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ORIGINAL RESEARCH ARTICLE

Budget Impact Analysis of Pulsed Field Versus Cryoballoon and Laser Procedures for Atrial Fibrillation in Italy

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Abstract

Background and Objectives Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, with a higher prevalence due to the ageing of the population. Traditional ablation techniques, such as cryoballoon ablation (CB) and laser ablation (LA), are widely used but may be associated with longer procedure times and a risk of collateral tissue injury. Pulsed field ablation (PFA) is an emerging non-thermal technology that uses electroporation, with early evidence suggesting a favourable safety profile and improved procedural efficiency. This study assessed the budget impact of the introduction of PFA within the Italian National Health Service (NHS) compared with current CB and LA practice, estimating short-term differences in healthcare costs to support resource allocation decisions.

Methods A 5-year budget impact model compared two scenarios: current clinical practice (CB and LA) and a progressive uptake of PFA, increasing from 20% in 2025 to 67.2% in 2029. The analysis included direct medical costs: device acquisition, staff time, procedural resources, complications and repeat interventions. The population and treatment assumptions were based on national and regional data from Italy. The analysis was conducted from the perspective of the NHS. A deterministic sensitivity analysis was performed to assess the robustness of the results.

Results The introduction of PFA resulted in cumulative cost savings of €11.7 million over 5 years. In the current scenario, costs increased from €36.2 million to €38.1 million. In contrast, costs in the PFA scenario decreased from €35.8 million to €33.2 million. The main savings came from reduced staff and procedural costs (€7.6 million), fewer recurrences (€5.9 million) and lower costs related to complication (€1.5 million). Sensitivity analysis confirmed the robustness of the results, with device cost, CB pricing and procedure time identified as the most influential parameters.

Conclusions Our study suggests that the progressive integration of PFA into routine AF care within the Italian NHS could generate meaningful cost savings while maintaining clinical outcomes.

Key Points

Pulsed field ablation (PFA) is a non-thermal technology designed to minimise collateral tissue injury, with early clinical evidence suggesting reduced procedure times and low recurrence rates.

From the perspective of the Italian National Health Service, a gradual adoption of PFA is projected to generate approximately €11.7 million in savings over 5 years, primarily driven by reduced use of procedure-related resources and fewer reinterventions.

Extended author information available on the last page of the article

1 Introduction

More than 59 million individuals worldwide are affected by atrial fibrillation (AF) [1]. Its incidence in Europe is between 2 and 3%, and it increases dramatically with age [2]. In Italy, an estimated 610,000 people, or 0.5–1% of the population, suffer from AF [3]. As the population ages, it is anticipated that this prevalence will rise, adding to the burden on public health through morbidity, mortality and complications related to hospitalisations and disease treatment. Additionally, the economic impact of AF is further amplified by indirect costs such as lost productivity [4].

According to recent guidelines from the European Society of Cardiology (ESC), AF has major negative effects on quality of life, increases mortality and increases the risk of stroke five times [5]. About 40% of all occurrences of

AF are paroxysmal [6], and antiarrhythmic medications are frequently used to treat it to preserve a normal heart rate and rhythm. However, according to the guidelines for management of AF [7], these drugs have serious adverse effects and recurrence rates between 43 and 47%.

The economic burden of AF is substantial, driven primarily by inpatient care and interventional procedures, which account for over 70% of total annual costs in several European countries [8]. In Italy, the annual direct cost per patient is estimated at €3019, with an additional €206 attributed to indirect costs, resulting in a total cost of €3225 per patient [9].

Catheter ablation has become a cornerstone in AF management, particularly in patients with drug-refractory symptomatic AF [10]. Specifically, pulmonary vein isolation (PVI) was initially performed using point-by-point radiofrequency ablation (RFA) energy. The development of cryoballoon ablation (CBA) introduced a "single-shot" technique, achieving long-term results comparable to RF ablation [11, 12]. Beyond safety considerations, procedural efficiency may differ between modalities. Comparative studies [13] have reported significantly shorter procedure times with CBA than with RFA (mean ± standard deviation [SD] 133.6 ± 45.2 min versus 174.6 ± 58.2 min; $P < 0.001$), with similar complication rates (53/982 [5.4%] versus 191/3675 [5.2%], CBA versus RFA; $P = 0.806$). Consistently, another study [14] observed no statistically significant difference in AF recurrence between CBA and RFA (27.5% versus 38.0%, $P = 0.258$), while atrial flutter recurrence was lower following CBA (3.9% versus 18.0%, $P = 0.020$); both procedure and ablation durations were shorter with CBA (160 ± 31 versus 197 ± 38 min; 36.7 ± 9.5 versus 55.3 ± 16.7 min; both $P < 0.0001$), with no significant difference in fluoroscopy time (21.5 ± 7.8 versus 23.4 ± 11.2 min; $P > 0.05$). Despite the effectiveness of established thermal techniques, arrhythmia recurrence and repeat ablation remain clinically relevant and may drive healthcare use.

Pulsed field ablation (PFA) has emerged as an innovative, non-thermal technique that uses high-intensity electric fields to induce irreversible electroporation. This approach selectively targets cardiomyocytes while sparing adjacent tissues such as nerves and blood vessels [15]. Clinical studies have demonstrated PFA's potential benefits, including high acute procedural success rates, a reduced risk of collateral tissue injury (including phrenic nerve and oesophageal injury), shorter procedural durations and potentially reduced hospitalisation costs [16–18]. The favourable safety profile and promising efficacy of PFA, as reported in recent studies, suggest that it can provide both cost savings and quality-of-life improvements for eligible patients.

This study aims to conduct a budget impact analysis (BIA) of implementing PFA in the Italian National Health Service (NHS) compared with CB and laser-assisted ablation (LA) procedures. Short-term cost differences between PFA and current treatment options are assessed using a BIA. From the perspective of the Italian National Health Service (NHS), this analysis aims to provide decision-makers with valuable information to optimise resource allocation and promote evidence-based medical practices.

2 Methods

A budget impact model was developed in Microsoft Excel, adhering to the principles outlined by The Professional Society for Health Economics and Outcomes Research (ISPOR) [19]. The analysis was structured to compare two alternative scenarios:

- "As is" scenario: The current treatment landscape without the introduction of PFA, consisting of cryoballoon and LA as the only options available for the treatment of paroxysmal atrial fibrillation (PAF) in the NHS.
- "To be" scenario: The introduction of PFA, with a progressive uptake starting at 20% of patients switching from CB and LA to PFA.

The model adopted the perspective of the Italian NHS.

2.1 Population

The population was divided into five age groups (65–69, 70–74, 75–79, 80–84 and 85+ years), and the Italian National Institute of Statistics (ISTAT) calculated the demographic projections for the period 2025–2029 [20]. For each age group, we used age-specific prevalence rates reported in the literature [3], which ranged from 3% in the youngest group to 16% in individuals aged 85 years and older. Among those with AF, approximately 90% are expected to have the non-valvular, chronic form of the condition [21]. According to historical data from the Tuscany Region, about one third (33.22%) of these patients are hospitalised with AF as the primary diagnosis [22]. Within this group, only 4.6% are estimated to be eligible for catheter ablation targeting pulmonary vein isolation. Of those eligible, around 20% may be suitable candidates for "one-shot" ablation techniques, such as focal pulsed field ablation [23].

As shown in Table 1, the number of patients with chronic non-valvular AF is expected to gradually rise, along with the number of AF hospitalisations, the percentage of patients eligible for pulmonary vein disconnection treatments and the number of patients specifically eligible for one-shot procedures such as CB and LA.

Data on the number of cryoballoon and laser ablation procedures purchased by public healthcare facilities were extracted from the Nuovo Sistema Informativo Sanitario (NSIS; New Healthcare Information System). These data indicated that the majority of the patients eligible for one-shot techniques were treated with cryoballoon ablation (91.89%), while a smaller proportion received laser ablation (9.11%). This distribution was assumed to represent the current practice (“as is” scenario).

2.2 Treatment Scenarios

In each scenario, the model replicated how patients were distributed among the various therapies (Table 2). On the basis of the existing market mix, patients were divided between CB and LA for the “as is” scenario. In the “to be” scenario, a progressive increase in PFA uptake was assumed, rising from 20% in 2025 to 67.2% in 2029, reflecting a gradual adoption of the new technology.

2.3 Clinical Events

Table 3 presents the re-intervention and adverse reaction rates associated with different procedures: CB, LA and PFA. The annual recurrence rate is reported as 32% for CB, 30% for LA and 15% for PFA [24, 25]. These event rates were used to parameterise the economic–epidemiologic model. Notably, 80% of patients experiencing recurrence were assumed to undergo repeat ablation across all three techniques.

In terms of complications, oesophageal injury occurred in 0.50% of CB procedures, while no incidents were reported for LA and PFA. Pulmonary vein stenosis was observed in 1.00% of CB cases, with no occurrences in either the LA or PFA groups. Persistent phrenic nerve palsy was recorded in 1.00% of CB patients and 0.50% of LA patients, but no cases were seen in the PFA group. Cardiac tamponade was reported at a rate of 0.40% for CB and PFA and 0.90% for LA. Severe vascular complications occurred in 2.00% of both CB and PFA procedures, while the rate was 0.90% for LA. Stroke rates were 0.70% for both CB and PFA, with no strokes occurring in LA procedures. Other severe complications were noted in 1.00% of CB patients, 0.50% of LA patients and 1.00% of PFA patients.

Table 1 Projections of population eligible for one-shot techniques

Population		2024	2025	2026	2027	2028	2029	Source
Italian population 65+ years		14,370,133	14,583,457	14,807,004	15,046,771	15,294,874	15,565,045	[20]
Prevalence								
65–69 years	3%	110,169	112,443	115,037	118,030	121,120	124,908	[3]
70–74 years	6%	182,335	182,627	183,813	187,040	190,992	194,812	[3]
75–79 years	8%	242,592	251,013	260,028	255,836	251,978	248,036	[3]
80–84 years	14%	304,453	297,002	287,426	301,496	315,601	330,673	[3]
85 + years	16%	375,381	389,302	401,932	406,697	409,517	411,547	[3]
Population with AF		1,214,931	1,232,387	1,248,237	1,269,099	1,289,207	1,309,976	
Prevalence of non-valvular AF	90%	1,093,438	1,201,475	1,194,812	1,210,893	1,226,495	1,242,967	[21]
Percentage (%) of total hospitalizations for primary diagnosis of AF		33.22%	33.26%	33.29%	33.33%	33.36%	33.40%	[22]
Projected total hospitalizations for primary diagnosis of AF		363,243	399,564	397,766	403,542	409,169	415,098	
Percentage (%) of population eligible for pulmonary vein disconnection treatment	4.60%							[22]
population eligible for pulmonary vein disconnection treatment		16,706	18,376	18,293	18,559	18,818	19,091	
Percentage (%) of population eligible for one-shot techniques (PAF)	20,00%							[23]
		3341	3675	3659	3712	3764	3818	

	No./year	Percentage (%)	
No. Pz, CB[a]	1994	91.89%	NSIS
No. Pz LA[a]	176	8.11%	NSIS

The table estimates, for each year 2024–2029, the size of the Italian population potentially eligible for “one-shot” pulmonary vein isolation techniques. AF, atrial fibrillation; PFA, pulsed field ablation; Pz, patient; CB, cryoballoon ablation; LA, laser ablation; No, number; NSIS, Nuovo Sistema Informativo Sanitario (New Healthcare Information System)

[a]The number of cryoballoon and laser ablation procedures purchased in 2024 by public healthcare facilities was extracted from the NSIS

Table 2 Market mix and patients

Market shares "As is" scenario							"To be" scenario						
	2024	2025	2026	2027	2028	2029		2024	2025	2026	2027	2028	2029
CB	91.89%	91.89%	91.89%	91.89%	91.89%	91.89%	CB	91.89%	73.51%	58.81%	47.05%	37.64%	30.11%
LA	8.11%	8.11%	8.11%	8.11%	8.11%	8.11%	LA	8.11%	6.49%	5.19%	4.15%	3.32%	2.66%
PFA	–	–	–	–	–	–	PFA[a]	–	20.00%	36.00%	48.80%	59.04%	67.23%
Total	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%	Total	100.00%	100.00%	100.00%	100.00%	100.00%	100.00%
Patients "As is" scenario							"To be" scenario						
	2024	2025	2026	2027	2028	2029		2024	2025	2026	2027	2028	2029
CB	3070	3377	3362	3411	3458	3508	CB	3070	2702	2152	1746	1417	1150
LA	271	298	297	301	305	310	LA	271	238	190	154	125	101
PFA	–	–	–	–	–	–	PFA	–	735	1317	1811	2222	2567
Total	3341	3675	3659	3712	3764	3818	Total	3341	3675	3659	3712	3764	3818

The table summarizes the expected market mix and corresponding patient volumes for one-shot pulmonary vein isolation technologies under two scenarios: the "as is" scenario (constant market shares reflecting current procurement) and the "to be" scenario (progressive uptake of pulsed field ablation). CB, cryoballoon ablation; LA, laser ablation; PFA, pulsed field ablation

[a]The "to be" scenario assumes PFA introduction: 20% of patients starting from 2025

2.4 Costs

This analysis focuses solely on direct costs from the perspective of the Italian NHS. The cost includes procedural and medical device expenses, as well as costs associated with complication events.

Table 4 reports the costs incurred for different ablation techniques referred to in this analysis. The procedure costs were calculated on the basis of the duration of the procedure, the number of health professionals involved and the operational costs of the operating room.

Table 3 Re-intervention rates and adverse reaction rates

Redo event rate				
	CB (%)	LA (%)	PFA (%)	
Annual rate of recurrence	32	30	15	[24, 25]
Proportion receiving repeat ablation	80	80	80	
Complication event rates				
Oesophageal injury	0.50	0.00	0.00	[24, 25]
Pulmonary vein stenosis	1.00	0.00	0.00	
Persistent phrenic nerve palsy	1.00	0.50	0.00	
Cardiac tamponade	0.40	0.90	0.40	
Severe vascular complications	2.00	0.90	2.00	
Stroke	0.70	0.00	0.70	
Other severe complications	1.00	0.50	1.00	

CB, cryoballoon ablation; LA, laser ablation; PFA, pulsed field ablation

In the absence of published technology-specific Italian sources for procedure duration and personnel patterns, procedure time (minutes), number of physicians, involvement of the anaesthetist and use of the operating room for CB, LA and PFA were informed by expert opinion. A panel of clinicians experienced in AF ablation within Italian public hospitals provided estimates of procedure duration and standard team composition in routine practice.

Unit cost inputs were applied as follows: the physician cost per minute is €0.69 [26], while the anaesthetist's cost per minute is €0.65. Operating room costs are €20.42 per minute [27]. The total procedural costs are the highest for CB (€5230.45) compared with LA and PFA (€3796.30) each, primarily due to differences in time requirements and device costs. Direct medical costs vary between techniques, with CB at €5025.73, LA at €5999.55 and PFA at €5500.00 [28].

Complication-related costs (Table 5) were included to capture additional healthcare expenditures associated with severe adverse events, valued using daily rates for intensive care unit (ICU) stays (€1966.59/day) and inpatient hospitalisations (€814.19/day). All costs have been updated to reflect values as of November 2024. For each complication, the total cost of the event was calculated as: total event cost = (ICU days × ICU cost/day) + (inpatient days × inpatient cost/day), where the number of ICU and hospital days required to manage each event was obtained from the literature [29]. For example, an oesophageal injury that requires 14 days in the ICU and 7 days in inpatient care amounts to €26,307.33 [29]. Other adverse events, such as pulmonary vein stenosis or cardiac

Table 4 Costs of healthcare personnel and procedure

Health professionals (quantity/time)	CB	LA	PFA	Source	Costs	Unit cost (€/unit)	Source
Time procedure (min)	124	90	90	Expert opinion	Physician (€/min)	€0.69	[26]
Physician (No.)	2	2	2	Expert opinion	Anaesthetist (€/min)	€0.65	
Anaesthetist (No.)	1	1	1	Expert opinion	Operating room (€/min)	€20.42	[27]
Operating room	1	1	1	Expert opinion			
Total procedure cost	5230.45 €	3796.30 €	3796.30 €				
Medical device costs	5025.73 €	5999.55 €	5500.00 €	[29]			

The table reports the unit-cost parameters used to estimate the per-procedure cost of the index ablation for CB, LA and PFA. Resource use assumptions (procedure duration in minutes, number of physicians and anaesthetists and operating room use) are based on expert opinion. Personnel and facility costs are valued using the reported unit costs (€/min) for physician time, anaesthetist time and operating room time ([26] or [27]). The total procedure cost is calculated by multiplying each resource input by its corresponding unit cost and summing across components (personnel + operating room). Medical device costs (single-use/disposables and associated technology-specific consumables) are applied as technology-specific acquisition costs [29] and reported separately to allow transparent identification of the cost drivers. CB, cryoballoon ablation; LA, laser ablation; PFA, pulsed field ablation; No, number

tamponade, have lower associated costs, reflecting shorter care durations or outpatient management. Severe complications such as stroke incur costs of up to €6207 [30].

The total costs of a single procedure, summarised in Table 6, include the costs of healthcare professionals and procedures, medical devices and complications.

2.5 Time Horizon and Discounting

The model covers a 5-year time frame, so discounting was not applied [19]. To take into consideration population dynamics, such as changes brought on by mortality and the incidence of AF over time, as well as re-intervention and

Table 5 Costs of adverse reactions

Complication event costs				
	Unit cost			Source
ICU (€/day)	€1966.59			[36]
Inpatient hospitalization (€/day)	€814.19			[37]
	No. days in ICU	No. days in inpatient hospitalization	Total event cost	
Oesophageal injury	14	7	€26,307.33	[29]
Pulmonary vein stenosis	–	4	€3256.76	
Persistent phrenic nerve palsy	–	–	€160.60	[38] Outpatient tariffs: 87.41.1 and 89.01.3
Cardiac tamponade	–	3	€2442.57	[29]
Severe vascular complications	–	2	€1628.38	[29]
Stroke	–	–	€6207	[30] Inpatient tariffs: DRG 555
Other severe complications	–	2	€1628.38	[29]

The table summarizes the cost inputs used to value severe procedure-related adverse events in the model. Event costs are derived by combining (i) daily unit costs for ICU stay and inpatient hospitalization (€/day) with (ii) assumed lengths of stay (number of ICU and/or inpatient days) for each complication, using outpatient tariff codes or inpatient DRG tariffs, as reported in the cited sources. The resulting total event cost values are subsequently combined with technology-specific complication rates (Table 3) to calculate expected complication costs per procedure. ICU, intensive care unit; No, number; DRG, Diagnosis-Related Group adverse reaction rates, the results are shown both annually and cumulatively over the course of the 5 years.

2.6 Sensitivity Analysis

A deterministic sensitivity analysis was conducted to evaluate the robustness of the budget effect study and take into account model uncertainties [19]. In this analysis, the most important uncertain parameters were changed from the base case to see how they affected the results. To determine which parameters in the economic evaluation model, when changed within their range, resulted in the greatest deviation from the base case results, a univariate sensitivity analysis was carried out, assuming a 20% uncertainty range for the parameters, as recommended in the Italian Health Economics guidelines [31].

3 Results

3.1 Budget Impact Analysis

Based on estimates of the eligible population and the predicted market mix of available ablation techniques, resource use was calculated for both scenarios over the 5 years. As shown in Fig. 1, annual expenditure is consistently lower in the PFA scenario compared with current practice. Although costs in the current scenario increase from €36,177,168 in 2025 to €38,141,890 in 2029, the PFA scenario exhibits a downward trend, with total costs falling from €35,820,141 in 2025 to €33,186,543 in 2029. The most notable difference arises in the later years: by 2029, the annual cost gap between the two scenarios approaches approximately €5 million.

The annual costs for the "as is" scenario (Supplementary Table S1), which maintains current interventions, and the "to be" scenario, which introduces PFA as an alternative, are shown in Supplementary Table S2. Supplementary Table S3 reports the differences between the two scenarios.

The "as is" scenario describes the main drivers of healthcare spending over 5 years under the current standard of care for atrial fibrillation. The largest share of expenditure is attributed to direct medical costs, which account for 51.2% of total cumulative spending (approximately €95.1 million out of €185.7 million). This is followed by costs related to healthcare professionals and procedures, contributing €50.7 million, or 27.3% of the total. The economic impact of AF recurrence is also considerable, amounting to €34.6 million (18.7%), while complications represent a smaller portion, with cumulative costs of approximately €5.2 million (2.8%).

In the scenario including PFA, the allocation of healthcare resources changes significantly over the 5-year horizon. Although medical device costs remain the largest cost component, reaching €98.5 million, or 56.6% of total expenditure, they are slightly higher than in the current scenario, likely due to the adoption of newer, more technologically advanced procedures.

The costs related to healthcare professionals and procedures total €43.1 million, accounting for 24.8% of the overall cost. Notably, this represents a reduction of over €7.6 million compared to the current scenario, suggesting increased procedural efficiency with PFA.

AF recurrence costs decrease from €34.6 million in the "as is" scenario to €28.7 million (16.5%) in the "to be" scenario, reflecting lower recurrence rates assumed for PFA in the model. Similarly, complication-related costs are also lower, amounting to just €3.7 million (2.1%) over 5 years, compared with €5.2 million in the current scenario. Cumulatively, implementing PFA results in a substantial reduction in total expenditure over 5 years, with approximately €11.7 million in savings (Fig. 2).

A more detailed breakdown of cost drivers is presented in Fig. 3. The transition scenario generated considerable savings through the gradual replacement of cryoballoon and laser procedures, offset by increased uptake of PFA. During the 5 years, the reduction in costs related to cryoballoon ablation represented the largest share of savings (€76.1 million), while the additional costs for PFA procedures amounted to €70.1 million. Laser ablation had a relatively smaller impact, with a net cost reduction of €5.7 million.

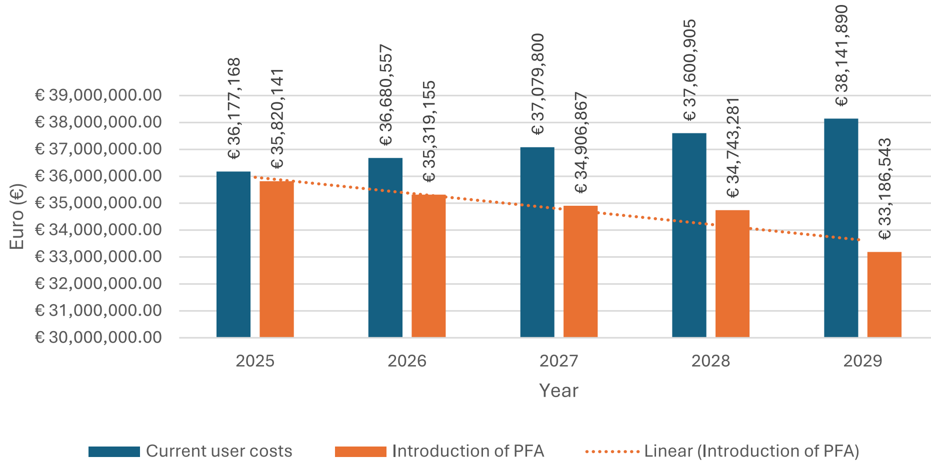
From a clinical resource perspective, the main contributors to cost reduction were a decreased incidence of AF recurrence and lower complication rates associated with

Table 6 Total single-procedure cost

	CB	LA	PFA
Health professionals and procedure	€2784.25	€2020.83	€2020.83
Medical devices cost	€5025.73	€5999.55	€5500.00
Complications costs	€302.40	€45.58	€102.07
Total single-procedure cost	€8112.38	€8065.96	€7622.90

This table consolidates the per-patient expected cost of a single index ablation for CB, LA and PFA by summing three components: (i) healthcare professionals and procedure costs (personnel time and operating room use valued at unit costs), (ii) device acquisition costs (technology-specific disposable/device costs) and (iii) expected complication costs, calculated as the weighted average of severe adverse events (event rate × unit cost per event). The total single-procedure cost equals the sum of these components for each technology and represents the base-case index-procedure cost applied in the model

CB, cryoballoon ablation; LA, laser ablation; PFA, pulsed field ablation



PFA: Pulsed Field Ablation

Fig. 1 Comparison between scenario 1 and scenario 2. The figure shows the total annual costs (€) associated with one-shot pulmonary vein isolation procedures under two alternative scenarios. Blue bars represent scenario 1 ("as is" scenario; current user costs), assuming a constant market mix over time based on 2024 procurement shares (cryoballoon and laser ablation only and no PFA uptake). Orange bars represent scenario 2 ("to be" scenario; introduction of PFA), in which pulsed field ablation is progressively adopted and replaces a share of cryoballoon and laser ablation procedures. The dotted line depicts the linear trend in total annual costs under scenario 2 over the study period. PFA, pulsed field ablation

PFA. As illustrated in Fig. 4, the largest part of the savings was derived from lower costs for healthcare professionals and procedures, which gradually increased year by year and peaked at €23.4 million in 2029. Additional savings in the management of complications and direct medical costs were observed. Importantly, the reduction in AF recurrence alone resulted in savings of more than €2.1 million by 2029.

3.2 Sensitivity Analysis

The sensitivity analysis shows the main factors that affect the budget impact findings, and the most significant variable is the PFA ablation costs (Fig. 5). The variation in this input generates a cost differential ranging from – €22,046,885 to – €1,361,785, indicating that even modest changes in the cost of PFA ablation can lead to substantial differences in overall expenditure. This underscores the critical importance of price negotiation and cost control in maximising the economic sustainability of PFA adoption.

Cryoballoon ablation costs also play a pivotal role, with a range of – 21,134,968 to – 2,273,703. A reduction in CB-related expenses translates into meaningful savings, contributing to the potential cost-efficiency of transitioning to PFA technology. Additionally, the time required to perform the procedures significantly affects the budget: for CB and LA, the duration of the procedure contributes to cost variations of up to –€16,928,900 and – €15,199,029, respectively. These findings emphasise the operational benefits of adopting faster and more efficient ablation techniques.

Other relevant factors include the percentage of total hospitalisations with atrial fibrillation as the primary diagnosis, the proportion of patients eligible for single-shot techniques and the recurrence and re-ablation rates, particularly in the CB cohort. Although clinical complications (e.g. oesophageal injury or ICU use) have relatively less influence, the analysis confirms that procedural costs, efficiency and patient selection criteria are the dominant levers in shaping the economic impact of ablation strategies.

4 Discussion

This study provides a comprehensive assessment of the economic impact associated with the adoption of PFA for the treatment of AF, compared with traditional ablation techniques such as CB and LA. The results of the budget impact analysis suggest that PFA has the potential to generate significant cost savings for the healthcare system, particularly when procedural efficiency and reductions in recurrence rates are considered within the Italian NHS. The favourable economic profile observed in our analysis is driven primarily by improvements in procedural efficiency and a reduction in repeat interventions, findings that are increasingly supported by the international literature.

These findings are consistent with growing international evidence showing that PFA substantially improves intra-procedural efficiency. In particular, a European multicentre study [32] demonstrated that PFA is associated with

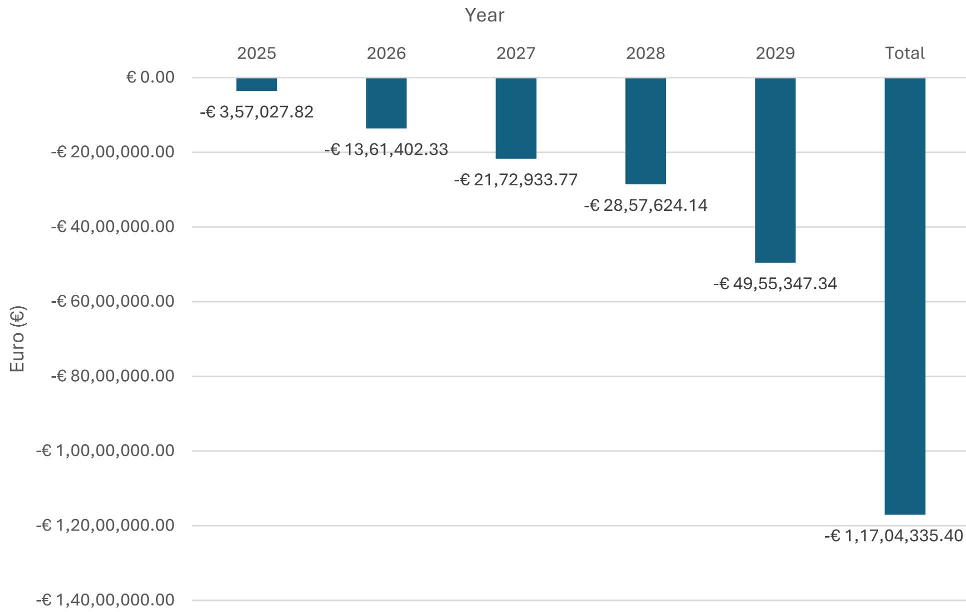
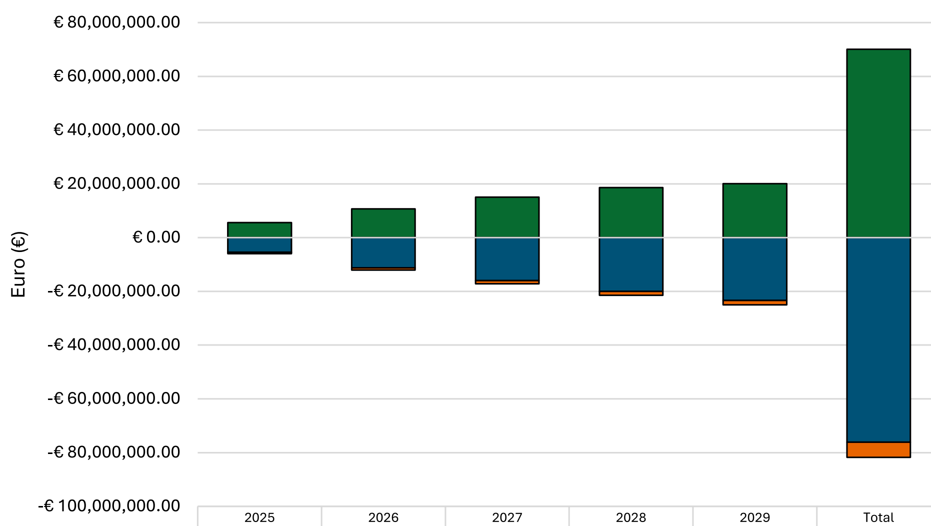


Fig. 2 Differential analysis of budget impact of transitioning from the "as is" scenario to the "to be" scenario. The figure presents the incremental budget impact (€) of moving from the baseline "as is" scenario (current market mix) to the "to be" scenario (progressive adoption of pulsed field ablation). Bars show the annual difference in total costs calculated as: ΔCost_year = Total cost_to be,year – Total cost_as is,year. Negative values therefore indicate cost savings in the "to be" scenario relative to the "as is" scenario. The "Total" bar reports the cumulative budget impact over 2025–2029, equal to the sum of the annual differences. PFA, pulsed field ablation

markedly shorter procedure times compared with cryoablation and radiofrequency ablation. Such reductions translate into meaningful per-patient cost savings through lower operating room occupancy and simplified peri-procedural management. In publicly funded healthcare systems, where procedural time represents a key constraint on capacity and performance, these efficiency gains have direct and immediate economic relevance.

Importantly, the economic advantages of PFA do not appear to be limited to the short term. Beyond procedural efficiency, emerging evidence suggests that PFA may deliver sustained value over longer time horizons by improving clinical durability. The cost-effectiveness analysis based on data from the ADVENT trial [33] reported that PFA is a dominant strategy compared with thermal ablation, achieving both higher effectiveness and lower lifetime costs. Using a lifetime horizon of up to 40 years and adopting the perspective of the US healthcare system, PFA generated an incremental gain of 0.044 quality-adjusted life years (QALYs) alongside a cost savings of $2871 per patient. These long-term benefits were



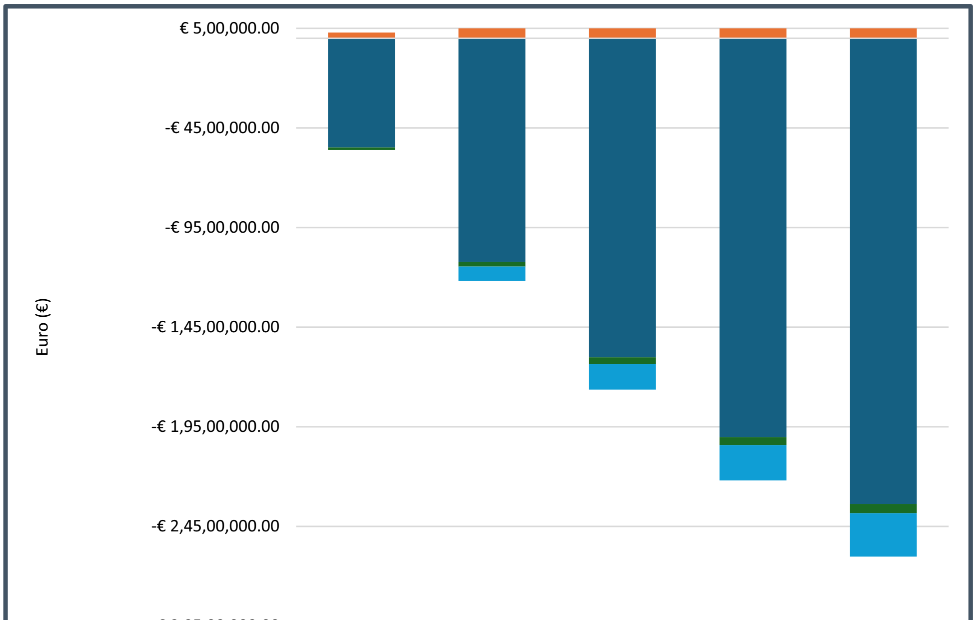
	2025	2026	2027	2028	2029	Total
Pulsed field ablation [PFA]	€ 5,603,199.03	€ 10,721,425.37	€ 15,028,311.94	€ 18,616,610.15	€ 20,099,844.23	€ 70,069,390.72
Laser [LA]	-€ 480,867.01	-€ 861,664.06	-€ 1,184,995.41	-€ 1,453,642.42	-€ 1,679,326.57	-€ 5,660,495.46
Cryoballoon [CB]	-€ 5,479,359.84	-€ 11,221,163.64	-€ 16,016,250.30	-€ 20,020,591.88	-€ 23,375,865.00	-€ 76,113,230.66

Year

Fig. 3 Projection of differential analysis of costs for procedures in "as is" and "to be" scenarios. The figure shows the incremental costs (€) attributable to each ablation technology when comparing the "to be" scenario (progressive adoption of pulsed field ablation) with the "as is" scenario (constant baseline market mix). The "Total" column reports the cumulative differential cost over the full time horizon. CB, cryoballoon ablation; LA, laser ablation; PFA, pulsed field ablation

CB: cryoballoon; LA: laser ablation; PFA: Pulsed Field Ablation

Fig. 4 Projection of healthcare resources use resulting from the differential analysis of the two scenarios. The figure presents the incremental costs (€) associated with changes in healthcare resource use resulting from the transition from the baseline "as is" scenario to the "to be" scenario with progressive PFA adoption. Stacked bars report the annual differential cost by cost component, including healthcare professionals and procedure costs, medical device costs, complication-related costs and AF-recurrence-related costs. Values are computed as ΔCost{component,year} = Cost{to be,component,year} − Cost{as is,component,year}; negative values indicate cost savings in the "to be" scenario. AF, atrial fibrillation



	2025	2026	2027	2028	2029
AF recurrence costs	€ 0.00	-€ 7,21,645.31	-€ 12,93,113.95	-€ 17,78,342.81	-€ 21,81,505.96
Complications costs	-€ 1,31,942.66	-€ 2,36,427.63	-€ 3,25,144.88	-€ 3,98,857.58	-€ 4,60,781.90
Medical devices costs	€ 2,90,555.34	€ 5,20,645.19	€ 7,16,012.40	€ 8,78,337.58	€ 10,14,703.21
Health professionals and Procedure costs	-€ 54,79,359.84	-€ 1,12,21,163.64	-€ 1,60,16,250.30	-€ 2,00,20,591.88	-€ 2,33,75,865.00

AF: Atrial fibrillation.

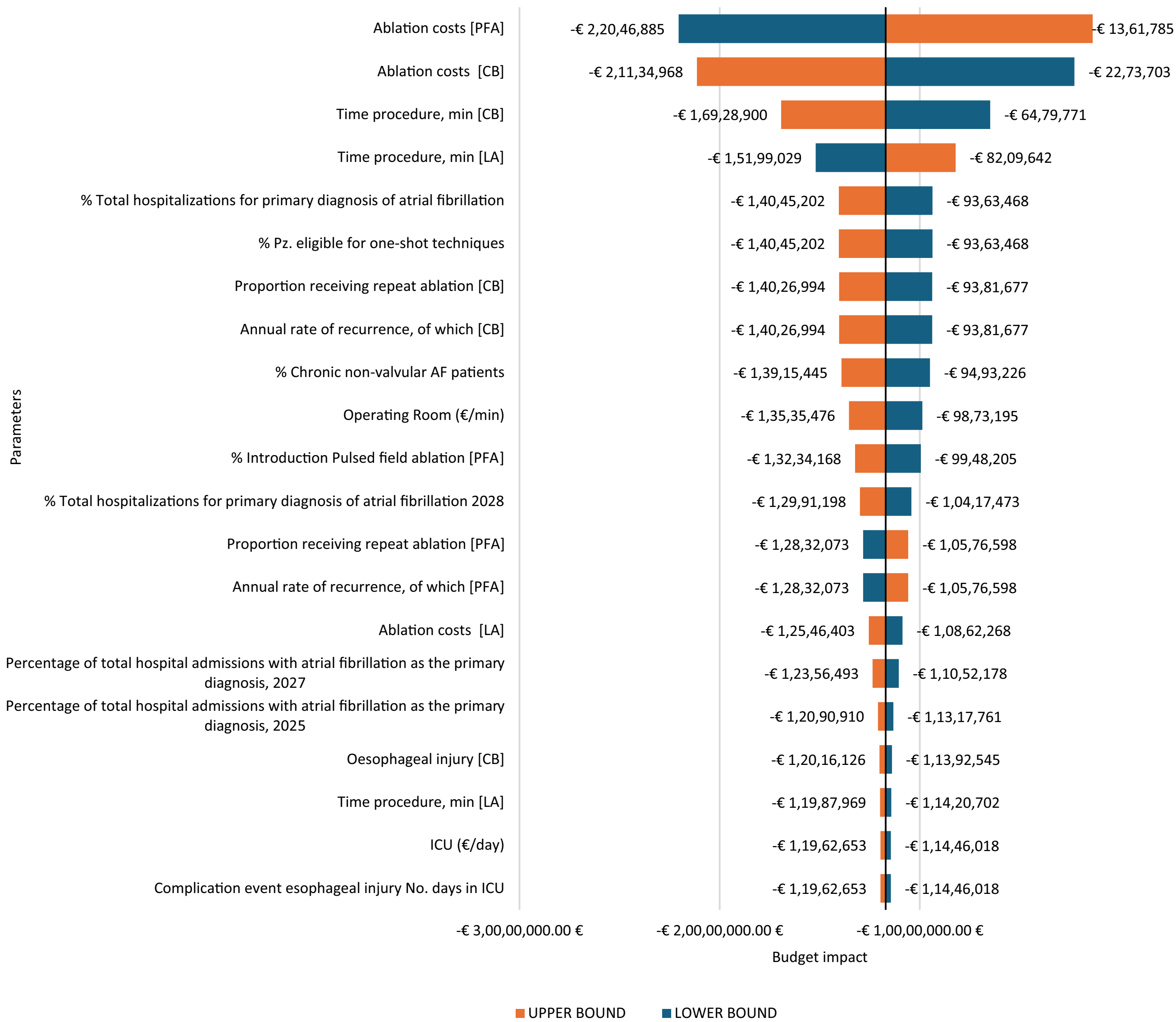
primarily driven by improved clinical outcomes, including fewer recurrences and a reduced need for repeat procedures, reinforcing the central role of recurrence reduction as a key economic driver, also reflected in the present model.

The clinical advantages of PFAs, such as reduced procedure times and a decreased chance of collateral damage, further encourage its use as an affordable substitute for traditional methods. A meta-analysis published in 2025 [34], which examined 30 studies including 7167 patients, confirmed that PFA is associated with shorter procedural times and lower rates of atrial arrhythmia recurrence compared with both radiofrequency and cryoballoon ablation. Importantly, PFA was also associated with a lower rate of post-procedure complications relative to cryoballoon ablation, an aspect of substantial economic relevance given the high costs associated with the management of adverse events. Although PFA was associated with longer fluoroscopy times and higher troponin release, these findings did not translate into worse clinical outcomes and should be interpreted within the broader context of its non-thermal mechanism and overall favourable safety profile.

From a health system perspective, evidence from other European settings further supports the transferability of these findings. In the UK, an economic evaluation [25] showed that PFA was modestly less costly than cryoablation over a 12-month period, despite the higher initial catheter costs. These upfront expenditures were more than offset by a substantial reduction in re-ablation procedures and complication-related costs, underscoring the importance of adopting at least a medium-term time horizon when assessing innovative ablation technologies. Similar conclusions were reached in a recent systematic review [35], which found that PFA was cost-effective in the majority economic evaluations, with observed variability largely explained by local device pricing and procurement conditions.

Consistent with this evidence, our sensitivity analysis identified procedural costs, particularly those related to PFA, as the most influential parameters that affect total expenditures. Variations in PFA costs alone generated a differential of more than €20 million, emphasising the critical role of price negotiation and procurement strategies in shaping the value proposition of this technology. Similarly, CB ablation costs and the time required to perform the procedures were also shown to be major drivers of economic outcomes.

Despite the growing body of evidence supporting the clinical and economic value of PFA, our analysis highlights a significant structural barrier to its sustainable adoption in Italy. The Diagnosis-Related Group (DRG) 518 tariff value of €4018 is the current national and regional reimbursement for advanced one-shot ablation procedures, which is insufficient to cover related expenses. The actual costs of these operations, excluding the costs associated with



PFA: Pulsed Field Ablation; CB: Cryoballoon Ablation; LA: Laser Ablation; Pz: Patients; AF: Atrial Fibrillation; Min: Minutes; ICU: Intensive Care Unit; No. = Number.

Fig. 5 Deterministic sensitivity analysis. This tornado diagram illustrates the results of a deterministic one-way sensitivity analysis assessing the impact of parameter uncertainty on the cumulative budget impact (€) of transitioning from the "as is" scenario to the "to be" scenario with pulsed field ablation adoption over the 2025–2029 time horizon. Each horizontal bar represents the change in the cumulative budget impact obtained by varying one model parameter at a time while holding all other parameters at their base-case values. The central vertical line corresponds to the base-case cumulative budget impact. Orange bars (upper bound) indicate the budget impact when the parameter is set to its upper plausible value, whereas blue bars (lower bound) indicate the result when the parameter is set to its lower plausible value. Parameters are ranked from top to bottom according to their influence on the model outcome, with the most influential drivers shown at the top. PFA, pulsed field ablation; CB, cryoballoon ablation; LA, laser ablation; Pz, patients; AF, atrial fibrillation; ICU, intensive care unit; No., number

complications, determined by our analysis, are the following: €7,809.98 for CB, €8,020.38 for LA and €7,520.83 for PFA. This misalignment between reimbursement and real-world costs risks discouraging the adoption of innovative yet cost-effective technologies and may exacerbate regional inequities in access to advanced AF treatments.

In conclusion, the integration of PFA into routine clinical practice can improve patient outcomes while promoting a more efficient allocation of healthcare resources. However, the realisation of these benefits within the Italian National Health Service will critically depend on the alignment of reimbursement policies with actual procedural costs. Ensuring adequate and technology-sensitive reimbursement mechanisms appears essential to support equitable access, foster innovation and maintain the long-term sustainability of the healthcare system.

4.1 Limitations

Despite the positive outcomes, it is crucial to acknowledge certain limitations. The safety and efficacy of PFA have not been fully established due to its recent introduction into clinical practice. The absence of robust long-term data can affect the accuracy of projected outcomes, particularly regarding recurrence and complication rates. In addition, the available data on PFA mainly come from controlled clinical settings rather than real-world scenarios. This limitation could restrict the generalisability of the findings to broader populations of patients. Projections on the future adoption rate of PFA should be interpreted with caution. These rates may be influenced by rapidly evolving clinical guidelines, technological advances and operational dynamics at the hospital level.

Although the analysis was conducted from the perspective of the Italian NHS, some epidemiological and use inputs were derived from data collected in a single Italian region. This may introduce uncertainty, as regional variability in healthcare organisations, procedural volumes and clinical practice patterns may not be fully captured. In addition, some cost inputs, particularly those related to procedure duration, staffing and operating room use, were informed by expert opinion due to the lack of published Italian technology-specific data. Although these assumptions reflect routine practice, they may not capture variability across centres and therefore introduce uncertainty into cost estimates. A further limitation concerns the exclusion of indirect costs associated with AF, such as productivity losses, informal caregiving and other societal burdens. Although these costs can represent a substantial proportion of the total economic impact of AF, particularly in patients of working age and those requiring long-term assistance, they were not included due to the lack of reliable context-specific data. As a result, the findings may underestimate the true societal burden of AF, especially when considering the broader implications beyond direct healthcare spending.

These limitations highlight the need for further research to validate the findings and improve the robustness of the economic evaluation of PFA in the treatment of atrial fibrillation.

5 Conclusions

Our study suggests that the introduction of PFA for the treatment of atrial fibrillation in Italy may offer economic advantages compared with established ablation techniques. The potential benefits associated with procedural efficiency, reduced recurrence and lower healthcare costs highlight the role of PFA as a promising treatment option. More research is required to overcome the limitations recognised by this research and validate the findings using long-term data.

Future health policies should focus on optimising resource allocation and updating reimbursement mechanisms to better reflect the costs of innovative ablation technology. To ensure the successful implementation of PFA and maintain equitable access to high-quality care across the Italian healthcare system, alignment between reimbursement policies and actual procedural costs will be essential, alongside continued evidence generation and monitoring of real-world outcomes.

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Declarations

Conflict of interest The authors have no competing interests to declare that are relevant to the content of this article.

Ethics approval All data used in this study were fully de-identified; ethics approval was not required and was not sought.

Consent to participate Not applicable.

Consent for publication Not applicable.

Code availability Not applicable.

Data availability statements All data supporting the findings of this study are available within the paper and its Supplementary Information.

Author contributions E.F., I.V. and C.F. were responsible for the study concept and study design. All authors were responsible for study conduct and data acquisition. E.F., I.V. and C.F. were responsible for analysis and interpretation. I.V. was responsible for original draft preparation. E.F., I.V. and C.F. were responsible for draft review and editing. All authors have read and agreed to the final version of this manuscript. All authors also confirm accountability for the accuracy and integrity of the work.

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