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RESEARCH ARTICLE

Procurement of devices for pulsed-field ablation of paroxysmal atrial fibrillation: the experience of the Tuscany region in Italy

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ABSTRACT

In this Health Policy article, we describe the experience conducted in Italy in the Tuscany region to implement an appropriate management of the devices available for pulsed-field ablation of paroxysmal atrial fibrillation. For patients who do not respond to pharmacological treatment, ablation techniques have long been a recognized therapeutic standard. Radiofrequency ablation and cryoballoon ablation (both referred to as thermal ablation options) were the first two techniques made available for this therapeutic indication. More recently, pulsed-field ablation has been developed as a means of achieving the same clinical result without any thermal intervention; iIn fact, thermal techniques are more often involved in determining local tissue damages. In 2024, there are already three different devices available to perform pulsed/field ablation, thus minimizing the risk of thermal damage to local tissues. These three devices include Farawave (from Boston), PulseSelect (from Medtronic), and Varipulse (from Johnson & Johnson).

Our paper reports on the technical characteristics of these three devices and the available clinical evidence on their effectiveness. The clinical studies for Farawave (the first device developed in 2021) are more numerous than those for PulseSelect and Varipulse, whose development is much more recent.

Epidemiological data from the entire region were analysed to determine the total number of the three devices needed by our hospitals on an annual basis. These regional data were interpreted in comparison with the national consumption of these devices.

In conclusion, the main strength of the experience described here is that the principles of HTA have been successfully applied in daily practice. For more than 5 years, this policy has been applied in our Centro Operativo in the management of about 80 devices classified as class IIb, III or active implantable.

Keywords: meta-analysis; Kaplan-Meier curves; Shiny method; IPDFROMKM method; artificial intelligence; reconstructed individual patient data.

Introduction

In the Tuscany region in Italy, the assessment of pulsed-field ablation systems began with Farawave (Boston Scientific company) in spring 2022; at that time, Farawave was the only device on the market in this class, having obtained the CE mark in January 2021. According to the regional regulation of class III devices, Farawave entered the pathway of HTA assessment. The Centro Operativo (CO), which is the regional organism responsible for HTA assessments, issued a mini-HTA report which was the basis for the approving its acquisition at regional level; since the list price of the device was euro 6,500, the favorable decision for the acquisition of the device was however subjected to price reduction, which implied that Farawave device should not cost more than 5,500 euro. This condition was justified by the fact that Farawave was priced higher than radiofrequency and cryoablation devices, which were already in use, although it did not demonstrate an incremental benefit over them. Boston Scientific did not accept the price reduction and, as a consequence, this device was not made available to the hospitals of Tuscany.

Two new systems for pulsed-field ablation in the treatment of atrial fibrillation have recently become available: PulseSelect by Medtronic (CE mark: 20/11/2023) and Varipulse by Johnson & Johnson (CE mark: 28/02/2024). In light of this, the CHTA once again expressed its opinion on the use of pulsed-field techniques by instructing ESTAR (our regional procurement agency) to call for a tender between Farawave, PulseSelect and Varipulse in which the auction base could be set at euro 5,500. Being aware of the differences in the characteristics of the three devices and taking into account both the greater amount of evidence available for Farawave and the difficulty of weighing these variables by means of a tender score, it was decided that the tender would empower each in-hospital centre to choose, among the three devices, the one to which it would give preference[1].

This document on pulsed-field ablation systems for the treatment of paroxysmal atrial fibrillation was drafted by the CO with the aim of providing technical/scientific support for the work of the future technical panel that will be called to draw up the technical specifications of the tender for the acquisition of pulsed-field ablation for our region.

Clinical problem

Electrical isolation of the pulmonary veins is the main strategy in any atrial fibrillation ablation procedure, whether percutaneous or surgical[2]. Percutaneous pulmonary vein isolation is traditionally performed using focal or single-shot ablation catheters, which rely on heat energy sources (radiofrequency and cryoablation) to promote thermal ablation of cardiac tissue. However, achieving safe and effective electrical isolation through heat-based technologies may be difficult due to the lack of tissue selectivity and the high rate of electrical reconnection of pulmonary veins. In particular, radiofrequency and cryoablation ablation devices carry a low, but not negligible, risk of collateral damage to adjacent tissues (e.g. phrenic nerve and oesophagus) and the rate of electrical reconnection of pulmonary veins has been reported to be as high as 70%[3]; however, this rate is likely to be lower with newer generation ablation systems.

In recent years, a new energy delivery modality, pulsed-field ablation, has emerged as a potential alternative to radiofrequency and cryoablation for pulmonary vein isolation procedures[4-9]. Pulsed-field ablation uses ultra-short, high-amplitude electric pulses to create non-thermal ablation of tissue. The basic mechanism that leads to cardiac cell death is known as irreversible electroporation, based on a prolonged membrane permeabilisation that leads to irreparable disruption of cellular homeostasis. As such, cell death occurs due to an alteration in cardiomyocyte cell physiology rather than a thermal process (either heating or freezing of tissue). Farawave was the first pulsed-field system for paroxysmal atrial fibrillation to receive CE marking; two other systems, PulseSelect and Varipulse, have recently received marketing approval in Europe.

Epidemiology of atrial fibrillation in the region of Tuscany

Figure 1 shows the incidence of atrial fibrillation in the region of Tuscany in 2023, broken down by the three so-called Area Vasta which correspond each to about one-third of our region. The data were processed by ARS Toscana (our regional health agency) and represent a summary of what is available at the respective website (i.e. https://www.ars.toscana.it/banche-dati/dettaglio_indicatore-3178-malati-cronici-fibrillazione-atriale-non-valvolare?provenienza=home_ricerca&par_top_geografia=090&dettaglio=ric_anno_geo_aus).

In particular, if we look at the regional figures, there were 85,508 chronic non-valvular atrial fibrillation patients in 2023, which represents 2.4% of the assisted population in the region as of 01/01/2023.

Chronic non-valvular atrial fibrillation patients: epidemiology

https://www.ars.toscana.it/banche-dati/dettaglio_indicatore-3178-malati-cronici-fibrillazione-atriale-no

-

Source: RT Anagrafe Assistibili Toscana, ARS Banca dati Malattie Croniche (MACRO) Non-valvular atrial fibrillation

Numerator: Assisted Tuscan residents aged 16+ chronically ill with non-valvular atrial fibrillation at 1/1 of the reference year

Denominator: Assisted Tuscan resident population aged 16+ at 1/1 of the reference year

Residence	Number	Rough rate	Standard rate	Lower limit	Upper limit
TUSCANY REGION	85,508	24.46	20.06	19.92	20.19
AUSL CENTRE	36,191	23.85	19.95	19.74	20.15
AUSL NORTH-WEST	30,731	25.74	20.97	20.73	21.2
SOUTH-EAST AUSL	18,586	23.71	18.91	18.64	19.18

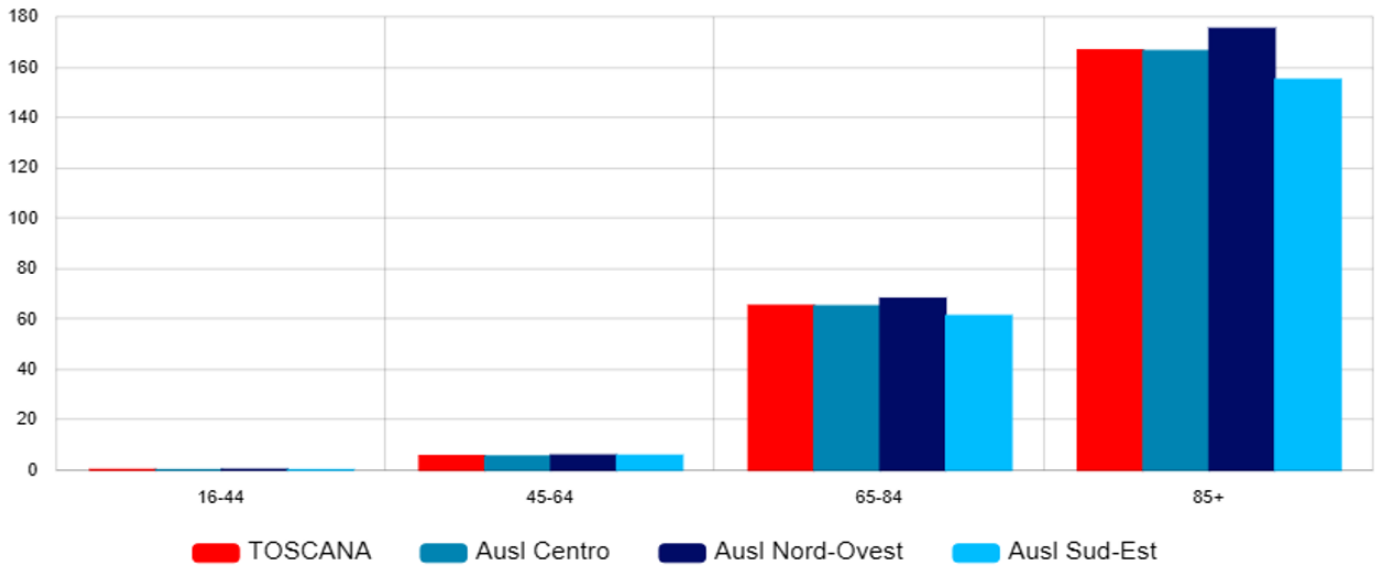

Figure 1. Distribution by age group and AUSL of chronic non-valvular atrial fibrillation patients.

The total number of admissions for a principal diagnosis of atrial fibrillation (diagnosis code 427.31) was 28,406, of which 1,305 (4.6%) correspond to "Removal or destruction of other tissues or lesions of the heart, other approach" (procedure code 3734). The admissions with procedure code 3734 correspond mainly to DRG 518 ("Interventions on the cardiovascular system by percutaneous route without stent insertion in the coronary artery without IMA"; 63.5%) and DRG 555 ("Interventions on the cardiovascular system by percutaneous route with major cardiovascular diagnosis"; 18.8%).

In 2023, total spending on hospital care was approximately 120,000,000 euro, while per capita spending was 1,406 euro and age-standardised per capita spending was 1,411 euro (see Figure 2).

Chronic non-valvular atrial fibrillation patients: Per capita expenditure on hospital care

https://www.ars.toscana.it/banche-dati/dettaglio_indicatore-3249

Source: RT Hospital Discharge Sheet (SDO), RT Assistible Tuscany Registry, ARS Chronic Diseases Data Bank
Numerator: Total Expenditure for hospital care of the chronically ill at the denominator in the reference year
Denominator: Assisted Tuscan residents aged 16+ chronically ill with non-valvular atrial fibrillation at 1/1 of the year

Age-standardised average - Year 2023 - Total

Residence	Number	Raw rate	Standard rate	Lower limit	Upper limit
TUSCANY REGION	120,295,776	1,406.84	1,411.30	1,411.05	1,411.56
AUSL CENTRE	50,021,699	1,382.16	1,388.03	1,387.65	1,388.42
AUSL NORTH-WEST	44,918,140	1,461.66	1,466.25	1,465.82	1,466.69
SOUTH-EAST AUSL	25,355,937	1,364.25	1,364.05	1,363.52	1,364.59

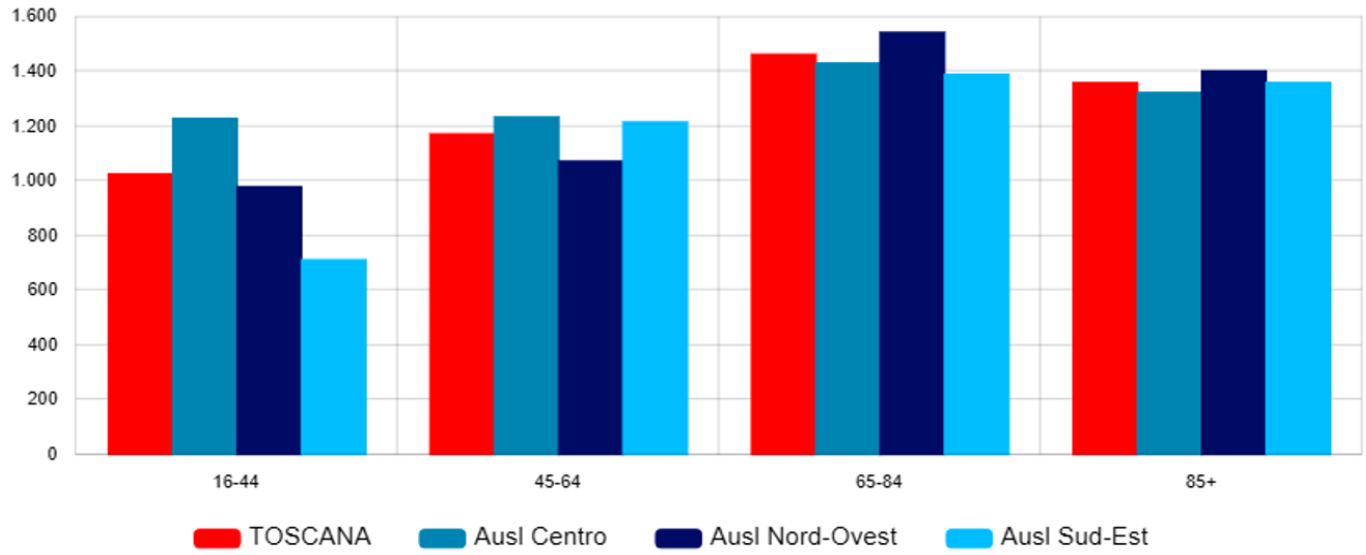

Figure 2. Total expenditure for hospital care and per capita expenditure by age group and by LHA of chronic non-valvular atrial fibrillation patients.

Description of the three pulsed-field ablation systems

FARAWAVE (BOSTON SCIENTIFIC)

Boston Scientific's FARAPULSE pulsed-field ablation system consists of the pulsed-field ablation FARAWAVE catheter, an over-the-wire multi-electrode device for pulsed-field ablation, which connects electrically to the pulsed-field ablation FARASTAR generator. The Farawave over-the-wire ablation catheter consists of 20 electrodes and a distal section with five splines that unfold in a variety of configurations that can be adjusted by the user, a non-deformable shaft and a proximal handpiece with a manually operated insertion control. The catheter is available in two sizes 31 mm or 35 mm and is indicated for ablation of cardiac tissue for the treatment of paroxysmal atrial fibrillation.

The FARASTAR pulsed-field ablation generator is a 12-channel pulsed electric field generator that is used with the FARAWAVE pulsed-field ablation catheter for ablation of cardiac tissue. FARASTAR consists of a two-channel cardiac stimulator that can be used for optional synchronous energy delivery. These medical devices of Boston Scientific all belong to Class III. They obtained CE marking in January 2021 and FDA approval in January 2024.

PULSESELECT (MEDTRONIC)

The PulseSelect ablation system from Medtronic consists of a generator for pulsed-field ablation that enables pulsed-field energy delivery via connection to the dedicated PulseSelect catheter. The PulseSelect pulsed-field ablation catheter is a circular multi-electrode catheter capable of delivering pulsed-field energy reproducibly and consistently to cardiac tissue. The catheter is bidirectionally deflectable and has an over-the-wire design, the distal end of which consists of a circular-helical array, only available in a 25mm size, on which 9 electrodes are arranged. It is possible to acquire signals, ablate and stimulate through all 9 electrodes in the ring.

The PulseSelect pulsed-field ablation system is indicated for the treatment of both paroxysmal and persistent atrial fibrillation. These medical devices of Medtronic all belong to Class III, and received both CE marking and FDA approval in November 2023.

VARIPULSE (JOHNSON & JOHNSON)

The Biosense Webster VARIPULSE platform comprises the Varipulse catheter, a variable loop multi-electrode catheter, the Trupulse™ generator multi-channel pulsed-field ablation generator, and the CARTO™ 3 system (3D cardiac mapping system). The Trupulse generator creates pulsed fields by delivering bipolar biphasic energy through pairs of up to 10 electrodes in a compatible catheter. The generator includes a touch screen that allows the user to select electrodes and apply treatment individually or in a series, setting the time between successive applications. The circular tip of the Varipulse catheter is a ring that can be expanded and contracted to conform to the anatomy of the left atrium. The diameter of the non-contracted ring is 34±1 mm and the diameter of the contracted ring is ≤ 25 mm at room temperature. On the catheter ring are three single-axis sensors (SAS) that transmit position information to the CARTO™ 3 system for visualisation of the catheter.

These medical devices of Johnson & Johnson all belong to Class III and received CE marking in February 2024; they do not yet have FDA approval.

Table 1 compares the main technical characteristics of Farawave, PulseSelect and Varipulse.

Table 1. Technical characteristics of the three systems for pulsed-field ablation of atrial fibrillation. Abbreviations: PFA, pulsed-field ablation; CE, European Community; FDA, Food and Drug Administration.

	Farawave 	**PulseSelect** 	**Varipulse** 
Approvals	CE mark, FDA	CE mark, FDA	CE mark
Catheter configuration	Basketball and flower	circular	circular
Catheter sizes	31 mm, 35 mm	25 mm	25 mm, 35 mm
Over-the-wire use	YES	YES	NO
Number of electrodes	20	9	10
Integrated mapping system	NO	NO	YES
Vein isolation mode	single delivery	single delivery	single delivery
Type Energy	PFA only	PFA only	PFA only
Catheter size	12F	9F	7,5F

Summary of evidence on pulsed-field ablation systems

STUDIE ON FARAWAVE

In patients with paroxysmal atrial fibrillation, pulsed-field ablation has been developed for several years with Farawave which, as mentioned above, was the first system to be CE-marked. Farawave has been evaluated in several single-arm studies[5-9] and in the randomised trial by Reddy et al. published in late 2023[4]. With regard to single-arm studies, four studies were recently published (with publication year in 2023 and 2024[6-9], while the IMPULSE, PEFCAT and PEFCAT II trials, summarised in Reddy et al.'s 2021 study[5], were the first single-arm studies that evaluated Farawave.

Reddy's study[4] is a randomised non-inferiority trial in which 607 patients with drug-refractory paroxysmal atrial fibrillation underwent either pulsed-field ablation (n=305) or conventional ablation with radiofrequency or cryoablation (n=302). The primary efficacy endpoint was freedom from a composite of initial procedure failure, documented atrial tachyarrhythmia after a 3-month blanking period, use of antiarrhythmic drugs, cardioversion or repeat ablation. The primary safety endpoint included acute and chronic serious adverse events related to the device and the procedure. At 1-year follow-up, the primary efficacy endpoint was met (i.e., no events occurred) in 204 patients (73.3%) who underwent pulsed-field ablation and in 194 patients (71.3%) who underwent thermal ablation (difference between groups: 2 percentage points; 95% Bayesian credibility interval, -5.2% to 9.2%; probability of non-inferiority, >0.999). Primary safety end-point events occurred in 6 patients (2.1%) undergoing pulsed-field ablation and in 4 patients (1.5%) undergoing thermal ablation (difference between groups: 0.6 percentage points; 95% Bayesian credibility interval, -1.5% to 2.8%; probability of non-inferiority, >0.999). Therefore, pulsed-field ablation was non-inferior to conventional thermal ablation with regard to the primary efficacy end-point and with regard to device- and procedure-related serious adverse events at 1 year.

Aldaas and co-workers[10] conducted a systematic review of studies that compared atrial fibrillation ablation between pulsed-field ablation and thermal ablation. This review included 6 comparative studies with a total of 1,012 patients of which 441 (43.6%) were treated with pulsed-field ablation and 571 (56.4%) with thermal ablation. The results reported that the procedure times with pulsed-field ablation were significantly shorter (mean difference [MD] -21.95 min, 95%CI -33.77 min to -10.14 min, p = 0.0003), but with significantly longer fluroscopic times (MD +5.71 min, 95%CI +1.13 min to +10.30 min, p=0.01). There were no statistically significant differences in periprocedural complications (RR 1.20; 95%CI, 0.59-2.44) or recurrences of atrial tachyarrhythmias (RR 0.64; 95%CI 0.31-1.34) between the pulsed-field and thermal ablation cohorts. The authors argue that randomised controlled trials with large case series are needed.

STUDIES ON PULSESELECT

PulseSelect was evaluated in the prospective, non-randomised pivotal study PULSED atrial fibrillation[11] in which patients with symptomatic paroxysmal (n=150) or persistent (n=150) atrial fibrillation refractory to antiarrhythmic drugs were treated with pulsed-field ablation. All patients were monitored for 1 year. The primary efficacy endpoint was freedom from a composite of acute procedural failure, arrhythmia recurrence or antiarrhythmic escalation up to 12 months, excluding a 3-month blanking period to allow recovery from the procedure. The primary safety endpoint was the absence of serious adverse events related to the procedure and the device. In total, 146 of 150 (97%) patients with paroxysmal atrial fibrillation and 141 of 150 (94%) patients with persistent atrial fibrillation completed the follow-up. The results showed that pulsed-field ablation was effective at 1 year in 66.2% (95%CI, 57.9-73.2) of patients with paroxysmal atrial fibrillation and 55.1% (95%CI, 46.7-62.7) of patients with persistent atrial fibrillation. The primary safety endpoint occurred in 1 patient (0.7%; 95%CI, 0.1-4.6) in both cohorts of paroxysmal and persistent atrial fibrillation. Freedom from any recurrence of

atrial arrhythmia after the 90-day blanking period was 69.5% and 62.3% in the paroxysmal and persistent atrial fibrillation cohorts, respectively. Freedom from recurrence of symptomatic atrial arrhythmias, as documented by transtelephonic monitoring, was 79.7% and 80.8% in the paroxysmal and persistent atrial fibrillation cohorts, respectively.

STUDIES ON VARIPULSE

The inspIRE study (Study for Treatment of Paroxysmal Atrial Fibrillation by Pulsed Field Ablation System With Irreversible Electroporation evaluated the safety and efficacy of a fully integrated biphasic pulsed-field ablation system with a variable loop catheter (Varipulse) for the treatment of drug-refractory paroxysmal atrial fibrillation[12]. Patients underwent pulmonary vein isolation with Varipulse using at least 12 applications per vein. Wave I assessed initial safety, including with regard to oesophageal injury, silent brain injury and pulmonary vein stenosis; Wave II (in the pivotal phase) tested primary safety endpoints, the incidence of early-onset primary adverse events, and efficacy, expressed as confirmed pulmonary vein isolation with no documented atrial arrhythmia at 12 months. The primary efficacy endpoint was assessed by freedom at 12 months from documented asymptomatic or symptomatic atrial arrhythmia episodes (atrial fibrillation, atrial flutter or atrial tachycardia) of ≥30s duration based on electrocardiographic data after a 3-month blanking period. Clinical success was assessed by freedom at 12 months from documented recurrences of symptomatic atrial fibrillation/atrial flutter/atrial tachycardia. The study design included an interim analysis to determine early success once 30 patients had reached 12-month follow-up and all patients had reached 3-month follow-up. A total of 226 subjects who met the criteria for safety and efficacy evaluations and received pulsed-field ablation were enrolled at 13 centres in Europe and Canada. Wave I showed no oesophageal thermal injury or pulmonary vein stenosis. No primary adverse events were reported in Wave II. After initial success, 83 subjects reached the 12-month follow-up. Pulmonary vein isolation was achieved in 97.1% of the target veins. For Wave II, the primary efficacy endpoint according to Kaplan-Meier at the time of the interim analysis was 70.9%; freedom at 12 months from recurrences of atrial fibrillation/atrial flutter/symptomatic atrial flutter and from repeat ablations was 78.9% and 92.3%, respectively. The total procedure time was 70.1±27.7 minutes.

COMPARATIVE STUDIES OF THE THREE PULSED-FIELD SYSTEMS

The recent meta-analysis by Qamar et al.[13] studied the safety and efficacy of pulsed-field ablation, using all three systems now available for the treatment of atrial fibrillation. The main results are as follows: a) the acute procedural success in isolating all pulmonary veins was 99.7%; b) the overall rate of recurrent atrial arrhythmias within the blanking period was 10.3% and after the blanking period 17.3%; c) the overall complication rate was 2.8%.

A recent analysis, performed by our CO, carried out an indirect comparison between Farawave, PulseSelect and Varipulse in patients with paroxysmal atrial fibrillation[14]. The method used in the analysis is called IPDfromKM method, an artificial intelligence algorithm that studies the Kaplan-Meier graph and, based on this information, generates a database of reconstructed patients. In this way, head-to-head comparisons can be made between treatments that have never been compared in real patients. The endpoint of the analysis was the absence of recurrence of arrhythmia, either atrial fibrillation, atrial flutter or atrial tachycardia. The time horizon was set at a minimum of 12 months. A total of 9 studies were included in the analysis, of which 8 were single-arm studies (of these 8, 6 had evaluated Farawave, 1 PulseSelect and 1 Farapulse) and 1 randomised controlled trial had evaluated Farawave.

From the results of this analysis shown in Figure 3 (which has been drawn from the original article[11], the outcomes of most single-arm studies were consistently better than those observed in Reddy's randomised trial [7] (with p-values of <0.001 to 0.057 and a trend at p=0.121). This result could be explained

by the fact that the randomised study employed a slightly broader composite endpoint (based on four conditions) than the other studies in which the composite endpoint included three conditions; this might explain why the rates of endpoint occurrence were slightly higher. Furthermore, this analysis showed very similar results in the three formal single-arm studies[7–9] that evaluated Farawave, PulseSelect and Varipulse as confirmed by the fact that the differences in outcome between these devices remained far from statistical significance.

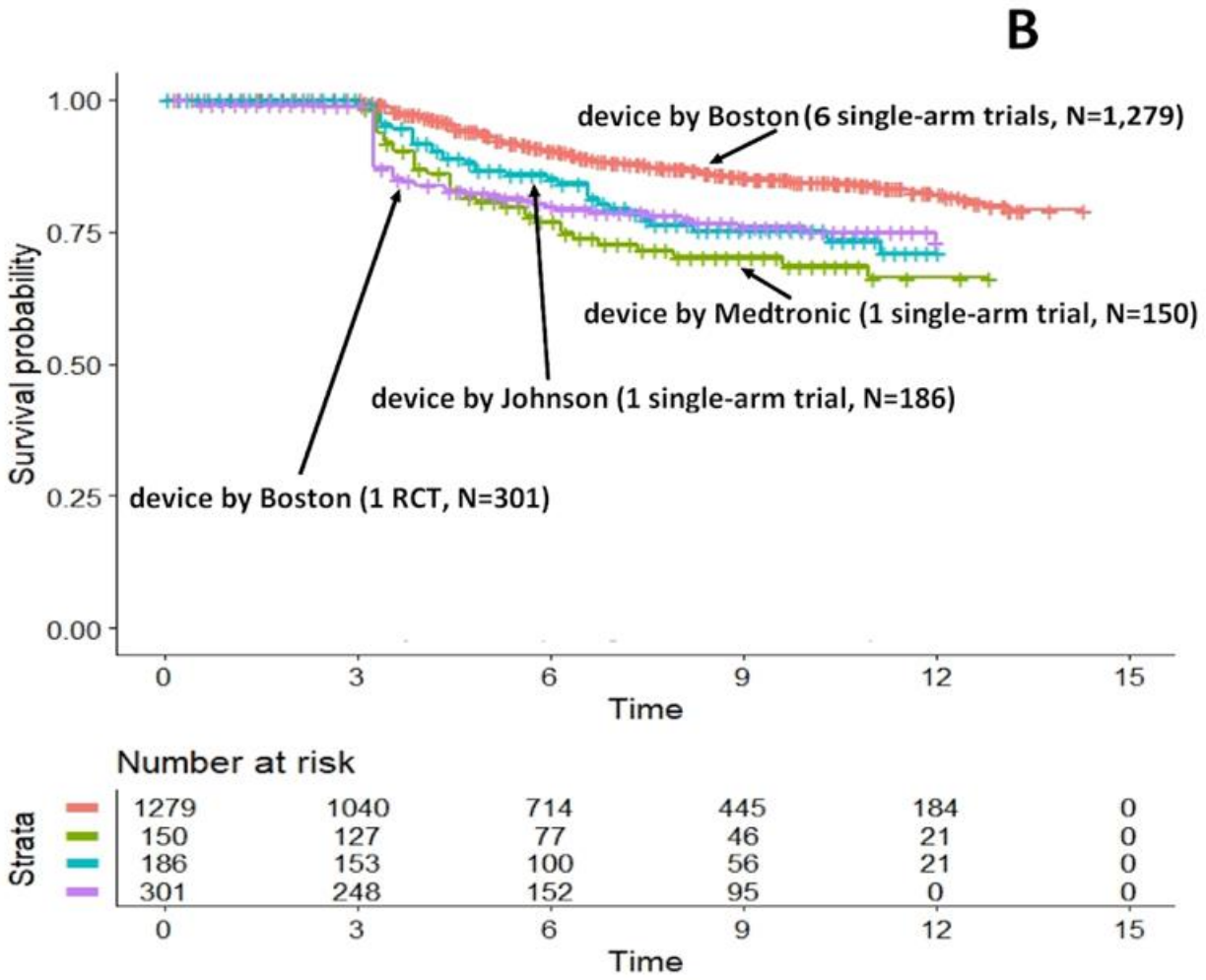

Figure 3. Indirect comparison of the three different ablation devices based on the endpoint of freedom from arrhythmia recurrence (reproduced with permission from Figure 1 panel B of the article by Messori et al.[10]

National consumption of Farawave by region and local health unit

The information on the national consumption of Farawave by region and local health unit in Italy was extracted from the Ministry of Health NSIS database for the year 2023. As shown in Table 2, in 2023 Farawave was used in 9 Italian regions in widely varying quantities from region to region. In all regions, the use of Farawave was concentrated in only a few healthcare companies. There are no reported uses of PulseSelect and Varipulse as these two systems were CE-marked at the end of 2023 and the beginning of 2024, respectively.

Table 2. Farawave consumption in Italy by region and local health unit in 2023.

Region	Local health unit	Total per local health unit (pieces)	Total per region (pieces)
010 - PIEDMONT	010203 - TO3	72	106
	010206 - VC	14	
	010212 - AT	20	
030 - LOMBARDY	030721 - ASST DEGLI SPEDALI CIVILI DI BRESCIA	6	25
	030924 - S. MATTEO POLYCLINIC - PAVIA	19	
050 - VENETO	050503 - AZIENDA ULSS N. 3 SERENISSIMA	46	134
	050508 - AZIENDA ULSS N. 8 BERICA	88	
080 - EMILIA ROMAGNA	080101 - AZIENDA USL PIACENZA	8	68
	080904 - MODENA HOSPITAL COMPANY	10	
	080909 - AZ. OSP. ARCHISPEDALE S. ANNA	50	
100 - UMBRIA	100901 - MONTELUCE POLYCLINIC	8	8
110 - MARCHE	110905 - HOSPIT. UMBERTO I-G.M.LANCISI-G.SALESI	150	150
150 - CAMPANIA	150206 - A.S.L. NAPLES 3 SUD	22	22
190 - SICILY	190207 - ASP RAGUSA	7	41
	190927 - Azienda Ospedaliera 'Civico-Di Cristina-	34	
200 - SARDINIA	200905 - AZIENDA OSPED. UNIVERSITY HOSPITAL OF SASSARI	11	11
Total			565

Notes: Manufacturer: FARAPULSE INC; Repertoire number: 2209687 (manufacturer's part numbers, 41M402 and 41M401); Repertoire number: 2530942 (manufacturer's part numbers, M004PFCE41M401 and M004PFCE41M402).

Conclusion

Atrial fibrillation is the most widespread arrhythmia in the general population; its prevalence tends to increase with age and is often associated with symptoms that can invalidate and worsen quality of life, due to the complications to which it is often correlated[15]. In 2023, there were 85,508 patients with chronic non-valvular atrial fibrillation in the region of Tuscany, representing 2.4% of the assisted population.

The first treatments to control atrial fibrillation are usually pharmacological and, where anti-arrhythmic therapy is ineffective, cardiac ablation is used[15]. In most cases, this technique is performed transcatheterically and is aimed at scarring the tissue that causes the abnormal heartbeat or spreads it. Currently, cardiac ablation procedures for the treatment of arrhythmias are thermal, i.e. radiofrequency or cryoablation[2]. Despite improvements in these techniques over the years, these forms of energy delivery, as mentioned above, can nevertheless cause collateral thermal damage to tissue near the target area.

The new technique of pulsed-field ablation (or electroporation) is based on pulsed electric fields that do not cause thermal effects on the affected tissues and act exclusively on the target cells (cardiomyocytes); this technique is therefore characterised by high tissue selectivity and safeguards areas of cardiac tissue not involved in ablation[5]. Pulsed-field ablation therefore represents a promising advancement in the treatment of atrial fibrillation.

Farawave, the first pulsed-field ablation system to receive the CE mark, has more evidence[5-11] and is supported by comparative analyses against radiofrequency and cryoenergy ablation; these comparisons have reported significantly shorter procedure times, but no difference in periprocedural complications and recurrences of atrial tachyarrhythmias[11]. In contrast, the recently marketed PulseSelect and Varipulse systems are presently supported only by a single arm trial[12,13], which prevents sound comparisons between these devices to be made.

In conclusion, further clinical trials directly comparing these three devices are needed to provide a reliable comparative synthesis of the available evidence on both efficacy and adverse events.

Conflict of interest statement:

The authors declare no conflict of interest.

Acknowledgement:

Since this paper describes a real experience of medical device governance that has taken place in the health system of an Italian region, this paper is intended to be a Policy Article and therefore is not divided into the typical sections of an Original Article (Introduction, Methods, Results, Discussion and Conclusions).

Funding statement:

No funding.

Data availability:

All data that are pertinent to our study are directly reported in the article; other data cannot be obtained from the authors.

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Abbreviations

CO: Centro Operativo HTA, Regione Toscana
CHTA: Regional Commission for the Evaluation of Healthcare Technology and Interventions