an AA burden below 0.1%. By defining treatment response as achieving AA burden $<$0.1%—a threshold associated with improved quality of life and reduced need for clinical interventions—the cost per responder analysis enables comparison of the economic efficiency of different ablation modalities in delivering clinically meaningful outcomes. This approach accounts for both the upfront investment required for each procedure and the likelihood of achieving the desired therapeutic endpoint, offering healthcare decision-makers a value-based perspective on treatment selection.

Sensitivity analysis

One-way sensitivity analyses (OWSA) were performed to explore the uncertainty around model outcomes. The aim of the OWSA was to identify the model inputs that have the greatest impact on the

Table 1. Resource consumption real-world analysis: baseline characteristics of the cohort.

Baseline characteristics	Total ($N = 270$)	PFA ($N = 90$)	CRYO ($N = 100$)	RFA ($N = 80$)	p-value*
Age (years), mean ± SD	60.3 ± 10.4	59.8 ± 11.0	61.5 ± 10.3	59.5 ± 10.0	0.354
Proportion of male, N (%)	172 (63.7%)	55 (61.1%)	64 (64%)	53 (66.3%)	0.783
Weight (kg), mean ± SD	81.9 ± 15.0	81.4 ± 15.8	81.1 ± 15.2	83.8 ± 13.6	0.414
Height (cm), mean ± SD	172.3 ± 9.7	171.2 ± 9.8	171.6 ± 9.7	173.3 ± 9.7	0.516
History of stroke, N (%)	18 (6.7%)	7 (7.8%)	6 (6.0%)	5 (6.3%)	0.873
History of coronary artery disease, N (%)	18 (6.7%)	8 (8.9%)	6 (6.0%)	4 (5.0%)	0.565
Ejection fraction (EF), mean ± SD	0.6 0.1	0.6 0.1	0.6 0.1	0.6 0.1	0.229
$CHAD_2$ score, mean ± SD	1.7 ± 1.3	1.8 ± 1.4	1.8 ± 1.2	1.6 ± 1.4	0.375
Treatment with AAD, N (%)	209 (77.7%)	73 (81.1%)	81 (81%)	55 (69.6%)	0.122
Type of anesthesia, N (%)					
Sedation	262 (97.0%)	89 (98.9%)	100 (100%)	73 (91.3%)	0.001
General anesthesia	8 (3.0%)	1 (1.1%)	0 (0.0%)	7 (8.8%)	

*ANOVA test.
Abbreviations. AAD, antiarrhythmic drugs; CRYO, cryoablation; PFA, pulsed field ablation; PV, pulmonary vein; RFA, radiofrequency ablation; SD, standard deviation.

model outputs; results are presented as a tornado diagram. When available, the standard deviation (SD) was used to define the range of variation; otherwise, $a \pm 15\%$ variation from the base-case value was applied. In the probabilistic sensitivity analysis, each parameter was assigned a probability distribution informed by its mean and corresponding variance: a gamma distribution for cost data and a beta distribution for proportions. Parameters were then randomly sampled from these distributions over 1,000 Monte Carlo iterations. The results are presented alongside the base-case estimates as 95% credible intervals (95% CrI).

Results

Baseline characteristics

Data were collected from three participating centers, encompassing a total cohort of $N = 270$ patients distributed across ablation modalities as follows: $N = 90$ patients with PFA, $N = 100$ patients received CRYO, and $N = 80$ patients were treated with RFA. The distribution across centers was not uniform, with one center contributing a smaller proportion of RFA cases while providing a larger number of CRYO patients to the overall dataset. The cohort had a mean age of 60 ± 10 years, with 172 patients (64%) being male.

Overall, the characteristics of the patients at baseline were well balanced among the three groups, except for the type of anesthesia. Across all cardiac ablation strategies, more than 90% of patients received sedation. The majority of patients (78%) received treatment with AAD, primarily class Ic (50%) and class Ia beta-blockers (13%). A summary of baseline characteristics is reported in Table 1.

Index hospitalization

Resource consumption for index hospitalization

Pre-procedural duration averaged 26.7 min across all patients, with no statistically significant variation observed among the three treatment modalities ($p = 0.4094$; Table 2).

Skin-to-skin procedure duration differed markedly between ablation techniques, with PFA having a mean duration of 60.6 ± 21.6 min, followed by CRYO (82.2 ± 27.0 min), and then RFA (153.0 ± 49.0 min; $p < 0.0001$; Table 2). The Bonferroni test (1:1 comparison) revealed statistically significant pairwise differences, with both PFA and CRYO requiring substantially less procedural time than RFA ($p < 0.0001$ for both comparisons). Additionally, PFA demonstrated significantly reduced procedural duration (higher predictability and reproducibility) compared to CRYO ($p < 0.0001$). When examining the distribution of cases relative to median procedural time, a substantially greater proportion of PFA patients (86.7%) completed procedures in less than the median duration, compared to 49.0% of cryoablation patients and only 10.0% of RFA patients (median test: $p < 0.001$). The significant difference observed in the median test analyses suggests that PFA is more predictable and reproducible compared to other procedures.

Table 2. Resource consumption real-world analysis: procedural time and healthcare professional workload by phase and treatment option.

Time, mean ± SD	PFA ($N = 90$)	CRYO ($N = 100$)	RFA ($N = 80$)	*p*-value**			
				Overall	PFA vs CRYO	PFA vs RFA	CRYO vs RFA
Procedural time by phase							
Pre-procedure, min	24.56 ± 17.92	27.71 ± 22.80	27.71 ± 10.63	0.4094	0.706	0.784	1.000
Skin-to-skin, min	60.61 ± 21.60	82.21 ± 26.95	152.98 ± 48.97	<0.0001	<0.0001	<0.0001	<0.0001
Post-procedure, min	22.84 ± 13.28	33.20 ± 22.5	23.86 ± 12.05	<0.0001	<0.0001	1.000	<0.0001
Total, min	108.01 ± 36.24	143.12 ± 46.44	204.55 ± 51.17	<0.0001	<0.0001	<0.0001	<0.0001
Professional workload*							
Physician, min	123.87 ± 54.64	165.66 ± 72.48	310.82 ± 123.23	<0.0001	0.003	<0.0001	<0.0001
Nurse, min	181.59 ± 86.77	247.83 ± 177.70	341.71 ± 151.56	<0.0001	0.001	<0.0001	<0.0001
Technician, min	47.47 ± 37.29	58.90 ± 53.92	132.39 ± 85.59	<0.0001	0.592	<0.0001	<0.0001
Anesthesiologist***, min	5.73 ± 28.86	2.90 ± 20.45	17.75 ± 60.46	0.0252	1.000	0.118	0.028
Other°, min	48.04 ± 71.79	38.00 ± 78.64	0.00 ± 0.00	<0.0001	0.828	<0.0001	<0.0001
Total, min	406.70 ± 165.44	513.29 ± 196.06	802.68 ± 294.27	<0.0001	0.003	<0.0001	<0.0001

*Sum of the time spent by all the physicians/nurses/technicians/anesthesiologist involved in the procedure (if $N > 1$).
**ANOVA test.
***Anesthesiologist involved during the procedure: $N = 5$ (5.6%) for PFA, $N = 2$ (2.0%) for CRYO and $N = 7$ (8.8%) for CRYO. °The term "other professional" involved in the procedure refers specifically to medical fellows participating in the clinical activity.
Abbreviations. CRYO, cryoablation; HCP, healthcare professionals; PFA, pulsed field ablation; RFA, radiofrequency ablation; SD, standard deviation.

Post-procedural time also varied significantly across ablation modalities, with the PFA cohort experiencing shorter recovery periods compared to both alternative techniques ($p < 0.0001$; Table 2).

Table 2 also presents the cumulative healthcare personnel time investment required across the three cardiac ablation approaches. Total staff time was significantly reduced in the PFA cohort relative to both CRYO and RFA groups ($p < 0.01$) for all healthcare professionals. PFA had a total professional workload of 406.7 min, CRYO 513.29 min and RF 802.68 min. On top the SD was lowest for PFA, suggesting better plannability of a PFA procedure against CRYO and RF. Pairwise comparisons using Bonferroni correction demonstrated that both physician and nursing staff time commitments were significantly diminished in the PFA group when compared to either CRYO or RFA procedures ($p < 0.01$ for all comparisons). Technician time showed a significant reduction in PFA vs RFA (47.47 vs 132.39; $p < 0.05$), while no meaningful difference emerged between CRYO and RFA for technician involvement (47.47 vs 58.90; $p = 0.592$). When analyzing the distribution of cases relative to median time requirements, PFA consistently demonstrated superior efficiency, with a significantly greater proportion of patients requiring below-median time investments for physician, nursing, and technician resources compared to both alternative ablation modalities (median test: $p < 0.05$).

The number of professionals involved in the procedure varies and is reported in Supplementary Table 4.

The average total procedure time per patient was estimated to be 108 ± 36 min for PFA, 143 ± 46 min for CRYO and 205 ± 51 min for RFA.

The mean LOS was 1.81 days. LOS did not vary significantly between ablation modalities, with comparable durations observed for PFA (mean ± SD: 1.78 ± 1.13 days), CRYO (1.75 ± 1.23 days) and RFA (1.94 ± 1.12 days; $p = 0.5248$).

Costs for index procedure

Through micro-costing analysis of resource utilization data, PFA demonstrated cost advantages of 6% relative to CRYO and 24% relative to RFA procedures (Figure 1). The cost differential between treatment groups appears primarily attributable to the significantly consistent and predictable procedure duration associated with PFA. Other cost components, including medical therapy expenses (encompassing anesthesia), diagnostic examinations, and hospitalization costs, remained comparable across all treatment modalities. Standardized equipment requirements were consistent across procedures, with each cardiac ablation requiring one standard instrumentation set plus the respective ablation-specific kit, irrespective of the chosen therapeutic approach.

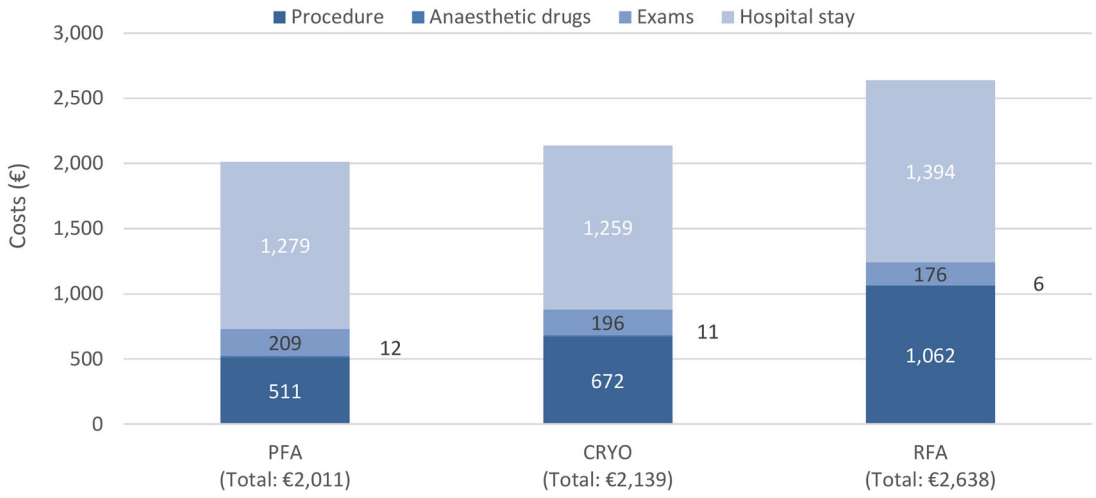

Figure 1. Total cost per patient for the index procedure by treatment option.
Abbreviations. CRYO, cryoablation; PFA, pulsed field ablation; RFA, radiofrequency ablation.
Disclaimer: Cost components associated with hospitalization may not be fully captured in the analysis, e.g. post-operative nursing care and other ancillary services. Such costs are assumed to be comparable across treatment options and, therefore, note relevant.

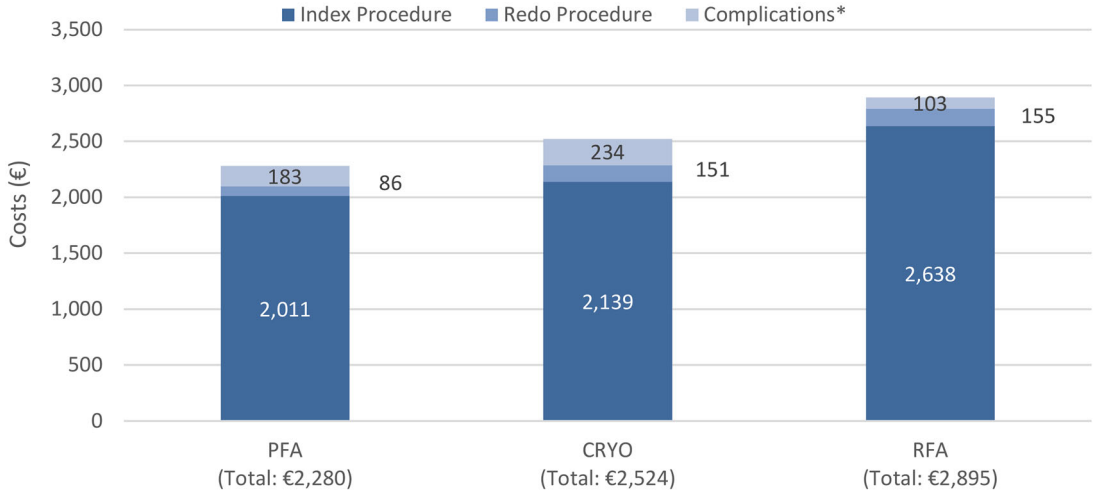

Figure 2. Total costs per patient.
*Including major adverse events, hospitalizations, and use of cardioversion.
Abbreviations. CRYO, cryoablation; PFA, pulsed field ablation; RFA, radiofrequency ablation; EUR, Euro.

Model results

Costs for index procedure, redo procedures, events, and complications

Figure 2 presents the comprehensive cost analysis encompassing index hospitalization, repeat procedures, use of cardioversion, and related to hospitalizations and complications across the three ablation modalities. Overall, PFA demonstrated cost reductions of 10% compared to CRYO and 21% compared to RFA. Based on this analysis, PFA would maintain a cost-saving advantage over CRYO (Δ total costs < 0) for kit price differences of up to €240, and over RFA for differences of up to €651. These thresholds represent the maximum additional device cost that can be absorbed while preserving the overall PFA procedural advantage.

Cost per responder (i.e. patient with <0.1% AA burden)

The analysis demonstrated that PFA achieved the most favorable cost per responder ratio (€2,566), followed by CRYO (€3,043; +19% vs PFA) and RFA (€3,629; +41% vs PFA (Table 3), reflecting both the lower procedural costs and higher efficacy rates associated with PFA technology.

Table 3. Costs per responder.

	PFA	CRYO	RFA
Costs*, EUR	2,102	2,307	2,689
<0.1% AA burden, %[15]	81.9%	75.8%	74.1%
Cost per responder, EUR	2,566	3,043	3,629

*Including major adverse events, hospitalizations, and use of cardioversion.
Abbreviations. AA, Atrial arrhythmia; CRYO, cryoablation; PFA, pulsed field ablation; RFA, radiofrequency ablation; EUR, Euro.

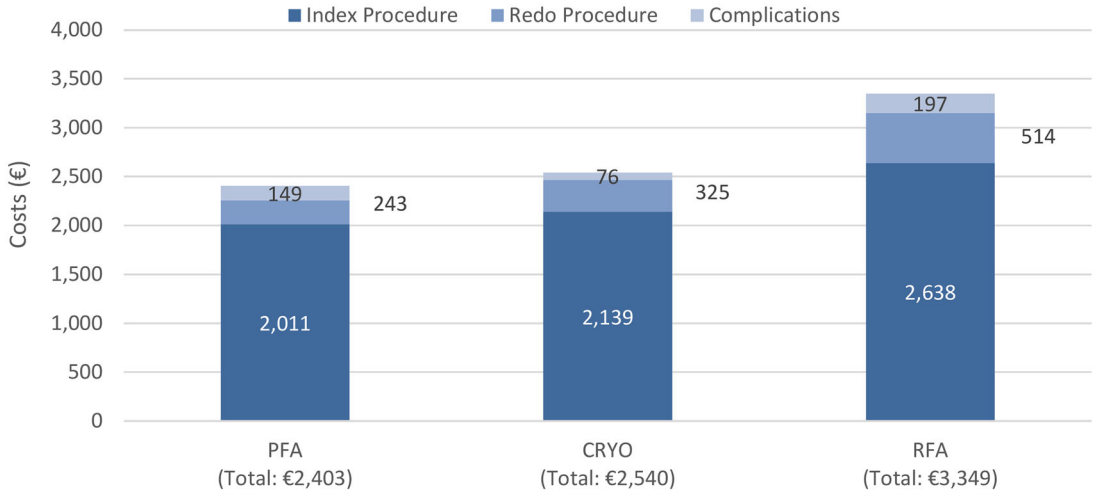

Figure 3. Total costs per patient (real-world data).
Abbreviations. CRYO, cryoablation; PFA, pulsed field ablation; RFA, radiofrequency ablation; EUR, Euro.

Scenario analysis

Figure 3 presents the analysis results, considering the real-world data as main source for the medium-term costs. Overall, the results are in line with the main analysis with PFA demonstrating cost reductions of 5% compared to CRYO and 28% reduction compared to RFA.

If the freedom from AA is considered as responder rate, PFA achieved the most favorable cost per responder ratio (€2,737), followed by CRYO (€2,995; +9% vs PFA) and RFA (€3,498; +28% vs PFA).

Sensitivity analysis

The tornado diagrams (Figure 4 and Figure 5) illustrate the relative influence of each parameter on the costs of PFA compared to CRYO and RFA. The OWSA identified LOS as the most sensitive input parameter influencing the cost per responder across all ablation strategies. Despite this, the overall variation in results remained modest, indicating the robustness of the base-case conclusions. Other influential parameters included procedural time and staff workload, but none altered the relative cost ranking of the three technologies. PFA consistently maintained the most favorable economic profile across all tested scenarios. Results of the probabilistic analysis are reported in the supplementary material (Supplementary Figure 1). Across the cost distributions, PFA demonstrated the lowest expenditure and the narrowest interquartile range, CRYO showed intermediate values, and RFA exhibited both the highest costs and the greatest variability. The results of the sensitivity analyses enhance the reliability of the base case and confirm the conclusions drawn from the base-case analysis are not overly reliant on specific assumptions or input values.

Discussion

The present analysis shows that PFA offers significant advantages in terms of procedural efficiency, with markedly improved procedural workflow accompanied by consistent and predictable procedure duration compared to both CRYO and RFA. These findings align with the inherent technical characteristics of PFA technology, which enables more rapid and precise tissue ablation through non-thermal mechanisms[19]. The present findings are in line with all other studies, that consider resource use or procedure

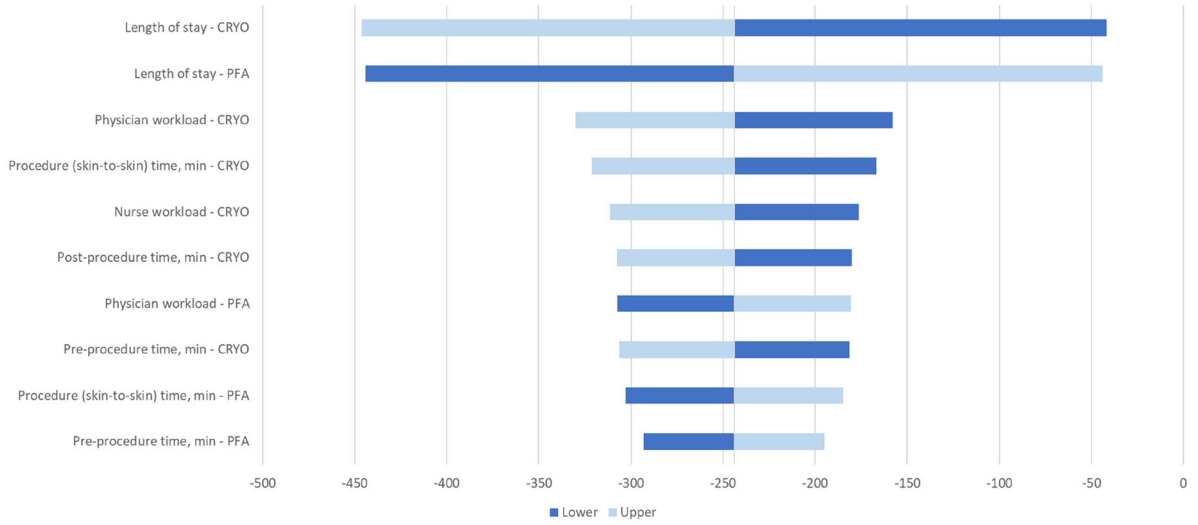

Figure 4. Tornado plot showing results of the one-way sensitivity analysis. PFA vs CRYO.

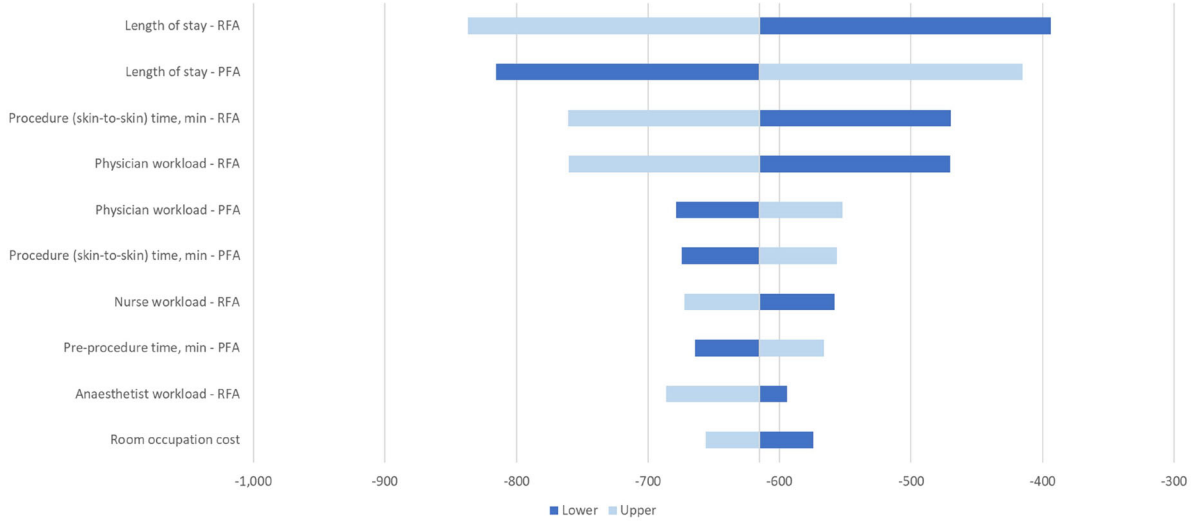

Figure 5. Tornado plot showing results of the one-way sensitivity analysis. PFA vs RFA.

time[10,20,–22]. In all the identified evidence, there is consistency that PFA is associated with greater procedural efficiency and lower costs compared to CRYO and RFA.

The present economic analysis indicates cost savings associated with PFA implementation, compared to CRYO and to RFA. The consistent trend toward PFA being economically advantageous remains evident across different healthcare systems and geographical regions. The cost advantages of PFA appear to be driven primarily by the significant difference in procedural time, which translates to lower utilization of expensive catheterization laboratory resources, reduced anesthesia requirements, and lower staff time commitments. Compared to the previous analysis[10], PFA demonstrated a statistically significant difference in procedural time compared to both CRYO and RFA. These findings support the potential procedural efficiency of PFA and reinforce the robustness of the current analysis due to the expanded patient cohort ($N = 270$ patients) and in additional countries. The observed differences in absolute cost savings can be attributed to variations in healthcare system pricing structures, labor costs, and resource utilization patterns across the countries and even between centers included in our analysis, reflecting the importance of conducting country-specific economic assessments.

Moreover, the cost per responder analysis provides additional insight into the value proposition of different ablation modalities by incorporating both economic and clinical effectiveness measures. This metric is particularly relevant in the context of value-based healthcare delivery, where treatment

selection should be guided by the optimal balance of clinical outcomes and resource utilization[11,12]. The lower cost per responder ratio observed with PFA reflects both the lower procedural costs and higher success rates associated with this technology, reinforcing its position as high-value therapeutic option.

Additionally, the improved procedural predictability may lead to optimized resource utilization and reduced overtime costs, further enhancing the economic benefits of PFA adoption. Assuming an 8-hour operating room schedule per day, the average number of procedures that could be completed in a day is 4 for PFA, 3 for CRYO, and 2 for RFA, based on their respective average procedure times. A particularly noteworthy finding is the enhanced predictability of PFA procedural duration, as evidenced by both the lower standard deviation in procedural times and the median time analysis demonstrating that 86.7% of PFA procedures were completed in below-median time. This procedural time reproducibility offers significant advantages for hospital resource planning and scheduling optimization, enabling more efficient utilization of catheterization laboratory resources and staff allocation. Such predictability represents a substantial operational benefit in contemporary healthcare environments where resource optimization is increasingly critical. The ability to accurately predict procedure duration allows for better patient scheduling, reduced waiting times, improved patient satisfaction, and enhanced overall departmental efficiency. This operational advantage extends beyond direct cost savings to encompass broader healthcare system benefits, including improved patient flow and number of cases, potential use of same-day discharge in appropriately selected patients, reduced costly cancellations due to overrunning procedures, and enhanced staff satisfaction through more predictable work schedules. The data did not allow for considering the cancellations caused by a larger standard deviation between the different energy sources, while it can be subject to potential future research. Based on research by Saunders et al. cancellations due to delay can cost from €183 in Germany to €2,780 in France. Also the burden for the patients is higher. Prolonged waiting time in the operating room significantly increases psychological burden by significantly increasing anxiety, short-term fear, and total fear levels in patients[23]. Preoperative fasting is required, further contributing to the patient's overall discomfort and stress[24]. This suggests, that based on the higher predictability PFA offers against CRYO and RFA, higher costs savings by avoiding cancellations can be estimated[25].

The landscape of cardiac ablation in AF continues to evolve, with CRYO and RFA experiencing declining utilization rates as PFA adoption increases across major cardiac centers worldwide. This shift reflects both the procedural advantages demonstrated in our analysis and the growing body of evidence supporting PFA's clinical effectiveness and safety profile[26,27]. The transition toward PFA represents a paradigm shift in ablation technology, driven by the convergence of improved clinical outcomes, enhanced procedural efficiency, and favorable economic profiles[28]. As healthcare systems increasingly focus on value-based care delivery, the multi-dimensional advantages of PFA technology position it as a preferred therapeutic option for atrial fibrillation management.

For the medium-term efficacy assessment, we utilized data from the ADVENT trial due to its comprehensive inclusion of all three ablation modalities and substantial patient cohort, providing a robust foundation for comparative effectiveness analysis[14,15]. However, recent studies have demonstrated positive and improving safety and efficacy outcomes for PFA technology, further supporting its clinical utility. Notable examples include the SINGLE SHOT CHAMPTION trial[29], which demonstrated high acute procedural success rates and favorable safety profiles, the MANIFEST-PF 17K study, which provided compelling evidence of PFA's effectiveness across diverse patient populations and clinical scenarios[30], and a prospective real-world study in France, enhancing the safety and acutely efficiency of PFA, despite considerable heterogeneity in the number of patients treated[28]. These studies have further validated the clinical benefits of pulsed field ablation and support its expanding role in atrial fibrillation management, suggesting that the medium-term outcomes observed in our analysis may be conservative estimates of PFA's long-term clinical and economic benefits. More data is being generated as this paper is written, as for instance the BEAT-AF trial, which is expected to be published in mid-2025[31]. This RCT can be considered in future research.

Some limitations should be acknowledged in our analysis that may influence the interpretation and generalizability of our findings. The integration of primary data with literature-derived inputs may have introduced variability in clinical and economic parameters, limiting the uniformity of the dataset. The medium-term efficacy data derived from the ADVENT trial, while comprehensive, may not fully reflect

the evolving landscape of PFA technology and techniques. Continued technological refinements, improved catheter designs, and enhanced procedural protocols may further improve the clinical and economic advantages of PFA beyond what was captured in our analysis. We acknowledge that the use of ADVENT trial data, rather than local follow-up outcomes, may introduce inconsistency. By referencing the ADVENT trial, we aimed to draw on high-quality, peer-reviewed evidence. Nonetheless, this reliance on external data represents a limitation and should be considered when interpreting the results. The definition of "responder" as an atrial arrhythmia burden below 0.1% was selected based on emerging evidence suggesting that ultra-low burden may correlate with improved clinical outcomes and reduced healthcare utilization. We recognize that this threshold is not universally accepted, and alternative definitions, such as symptom-based metrics, may offer broader insights. Future studies incorporating quality-adjusted life years (QALYs) or patient-reported outcomes would enhance health economic evaluation and provide a more comprehensive understanding of treatment impact. To overcome this limitation, an additional scenario analysis has been included considering European real-world data, to better reflect local practice[17,18]. Additional real-world evidence on PFA has demonstrated notable time efficiency and a consistently low rate of procedural complications[29,32,33].

From an economic perspective, the micro-costing approach enabled a detailed estimation of direct resource utilization. However, this method may not have fully captured all indirect costs associated with each procedure, such as staff training requirements, equipment maintenance, or facility overhead. Although these elements are difficult to quantify, they can substantially impact the overall assessment of the economic sustainability of the technologies under evaluation. The cost of the device was excluded from the analysis due to the inability to obtain consistent pricing information for all ablation systems. This was primarily attributed to substantial variability in costs across clinical centers and the confidential nature of pricing for complete kits (i.e. standard set plus ablation kit) from different suppliers. Furthermore, the analysis was conducted within specific healthcare systems, each with distinct practice patterns. As such, the generalizability of the results may be constrained by differences in healthcare environments with different staffing models, cost structures, mechanisms, or clinical practices[34,35]. For instance, other institutions may encounter different operational dynamics and clinical outcomes. Caution is advised when applying these insights to healthcare systems outside of Europe, and further research is recommended to explore these variables in more diverse settings.

An additional limitation of this study relates to the method of patient selection. The most recent 30 cases per modality per center, rather than enrolling patients through random sampling. This approach was chosen to capture contemporary practice and the operators' current technique for each modality; however, it may introduce selection bias. While the study was adequately powered to detect differences in procedural time, it was not designed to assess clinical safety endpoints; therefore, rare complications such as tamponade and stroke were extrapolated from available literature, and this limitation should be considered when interpreting safety-related findings. Additionally, different centers may follow varying clinical protocols, which could further affect both the comparability and generalizability of the findings. Finally, the learning curve associated with PFA adoption may influence procedural outcomes and costs, particularly during the early phases of implementation[36]. Operator experience has been shown to reduce fluoroscopy exposure during PFA, and with the incorporation of mapping systems into future PFA platforms, fluoroscopy use may be further decreased[14]. Nevertheless, the learning curve associated with the pentaspline PFA catheter suggests rapid adoption trajectory[37–39]. To mitigate potential temporal confounding from learning curves or adoption phases, we aligned the inclusion periods for each modality as closely as possible, ensuring substantial overlap in calendar time.

Interestingly, the present data reveal that the majority of ablation procedures, across all strategies, were performed under deep sedation. This finding highlights its widespread use in clinical practice and reinforces its viability as an alternative to general anesthesia. As documented in previous studies, deep sedation ensures a high level of safety and efficacy, while also delivering a favorable experience for both patients and operators[40,41]. The consistent application observed in this dataset further validates its practicality, even in complex interventions. With well-defined protocols and adequate training, deep sedation could be more broadly adopted, potentially enhancing procedural efficiency and overall outcomes.

Long-term studies examining durability of ablation effects, quality of life outcomes, and healthcare resource utilization over extended periods would provide valuable insights into the sustained benefits of

PFA technology. Additionally, real-world evidence studies examining PFA outcomes across diverse healthcare settings and patient populations would enhance the understanding of its broader clinical and economic impact.

Conclusion

In conclusion, our findings support the economic and operational advantages of the pentaspline PFA technology. It may offer economic and operational benefits, including more efficient resource utilization, reduced procedural complexity and lower consumables use compared to traditional ablation modalities, without compromising efficacy. These advantages, combined with the growing evidence of clinical effectiveness and safety, position PFA may play an increasingly important role in the management of AF. As healthcare systems continue to prioritize value-based care delivery, the multi-dimensional benefits of PFA technology could make it a compelling option for both clinicians and healthcare administrators seeking to improve patient outcomes and managing resource utilization effectively.

Transparency

Declaration of funding

This analysis was financially supported by Boston Scientific.

Declaration of financial/other interests

SU and JVR are employees of Boston Scientific. GB reports speaker's fees of small amount from Bayer, Boston, Daiichi Sankyo, Sanofi, Janssen outside the submitted work.

Author contributions

All authors were involved in the conception and design of the study. PN, AFL, AMB, LBS, DAM, PM, and GB participated in the data collection. SU and JVR were involved in the analysis and interpretation of data. All authors contributed to the drafting and critical revision of the manuscript. All authors approved the final version of the manuscript.

Acknowledgements

The authors would like to thank all participants who contributed to the study. Special thanks to Caroline Jacobsen for the insightful feedback throughout the course of this research.

Data availability statement

The data underlying this article will be shared on reasonable request to the corresponding author.

Reviewer disclosures

Peer reviewers on this manuscript have received an honorarium from CMRO for their review work but have no other relevant financial relationships to disclose.

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