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Rhythm outcomes of minimally-invasive off-pump surgical versus catheter ablation in atrial fibrillation: A meta-analysis of reconstructed time-to-event data

Massimo Baudo [*], Rocco Davide Petruccelli, Michele D'Alonzo, Fabrizio Rosati, Stefano Benussi, Lorenzo Di Bacco [1], Claudio Muneretto [1]

Department of Cardiac Surgery, Spedali Civili di Brescia, University of Brescia, Brescia, Italy

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ABSTRACT

Background: Mid- and long-term rhythm outcomes of catheter ablation (CA) for atrial fibrillation (AF) are reported to be suboptimal. Minimally invasive surgical off-pump ablation (MISOA), including both thoracoscopic and trans-diaphragmatic approaches, has been developed to reduce surgical invasiveness and overcome on-pump surgery drawbacks. We sought to compare the efficacy and safety of MISOA and CA for AF treatment.
Methods: A systematic review and meta-analysis of the literature was performed including studies comparing MISOA and CA. The primary endpoint was survival freedom from AF at follow-up after a 3-month blanking period. Subgroup analysis of the primary endpoint was performed according to the type of surgical incision and hybrid approach.
Results: Freedom from AF at 4 years was 52.1% ± 3.2% vs 29.1% ± 3.5%, between MISOA and CA respectively (log-rank $p < 0.001$; Hazard Ratio: 0.60 [95%Confidence Interval (CI):0.50–0.72], p < 0.001). At landmark analysis, a significant improvement in rhythm outcomes was observed in the MISOA group after the 5th month of follow-up (2 months from the blanking period). The Odds Ratio between MISOA and CA of postoperative cerebrovascular accident incidence and postoperative permanent pacemaker implant (PPM) were 2.00 (95% CI:0.91–4.40, $p = 0.084$) and 1.55 (95%CI:0.61–3.95, $p = 0.358$), respectively. The incidence rate ratio of late CVA between MISOA and CA was 0.86 (95%CI:0.28–2.65, $p = 0.787$), while for late PPM implant was 0.45 (95% CI:0.11–1.78, $p = 0.256$).
Conclusions: The current meta-analysis suggests that MISOA provides superior rhythm outcomes when compared to CA in terms of sinus rhythm restoration. Despite the rhythm outcome superiority of MISOA, it is associated to higher postoperative complications compared to CA.

1. Introduction

Atrial fibrillation (AF) represents the most prevalent supraventricular arrhythmia worldwide, with an increasing incidence in elderly (peak of 17.8% in patients above 85 years of age), representing an important risk factor for death and complications including heart failure, stroke and psychophysical enfeeblement [1]. Furthermore, AF significantly impacts the quality and expectancy of life owing to frequent hospitalizations and related morbidities [2].

To date, recent 2020 European Society of Cardiology (ESC) guidelines for the diagnosis and management of AF [3] confirm pulmonary veins catheter ablation (CA) as the first choice for invasive treatment of paroxysmal (PAF) or non-paroxysmal AF (nPAF). In spite of this, catheter ablation mid-and long-term results showed to be suboptimal especially in persistent and long-standing persistent AF, with a success rate ranging from 30% (after single procedure) to 50–60% after multiple CA [4–7].

Over the years, the Cox-Maze surgical ablation, and its evolutions, has demonstrated to be effective in restoring and maintain sinus rhythm at long-term [8,9]. Despite its efficacy, this procedure is burdened with high surgical invasiveness entailing a not negligible rate of complications [10]. With the aim to reduce surgical trauma, new minimally

* Corresponding author at: Cardiac Surgery Department, Spedali Civili di Brescia, Piazza Spedali Civili, 1, 25123 Brescia, Italy.
E-mail address: massimo.baudo@icloud.com (M. Baudo).
[1] These Authors share equal senior authorship.

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Table 1
Baseline patients' characteristics.

Variable	CA ($n = 1164$)	MISOA ($n = 1070$)	p-value
Age, mean (years ± SD)	59.3 ± 5.0	58.8 ± 5.1	0.752
Male sex, n (%)	861 (74.0%)	841 (78.6%)	**0.010**
BMI, mean	29.3 ± 3.0	29.2 ± 3.0	0.892
Previous CVA, n (%)	42 (5.8%)	113 (16.2%)	**<0.001**
CAD, n (%)	45 (12.4%)	24 (9.8%)	0.170
AF duration, mean (years ± SD)	4.7 ± 4.6	4.6 ± 3.8	0.853
LVEF, mean (% ± SD)	57.2 ± 5.0	57.4 ± 5.0	0.895
LA diameter, mean (mm ± SD)	44.9 ± 3.6	43.0 ± 10.4	0.467
nPAF, n (%)	701 (60.2%)	730 (68.2%)	**<0.001**
Diabetes, n (%)	118 (13.0%)	83 (10.1%)	*0.057*
Hypertension, n (%)	460 (48.0%)	401 (43.3%)	**0.040**
CHA2DS2-VASc, mean ± SD	1.4 ± 0.7	1.2 ± 0.5	0.316
Previous ablation, n (%)	137 (20.9%)	155 (24.6%)	0.118

AF = atrial fibrillation; BMI = body mass index; CAD = coronary artery disease; CVA = cerebrovascular accident; LA = left atrial; LVEF = left ventricular ejection fraction; nPAF = non-paroxysmal atrial fibrillation; SD = standard deviation.

Table 2
Meta-analysis of the primary and secondary outcomes.

Outcome	No. of studies	Estimate*, p-value	95% CI	Heterogeneity: I^2, p-value
Mean procedure time	20	SMD: 0.9598, $p = 0.0024$	0.3396–1.5801	97.0%, $p < 0.0001$
Conversion to sternotomy	12	PER: 4.80%	2.24–9.99	43.7%, $p = 0.0523$
LAA occlusion	17	PER: 91.83%	78.47–97.19	86.3%, $p < 0.0001$
Postoperative CVA	19	OR: 2.0024, $p = 0.0841$	0.9107–4.4032	0%, $p = 0.9988$
Postoperative PPM	10	OR: 1.5502, $p = 0.3588$	0.6077–3.9543	0%, $p = 0.9607$
Postoperative total adverse events	17	OR: 4.4408, $p < 0.0001$	2.3858–8.2659	66.3%, $p < 0.0001$
30-day mortality	21	OR: 1.9573, $p = 0.0871$	0.9068–4.2249	0%, $p = 0.9999$
Late CVA	8	IRR: 0.8559, $p = 0.7875$	0.2760–2.6537	0%, $p = 0.9575$
Late PPM	4	IRR: 0.4518, $p = 0.2562$	0.1146–1.7809	0%, $p = 0.9561$
Late total adverse events	4	IRR: 2.2711, $p = 0.0144$	1.1925–4.3255	32.3%, $p = 0.2191$
Late mortality	12	IRR: 1.2092, $p = 0.7070$	0.4492–3.2554	0%, $p = 0.9962$

CI = confidence interval; CVA = Cerebrovascular accident; IRR = incidence rate ratio; LAA = left atrial appendage; OR = odds ratio; PER = pooled estimated rate; PPM = permanent pacemaker; SMD = standardized mean difference; SR = sinus rhythm.
* CA set as reference.

invasive off-pump procedures have been developed in the last decades, preserving a comparable effectiveness of the original procedure and reducing the surgical complications [11,12].

The aim of the present meta-analysis was to compare the efficacy and safety of minimally invasive off-pump surgical AF ablation (MISOA), including both the thoracoscopic and transdiaphragmatic (or subxiphoid approach), to CA.

2. Materials and methods

2.1. Literature search strategy

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [13]. The PRISMA flow diagram is presented (Fig. A.1). Pubmed, ScienceDirect, Ovid EMBASE, SciELO, Google Scholar, and Cochrane databases were searched until March 2022 for publications reporting the clinical outcome of comparative studies between patients undergoing MISOA and CA for AF ablation. The search strategy can be seen in Table A.1. In addition, the bibliography of all studies and meta-analyses were searched to identify further articles, i.e. "backward snowballing". Studies were independently screened for inclusion by two authors (M.B. and R.D.P.). In case of disagreement, a consensus was reached with the aid of a third author (C.M.).

This review was registered with the PROSPERO register of systematic reviews (ID: CRD42022367116). There was no individual patient involvement in this study; as such, research ethics board approval or patient's consent was not required. The data that support the findings of this study are available from the corresponding Author upon reasonable request.

2.2. Selection criteria

Inclusion criteria for analysis were English language, two-armed studies comparing MISOA, including the hybrid approach (HA), and CA alone, which reported restoration to sinus rhythm (SR) as primary outcome. Studies were excluded if surgical ablation was performed with an open approach or using cardiopulmonary bypass; case reports, reviews and comments were also excluded. In case of multiple publications from the same center, the study period was assessed. In studies with overlapping populations, the study with the largest sample size was included.

2.3. Data extraction and critical appraisal

Microsoft Office 365 Excel software (Microsoft, Redmond, Washington) was used for data extraction. Categorical variables were expressed as frequency, while continuous ones were reported as mean with standard deviation. Data on study period, study center, country, type of ablation, sample size were retrieved. The following patient characteristics were abstracted: mean age, male sex, mean BMI, previous cerebrovascular accident (CVA), diabetes, hypertension, coronary artery disease (CAD), mean CHA_2DS_2VASc score, previous AF ablation, type of AF, mean AF duration, mean ejection fraction, mean left atrial (LA) size.

Individual patient data (IPD) were retrieved from the Kaplan–Meier graphs when available. Data ex- traction was performed as described by Liu et al. [14] as a 2-stage approach. In the first step, Kaplan– Meier curves were digitized using a dedicated software (WebPlotDigitizer, https://apps.automeris.io/wpd/), where the axes were defined, and using mouse clicks to select the points of the curve, raw data coordinates (time and freedom from AF probability) were extracted from each treatment arm in each of the Kaplan-Meier curves. Digitized Kaplan–Meier curves were checked graphically with the original ones. Kaplan–Meier data from different studies were stored together in the study database. In the second stage, the data coordinates were processed on the basis of the raw data coordinates from the first stage in conjunction with the numbers at risk at given time points and/or total number of patients, and IPD were reconstructed based on the R package "IPDfromKM". Finally, the reconstructed IPD from all the studies were merged to create the study data set.

The Newcastle-Ottawa Quality Assessment Scale for Cohort Studies was used for critical appraisal of the quality of included non-randomized studies [15], while the Cochrane Collaboration's tool bias risk for randomized clinical trials (RCTs) [16].

2.4. Statistical analysis

The primary endpoint was freedom from AF based on the reconstructed IPD. The author's definition of freedom from AF was used for each included paper. The secondary endpoints were procedure time,

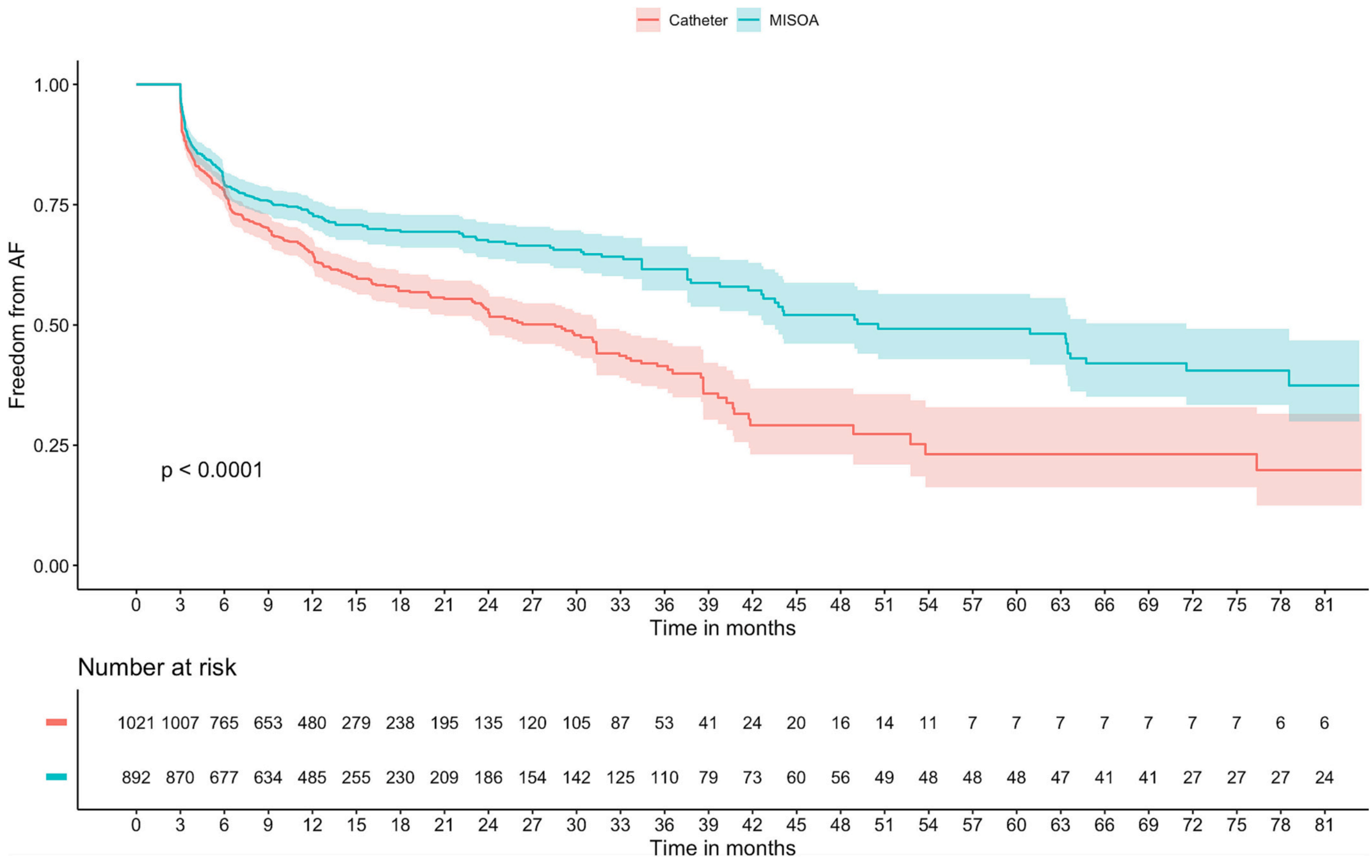

Fig. 1. Freedom from atrial fibrillation in the whole cohort.

postoperative CVA, postoperative permanent pacemaker (PPM) implant, conversion to sternotomy, postoperative total adverse events, 30-day mortality, late CVA, late PPM, late total adverse events, and late mortality. Postoperative and late total adverse events were calculated according to the overall adverse events as reported by the authors of each publication.

For late outcomes a Poisson regression modeling was used to account for the studies' different follow-up times, assuming a constant event rate [17]. The total person-time of follow-up was calculated from the total number of events and mean follow-up time. A log transformation to model the overall incidence rate ratio (IRR) and a random effect were used. For the other outcomes, the odds ratio (OR) and standard mean difference (SMD) were calculated from the reported events of the two groups for categorical and continuous variables, respectively. For all the CA group was set as reference group. The pooled event rate (PER) with 95% Confidence Interval (CI) was calculated for the conversion to sternotomy and LA appendage (LAA) occlusion in the surgery group, while the pooled event mean (PEM) with 95% CI was calculated for the follow-up time.

In all analyses, studies were weighted by the inverse of the variance of the estimate for that study, and between-study variance was estimated with DerSimonian-Laird (DL) method with random effects model. Studies with double zeros were included in meta-analysis and treatment arm continuity correction was applied in studies with zero cell frequencies.

Hypothesis testing for equivalence was set at the two-tailed 0.05 level. Heterogeneity was based on the Cochran Q test, with I^2 values.

IPD were represented through Kaplan-Meier curves and groups were compared with log-rank test. A 3-month blanking period was added in case the original paper did not consider it. In case of significant group outcome differences at log-rank test, a landmark analysis was performed to establish the significance time-point threshold. The Hazard Ratio (HR) with 95% CI for the difference between the two groups were calculated using the Cox regression. The proportionality of the hazards of each Cox model was checked with the Grambsch-Therneau test and diagnostic plots based on Schoenfeld residuals. In case of non-proportional hazards, a weighted estimated Cox regression was used to correct the estimate.

Subgroup analyses were conducted to evaluate the primary endpoint according to surgical approach (thoracoscopic and transdiaphragmatic) and whether the surgical group used a hybrid approach or not. In details, the non-hybrid subgroup (non-HA) analysis compared the CA with a pure MISOA, while the hybrid subgroup (HA) compared CA with a hybrid AF ablation.

All analyses were performed using R, version 4.2.1 (R Project for Statistical Computing) and RStudio version 2022.07.1 Build 554, using the packages "meta" and "metafor" for the meta-analysis, "IPDfromKM" for the IPD reconstruction, "survival" and "survminer" for the survival analysis, "jskm" for landmark analysis, and "coxphw" for non-proportional Cox regressions. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

3. Results

3.1. Literature search

An outline of the systematic review process is shown in Fig. A.1. The literature search identified 723 potentially eligible studies. Four additional articles were identified through backward snowballing. After removal of duplicates, 458 studies were screened. Among these, 56 full text articles were assessed for eligibility. Twenty-one articles [18–38] met our inclusion criteria with a total of 2234 patients, 1070 in the MISOA group and 1164 in the CA. The studies were published from 2011

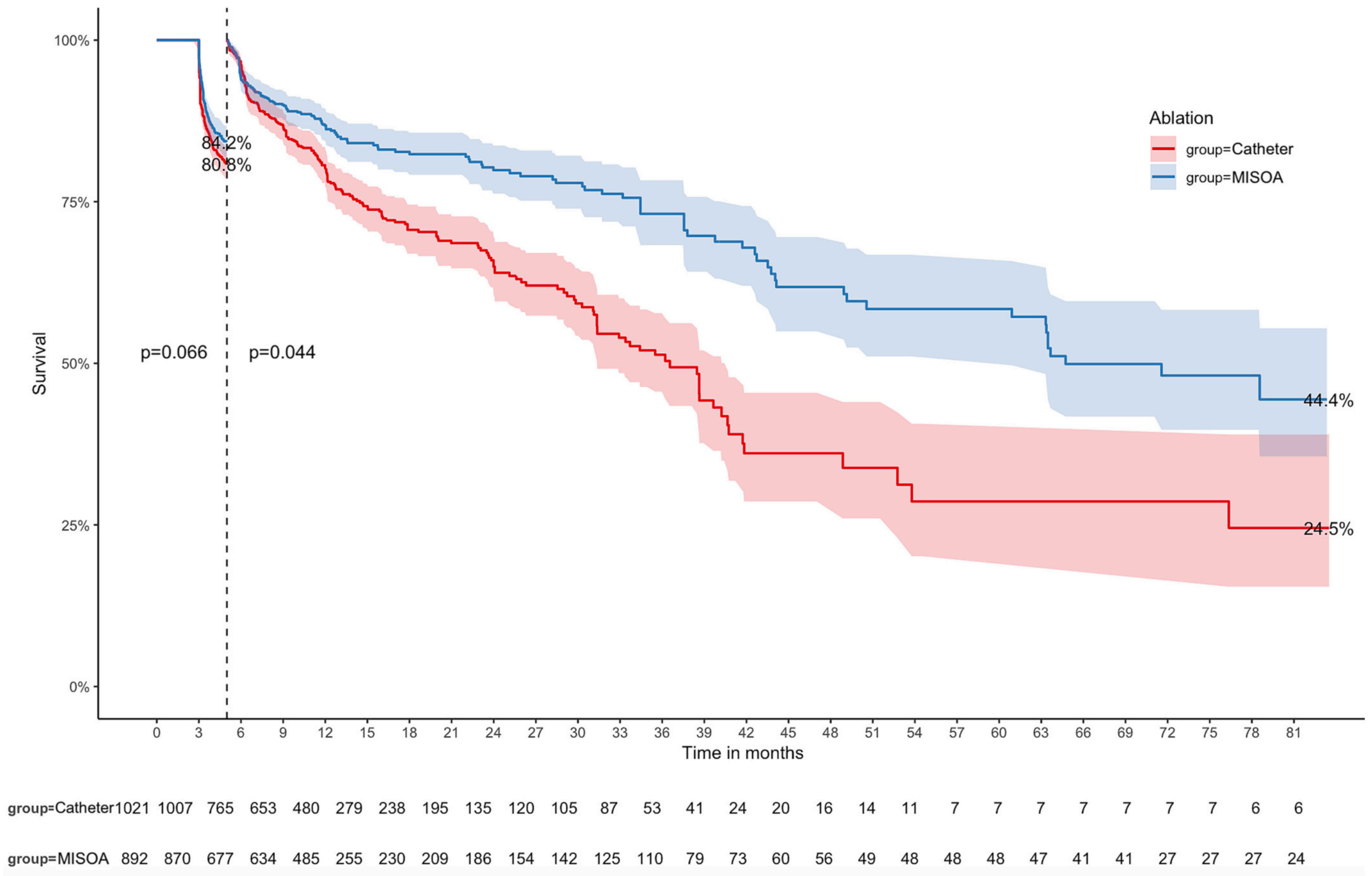

Fig. 2. Landmark analysis of freedom from atrial fibrillation in the whole cohort.

to 2021, and the sample size ranged from 21 to 256 patients. Details of the individual studies are shown in Table A.2. The studies included 9 RCTs, 4 propensity-matched studies and 8 observational studies. The critical appraisal of non-randomized and randomized included studies is shown in Tables A.3 and A.4, respectively. Among the surgical arm, 8 studies described a hybrid approach as part of the therapeutic strategy. The baseline patients' characteristics are shown in Table 1 and divided by study type (Table A.5); the pooled mean follow-up was 16.8 ± 7.5 months.

3.2. Meta-analysis

Catheter ablation procedure was identified as shorter than MISOA, with a reported SMD of the mean procedure time of 0.96 (95%CI: 0.34–1.58, p = 0.002). The PER of conversion to sternotomy and LAA exclusion in the surgical group were respectively 4.80% (95%CI: 2.24–9.99) and 91.83% (95%CI: 78.47–97.19).

Comparable outcomes were reported between MISOA and CA in terms of postoperative CVA incidence (OR: 2.00, 95%CI: 0.91–4.40, p = 0.084), postoperative PPM implant (OR: 1.55, 95%CI:0.61–3.95, p = 0.358) and 30-day mortality (OR: 1.96; 95%CI: 0.90–4.22, p = 0.087). However, the total number of postoperative adverse events were higher in MISOA than in CA (OR: 4.44; 95% CI: 2.38–8.27, $p < 0.001$).

No differences were reported between MISOA and CA in terms of late CVA (IRR: 0.85; 95%CI: 0.27–2.65, p = 0.787) and late PPM implant (IRR: 0.45; 95%CI: 0.11–1.78), as well as for late mortality (IRR: 1.21; 95%CI: 0.45–3.26, p = 0.707). In addition, the IRR of late total adverse events was significantly higher in the MISOA group (IRR: 2.27%/month; 95%CI: 1.19–4.33, p = 0.014). Primary and secondary outcomes are summarized in Table 2, and Table A.6 for absolute values.

3.3. Individual patient data analysis

Nine-teen studies out of the 21 included presented a Kaplan-Meier curve representing the survival freedom from AF. For the RCT by Boersma 2012, the updated follow-up paper by Castella 2019 [39] was used for the analysis. IPD of 1913 patients were constructed, 1021 patients in the CA group and 892 in the MISOA group. Freedom from AF in the whole cohort at 1, 2, 3, and 4 years were 64.8% ± 1.5% vs 73.1% ± 1.5%, 52.5% ± 2.0 vs 67.3% ± 1.9%, 41.5% ± 2.6% vs 61.6% ± 2.3%, and 29.1% ± 3.5% vs 52.1% ± 3.2%, between CA and MISOA respectively (log-rank p < 0.001), Fig. 1. At landmark analysis, a significant improvement in survival freedom from AF in the MISOA group was identified when compared to CA after the 5th month of follow-up (2 months from the blanking period) with a reported log-rank p-value = 0.044 at 5 months, Fig. 2. MISOA was found to be a protective factor for AF at univariable weighted estimation Cox regression (HR: 0.60 [95%CI: 0.50–0.72], p < 0.001).

3.4. Individual patient data analysis from randomized clinical trials

Of the 9 included RCTs, 8 studies included Kaplan-Meier graphs showing the survival freedom from AF. Overall, IPD of 737 patients were pooled, 355 for the CA group and 382 for the MISOA group. Analyzing only the RCT data, survival freedom from AF at 1, 2 and 3 years were 50.4% ± 2.7% vs 64.1% ± 2.5%, 35.7% ± 3.9% vs 60.0% ± 3.0%, 29.5% ± 4.3% vs 60.0 ± 3.0% between CA and MISOA respectively (log-rank p < 0.001), Fig. 3. At landmark analysis a significant improvement in survival freedom form AF could be identified in MISOA at the 7th month of follow-up when compared to CA (4 months from the blanking period), with a log-rank p-value = 0.006 at 7 months, Fig. 4. MISOA was identified as a protective factor against AF recurrence at

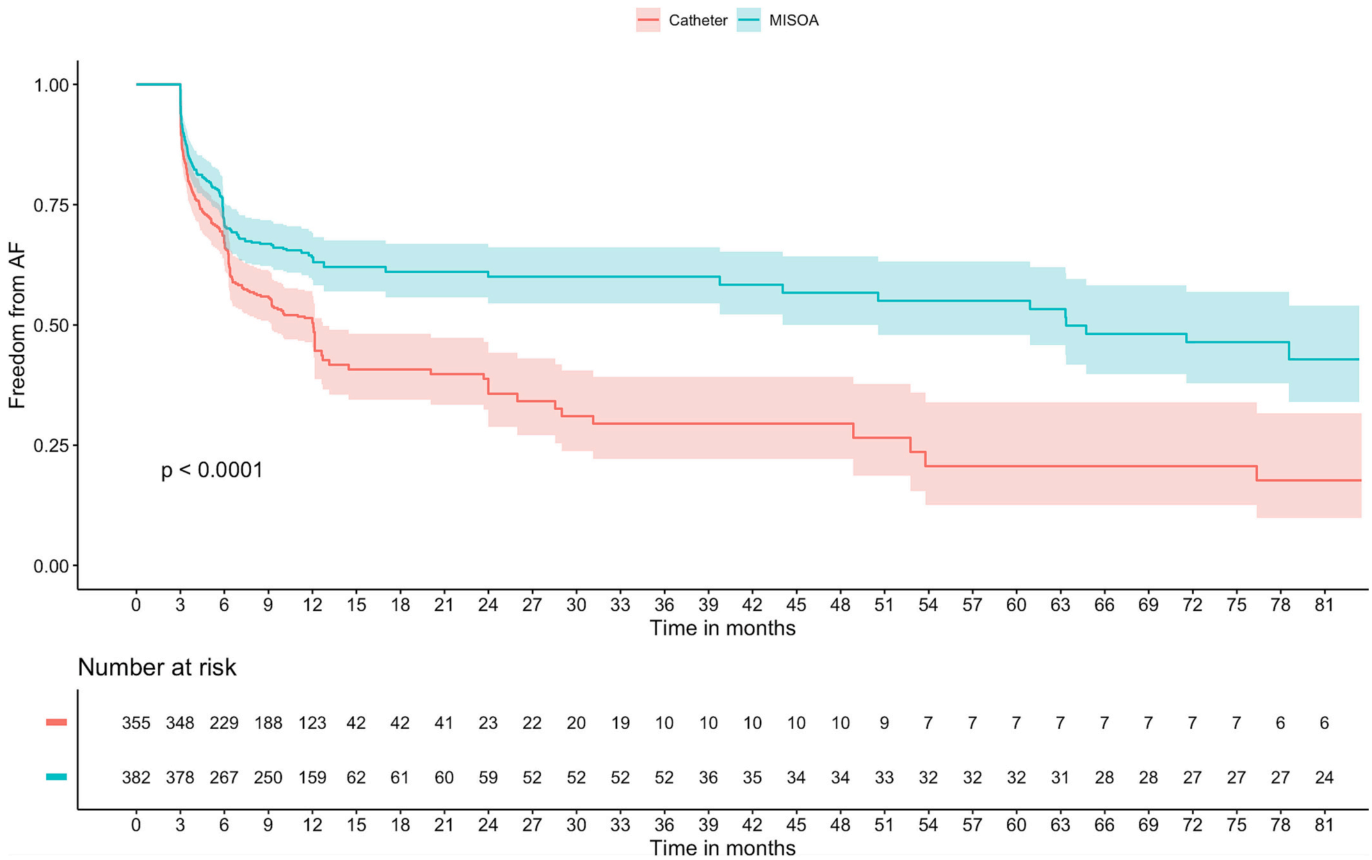

Fig. 3. Freedom from atrial fibrillation in RCT studies.

univariate weighted estimation Cox regression also in the RCTs only analysis (HR: 0.56 [95%CI: 0.44–0.71], p < 0.001).

3.5. Subgroup analysis

A subgroup analysis of the primary endpoint was conducted considering a hybrid (HA) or non-hybrid (non-HA) approach. In the HA subgroup survival freedom from AF at 1, 2 and 3 years were 68.5% ± 2.6% vs 74.3% ± 2.5%, 54.8% ± 3.0% vs 66.3% ± 3.0%, 40.5% ± 3.6% vs 56.4% ± 3.7% for CA and MISOA respectively (log-rank p = 0.00074), Fig. A.2. In the non-HA subgroup freedom from AF at 1, 2 and 3 years were 62.9% ± 1.9% vs 72.3% ± 1.9%, 53.6% ± 2.6% vs 69.5% ± 2.2%, 48.1% ± 3.5% vs 69.5% ± 2.2% for CA and MISOA respectively (log-rank p < 0.0001), Fig. A.3.

The primary endpoint was further analyzed in a stratified analysis based on the surgical incision site (thoracoscopic and trans-diaphragmatic approach subgroups). In the thoracoscopic subgroup freedom from AF at 1, 2 and 3 years were 64.7% ± 1.7% vs 73.7% ± 1.8%, 55.1% ± 2.2% vs 68.8% ± 2.2%, 48.4% ± 3.0% vs 66.9% ± 2.5% for CA and MISOA respectively (log-rank p < 0.0001), Fig. A.4. In the transdiaphragmatic subgroup freedom from AF at 1, 2 and 3 years were 65.0% ± 3.5% vs 71.2% ± 3.0%, 49.9% ± 3.9% vs 64.2% ± 3.5%, 34.5% ± 4.2% vs 54.1% ± 4.2% for CA and MISOA respectively (log-rank p = 0.00062), Fig. A.5.

4. Discussion

Rhythm control in symptomatic and drug-resistant AF patients is commonly performed through pulmonary veins isolation, in order to reduce its morbidity, mortality and improve the quality of life [3]. Percutaneous CA is recommended often as first-line approach, however long-term effectiveness in stable sinus rhythm restoration is modest, especially for nPAF [40]. On the other hand, SR restoration of surgical AF ablation through the Cox-Maze IV procedure is reported to be up to 77% at 10 years follow-up [10]. Despite it is not surprising that the Cox-Maze is considered the gold-standard treatment of AF given its high efficacy in rhythm control at long-term, the higher invasiveness and perioperative morbidity limited to date its wide acceptance among patients and physicians [41]. Since its first introduction in the clinical practice [9], the Maze procedure underwent several modifications that lead to the replacement of the surgical incisions ("cut-and-sew") with linear lesions performed by means of energy sources such as cryoenergy or radiofrequency [42]. The aim of the MISOA, which simplifies the lesion-set compared to the Cox-Maze, is to reduce the invasiveness of the procedure and to maintain the efficacy of the original technique [43,44] by using minimally invasive approaches, namely thoracoscopy (mono- or bi-lateral) and the transdiaphragmatic (or subxiphoid) surgical approaches.

To the best of our knowledge this is the first meta-analysis that has considered and analyzed both minimally invasive technologies together and has compared the outcomes to CA.

The current meta-analysis showed that MISOA significantly improved late rhythm control compared to the CA group. The landmark analysis revealed that the advantage of MISOA can be seen just few months after the blanking period, and the analysis of the RCTs confirmed these results. It is well-known that randomized studies are now typically regarded as the "gold standard" to evaluate the efficacy of a therapy or an intervention intended to improve outcome. However, these studies often include a very selected subset of patients (inclusion and exclusion criteria) and may not consider all forms of procedures/ treatments options. In addition, clinical decision making is still based on behaviors and treatments which have never been evaluated in clinical trials, considering that some interventions may never be subject to a randomization. Thus, the population studied may not reflect the real

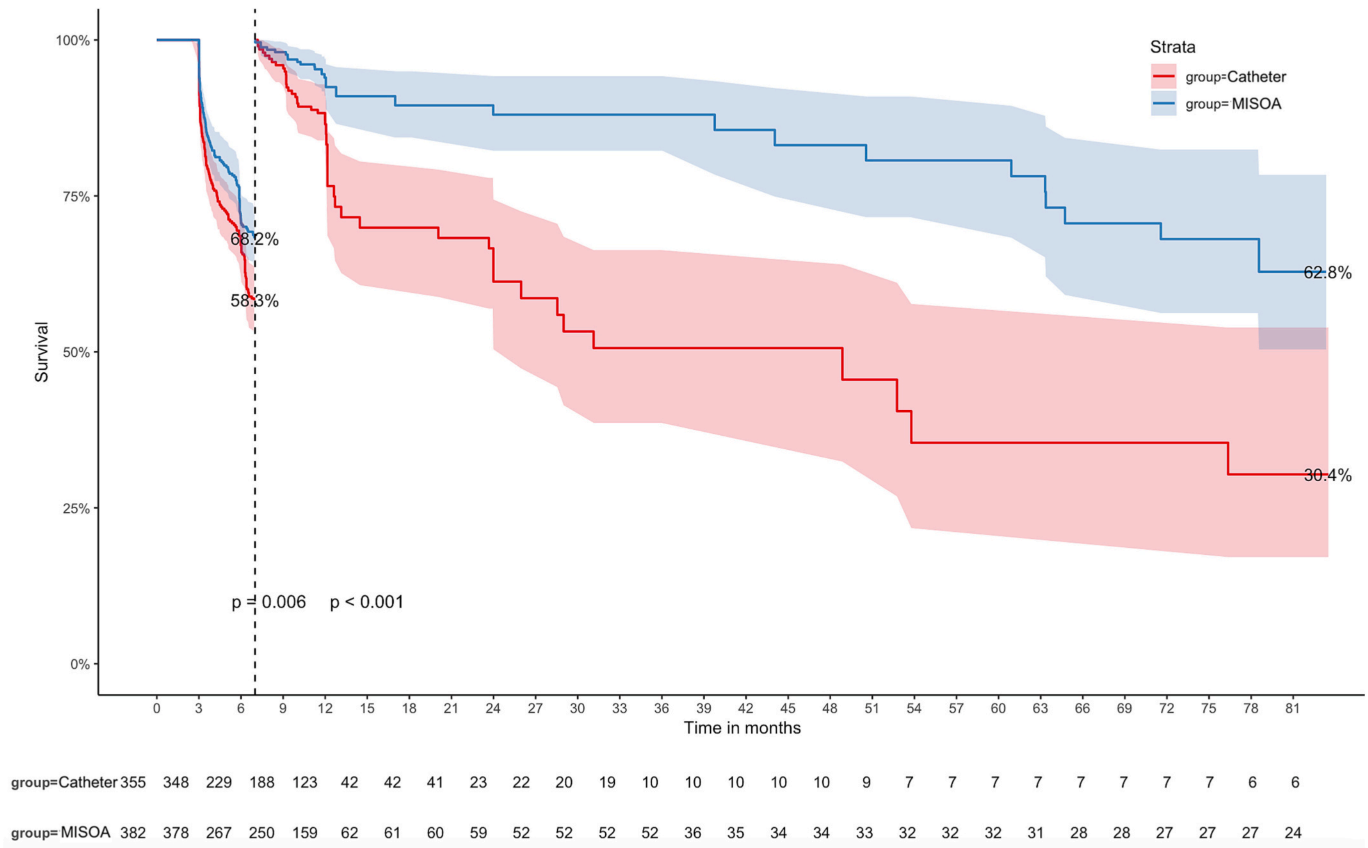

Fig. 4. Landmark analysis of freedom from atrial fibrillation in RCT studies.

world. This is the reason why also observational studies were included. Besides, including non-randomized studies enlarges the final sample size and may lengthen the follow-up time, as RCT generally have very often a fixed (and limited) follow-up time. Analysis of RCT only gave us a basis for comparison. Similarly to our results, a recent meta-analysis of RCTs showed how CA was associated with increased atrial arrhythmias recurrence when compared to surgical ablation (pooled relative risk = 1.85, 95%CI:1.44–2.39, $p < 0.001$), but associated with less total major adverse events (pooled relative risk = 0.29, 95% CI: 0.16–0.53, $p < 0.001$) [45].

In order to optimize rhythm control during follow-up, hybrid AF procedures combining a minimally invasive off-pump epicardial ablation with a percutaneous endocardial approach have been developed. In our subgroup analysis of HA strategy MISOA still demonstrated a superior survival freedom from AF when compared to lone CA. Even if the analysis of hybrid AF ablation was not the aim of the present analysis, it is consistent with previous meta-analyses [46,47].

In addition, a separate analysis of patients treated though the new emerging subxiphoid approach demonstrated a significant higher survival freedom from AF rates compared to CA, as reported in a recent meta-analysis [48].

Despite the rhythm advantage described for MISOA compared to CA, the surgical ablation reported significantly higher postoperative and late total adverse event rates. This finding is mostly related to its additional invasiveness. However, the most fearful complications represented by postoperative CVA, PPM implantation, early and late mortality were not significantly different between the two groups, with a tendency of higher incidence in MISOA. On the contrary, the late CVA and PPM implantation showed a trend towards a greater incidence in CA. This suggests that in the early postoperative period MISOA, with its invasiveness, may cause higher rates of strokes or pacemaker implant, while these complications at follow-up may be reduced due to the superior rhythm control at long-term. Besides, lower late CVA rates are potentially promoted by the LAA occlusion that was achieved in over 90% of the MISOA population among the included studies. As a matter of fact, LAA exclusion not only provides electrical isolation, but also prevents the formation of clots, thereby potentially reducing the risk of stroke [49,50], as recently reported in the LAAOS III Trial [51] in patients with AF undergoing cardiac surgery with other indications. Moreover, as demonstrated by the BELIEF Trial [52], LAA electrical isolation in CA provides superior long-term survival freedom from AF, even though LAA electrical isolation may lead to a higher risk of CVA if not excluded from the circulation. In addition, the postoperative management and discontinuation of oral anticoagulant(OAC) drugs is a very important issue in the treatment of atrial fibrillation. Given the different countries and year of publication of the paper included, the postoperative anticoagulation protocols adopted may differ between the studies. Moreover, the postoperative OAC protocol was seldom reported in the papers, but when it was specified the most common strategy was to continue oral anticoagulant drugs at least for 3 months after the procedure and attempted to stop thereafter if there was no evidence of AF recurrences. Restoring a stable sinus rhythm to allow OACs discontinuation is one of AF treatment's objectives in order to improve quality of life and reduce the risk of long-term anticoagulant therapy of complications. However, nowadays the administration of OACs is still mostly at the discretion of the individual caring physician/cardiologist based on the presence or absence of AF, prior stroke history, and the risk of thromboembolic event based on the CHA2DS2-VASc score, as recommended by the current 2020 ESC guidelines [3].

Finally, the technological improvements of CA achieved over the latest years are promising. Specifically, contact force, high power, short duration ablation, and pulsed-field ablation, are technologies that are still evolving and that will hopefully improve the safety and efficacy of percutaneous treatment of AF [53].

4.1. Strengths and limitations

In this paper we gathered different approaches to perform MISOA into a unique treatment group in order to compare the off-pump minimally invasive surgical ablation with percutaneous approaches AF. Moreover, to the best of our knowledge this is the first meta-analysis on atrial fibrillation surgical ablation that conducted individual patient data analysis through Kaplan-Meier-derived data.

On the other hand, the current meta-analysis has some limitations. First, non-randomized trials were included in the analysis, thus adding potential risk of bias due to confounding and selection of data to the analysis. Thus, a selective analysis of the included RCTs was performed, which confirmed the results.

The two groups significantly differed in the proportion of patients with a history of a previous ablation and type of AF, this may have influenced the final analysis of rhythm outcome. Of note, this clearly reflects the different indication of ablation between the two approaches as expressed by the current ESC guidelines [3].

Most of the data included in the meta-analysis come from centers that are highly experienced in performing MISOA. Therefore, results may vary according to center experience. The follow-up results were obtained from Kaplan-Meier-derived IPD, and not from real IPD. Besides, through this technique it is not possible to analyze possible predictors of the rhythm outcome.

Finally, the rhythm follow-up of the included studies was generally very limited with few exceptions, and this significantly limits the final analysis, especially at long-term. Besides, the quality of life (QoL) of such patients was rarely analyzed in the included papers, even if extremely important. Thus, an analysis of the QoL could not be performed.

5. Conclusion

The current meta-analysis suggests that minimally invasive surgical off-pump ablation for AF provides superior rhythm outcomes when compared to catheter ablation in terms of freedom from AF. Despite the superiority of the surgical approach for the primary endpoint, MISOA is associated to higher postoperative complications compared to CA. However, postoperative CVA and PPM implantation did not significantly differ between the two groups. Individual patient selection through an evaluation of risks and benefits is necessary for the appropriate choice of the ablation strategy.

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CRediT authorship contribution statement

Massimo Baudo: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization. **Rocco Davide Petruccelli:** Conceptualization, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization. **Michele D'Alonzo:** Investigation, Data curation, Visualization. **Fabrizio Rosati:** Conceptualization, Writing – original draft, Writing – review & editing. **Stefano Benussi:** Conceptualization, Resources, Writing – review & editing, Supervision. **Lorenzo Di Bacco:** Conceptualization, Writing – original draft, Writing – review & editing, Supervision. **Claudio Muneretto:** Conceptualization, Resources, Writing – review & editing, Supervision.

Conflict of interest

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None.

Appendix A. Appendix

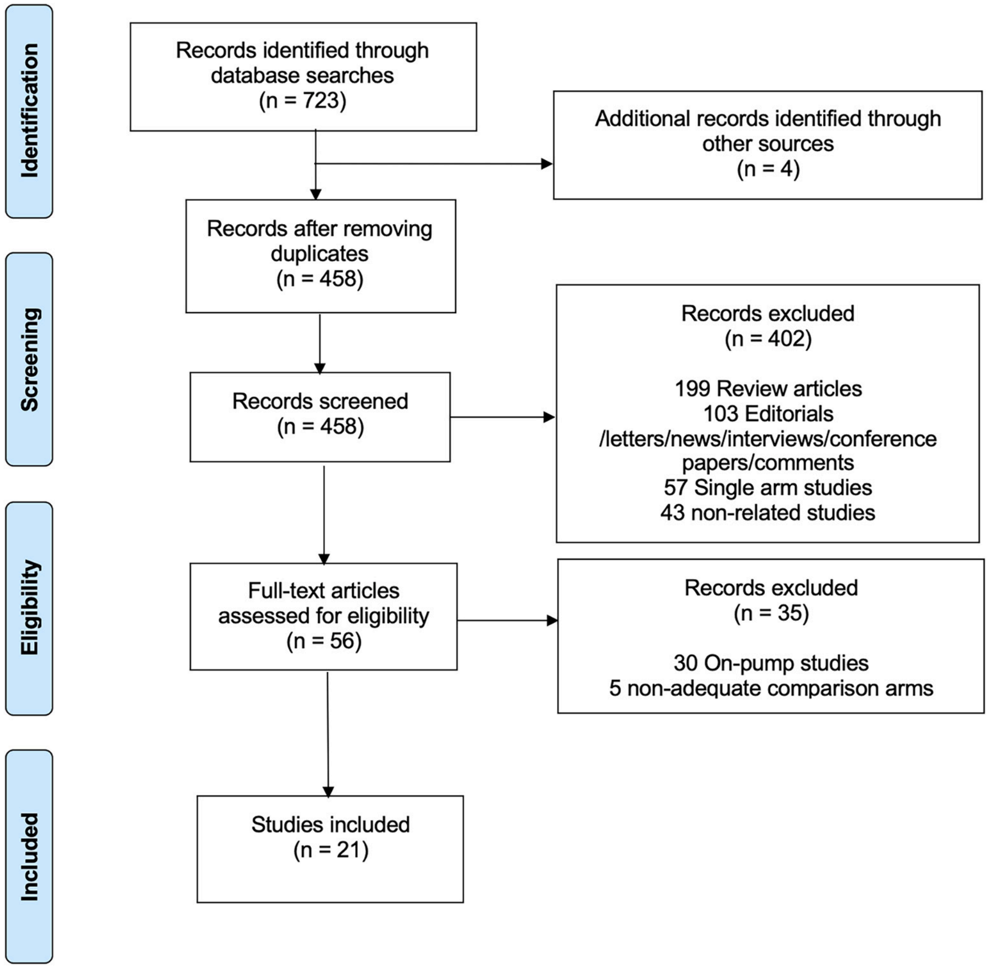

Fig. A.1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) of included studies.

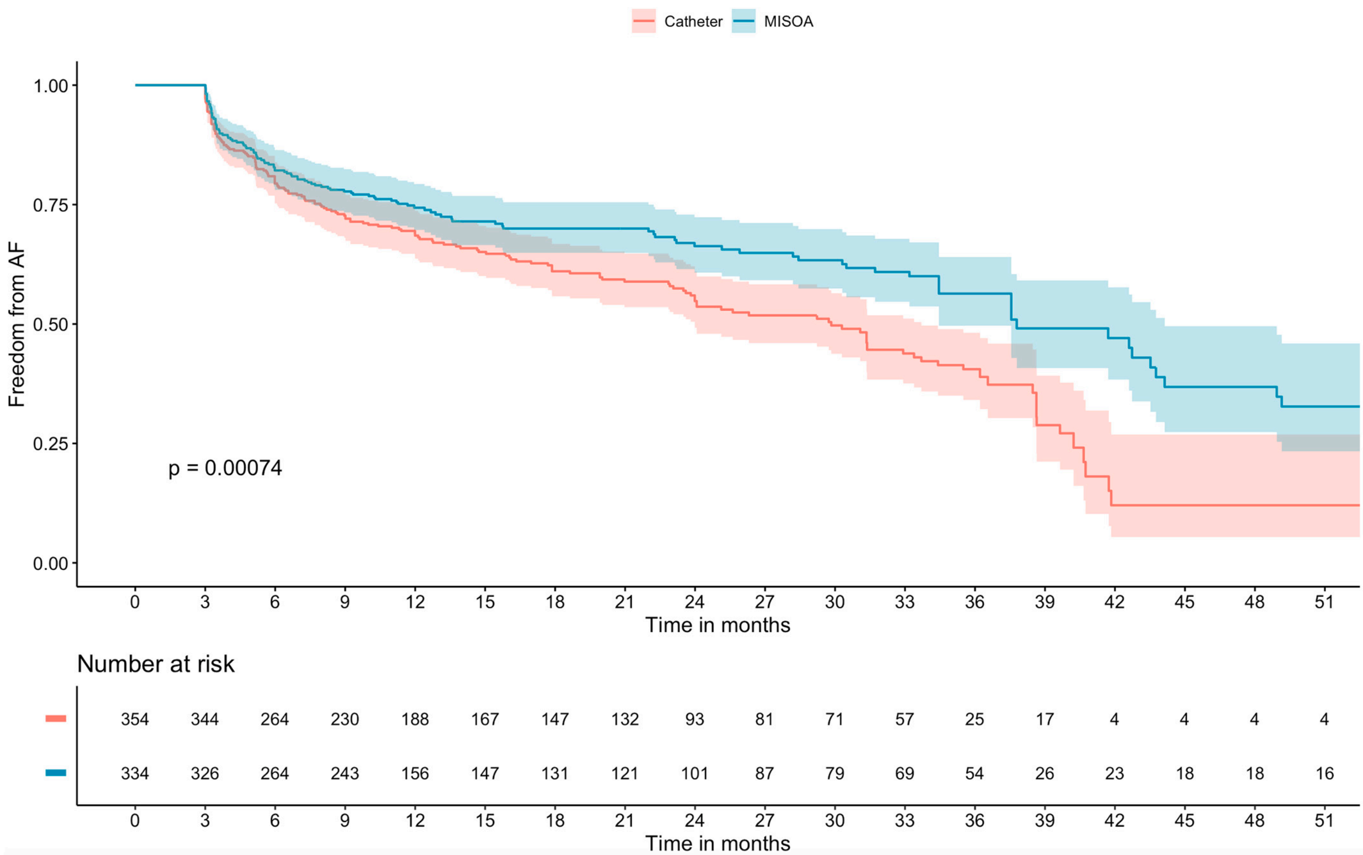

Fig. A.2. Freedom from atrial fibrillation in the hybrid subgroup.

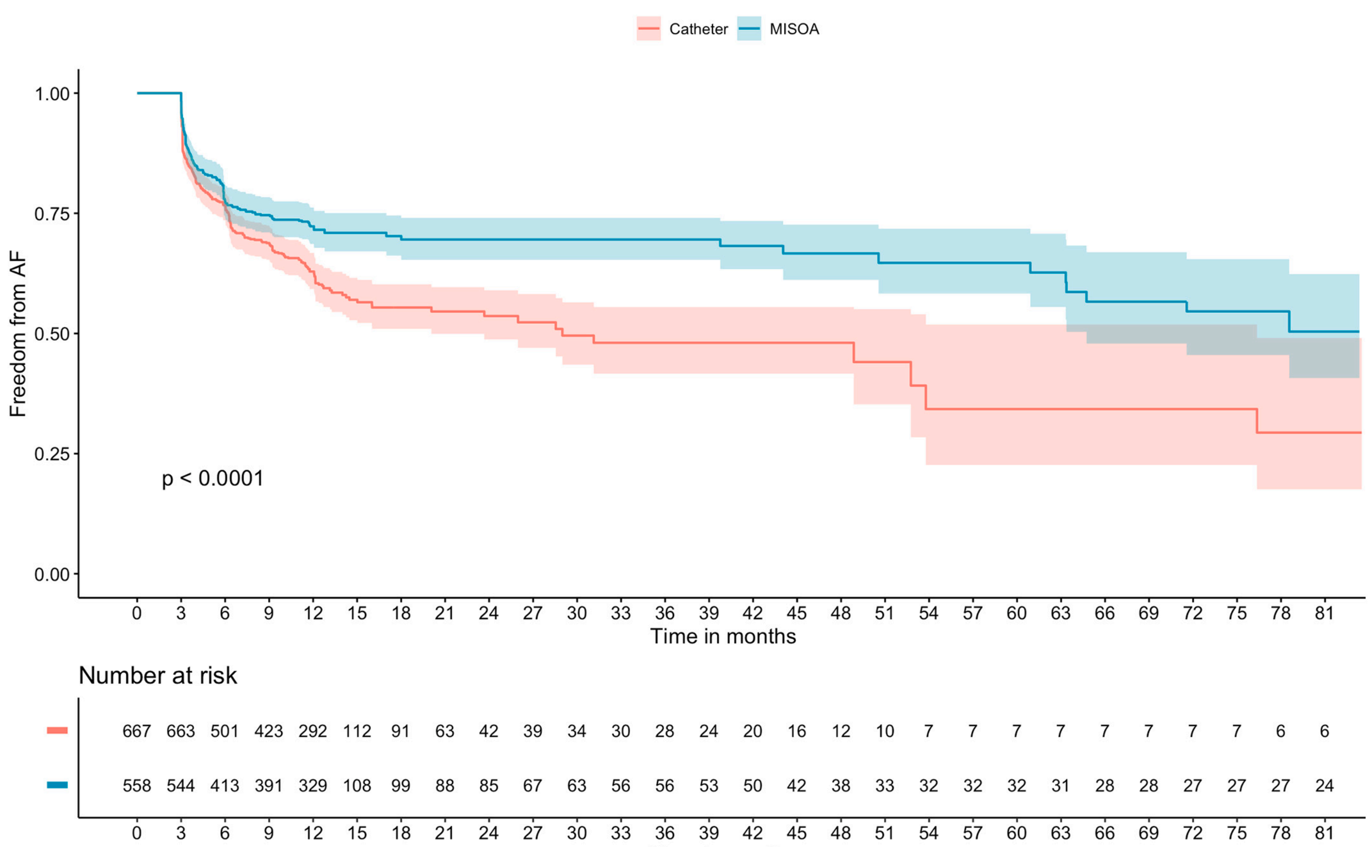

Fig. A.3. Freedom from atrial fibrillation in the non-hybrid subgroup.

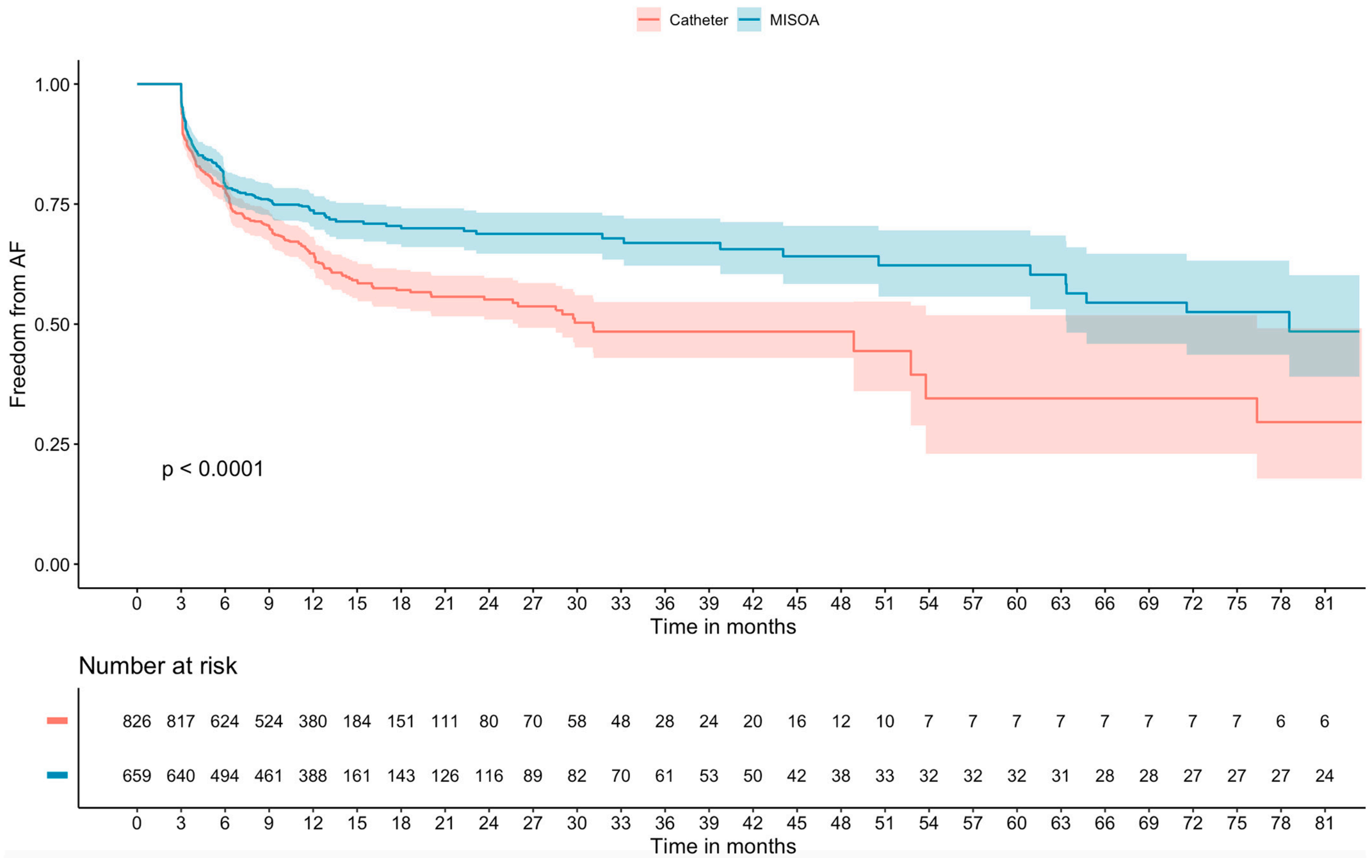

Fig. A.4. Freedom from atrial fibrillation in the thoracoscopic subgroup.

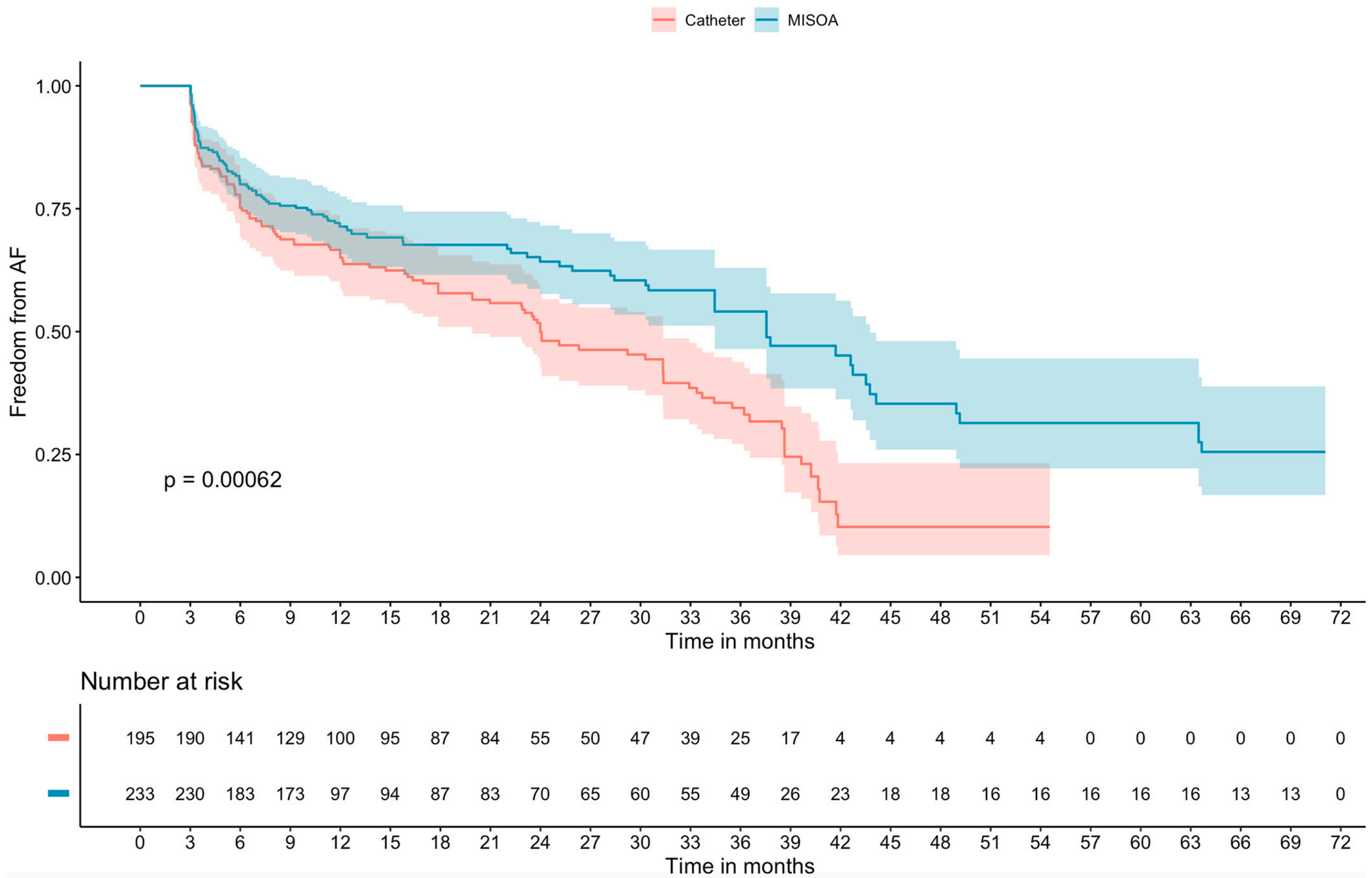

Fig. A.5. Freedom from atrial fibrillation in the transdiaphragmatic subgroup.

Table A.1
Search strategy.

#	Search
1	("thoracoscopes"[MeSH Terms] OR "thoracoscopes"[All Fields] OR "thoracoscope"[All Fields] OR "thoracoscopic"[All Fields] OR "thoracoscopical"[All Fields] OR "thoracoscopically"[All Fields])
2	("subxiphoid"[All Fields] OR "subxiphoidal"[All Fields])
3	"transdiaphragmatic"[All Fields]
4	("converge"[All Fields] OR "converged"[All Fields] OR "convergence"[All Fields] OR "convergences"[All Fields] OR "convergencies"[All Fields] OR "convergency"[All Fields] OR "convergent"[All Fields] OR "convergently"[All Fields] OR "convergents"[All Fields] OR "converges"[All Fields] OR "converging"[All Fields])
5	("ablate"[All Fields] OR "ablated"[All Fields] OR "ablates"[All Fields] OR "ablating"[All Fields] OR "ablation"[All Fields] OR "ablational"[All Fields] OR "ablations"[All Fields])
6	(1 OR 5) OR (2 OR 5) OR (3 OR 5) OR (4 OR 5)
7	("atrial fibrillation"[MeSH Terms] OR ("atrial"[All Fields] AND "fibrillation"[All Fields]) OR "atrial fibrillation"[All Fields])
8	7 AND 8

Table A.2
Outline of the included studies.

Study	Study period	Country	Study type	Arm 1	Arm 2	Surgical approach
Adiyaman 2018	2007–2016	Netherlands	RCT	CA	MISOA	Thoracoscopic
Boersma 2012 (Castella 2019)	2007–2011	Netherlands - Spain	RCT	CA	MISOA	Thoracoscopic
De Maat 2014	2009–2011	Netherlands	PSM	CA	MISOA	Thoracoscopic
DeLurgio 2020	2013–2018	USA + UK	RCT	CA	HA	Transdiaphragmatic
Edgerton 2016	NR	USA	OBS	CA	HA	Transdiaphragmatic
Haldar 2017	2011–2013	UK	OBS	CA	MISOA	Thoracoscopic
Haldar 2020	2015–2018	UK	RCT	CA	MISOA	Thoracoscopic
Hwang 2018	2012–2015	South Korea	OBS	CA	HA	Thoracoscopic
Jan 2018	2013–2015	Slovenia	RCT	CA	HA	Transdiaphragmatic
Kress 2017	2010–2014	USA	PSM	CA	HA	Transdiaphragmatic
Kwon 2021	2012–2019	Korea	OBS	CA	MISOA	Thoracoscopic
Maclean 2020	2013–2018	UK	PSM	CA	HA	Transdiaphragmatic

(continued on next page)

Table A.2 (*continued*)

Study	Study period	Country	Study type	Arm 1	Arm 2	Surgical approach
Mahapatra 2011	2007–2009	USA	OBS	CA	HA	Thoracoscopic
Nordsieck 2019	2014–2017	USA	OBS	CA	HA	Thoracoscopic
Pearman 2019	2013–2017	UK	PSM	CA	MISOA	Thoracoscopic
Pokushalov 2013	2011	Russia	RCT	CA	MISOA	Thoracoscopic
Sauren 2009	2007–2008	Netherlands	OBS	CA	MISOA	Thoracoscopic
Sindby 2018	2011–2013	Netherland - Denmark	RCT	CA	MISOA	Thoracoscopic
Sugihara 2018	2012–2015	UK	RCT	CA	MISOA	Thoracoscopic
Wang 2011	2006–2009	China	OBS	CA	MISOA	Thoracoscopic
Wang 2014	2008–2012	China	RCT	CA	MISOA	Thoracoscopic

CA = catheter ablation; HA = hybrid ablation; MISOA = minimally invasive surgical off-pump ablation; OBS = observational study; PSM = Propensity-matched study; RCT = randomized clinical trial;

Table A.3
The Newcastle Ottawa Scale of the non-randomized included studies.

Study	Selection (0–4)	Comparability (0–2)	Outcome (0–3)	Total (0–9)	AHRQ standard*
De Maat 2014	4	2	3	9	Good
Edgerton 2016	4	1	3	8	Good
Haldar 2017	4	1	3	8	Good
Hwang 2018	4	1	3	8	Good
Kress 2017	4	2	3	9	Good
Kwon 2021	4	1	3	8	Good
Maclean 2020	4	2	3	9	Good
Mahapatra 2011	4	1	3	8	Good
Nordsieck 2019	4	1	3	8	Good
Pearman 2019	4	2	3	9	Good
Sauren 2009	4	1	3	8	Good
Wang 2011	4	1	3	8	Good

AHRQ: Agency for Healthcare Research and Quality.

* Threshold for converting the Newcastle-Ottawa scales to AHRQ standards: Good quality: 3 or 4 stars in selection domain and 1 or 2 stars in comparability domain and 2 or 3 stars in outcome/exposure domain. Fair quality: 2 stars in selection domain and 1 or 2 stars in comparability domain and 2 or 3 stars in outcome/exposure domain. Poor quality: 0 or 1 star in selection domain or 0 stars in comparability domain or 0 or 1 stars in outcome/exposure domain.

Table A.4
The Cochrane risk of bias tool for the included randomized controlled trials.

Study	Random Sequence generation	Allocation concealment	Selective reporting	Other bias	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data
Adiyaman 2018	low	unclear	high	low	low	low	unclear
Boersma 2012 (Castella 2019)	low	low	low	low	low	low	low
DeLurgio 2020	low	unclear	low	low	low	low	low
Haldar 2020	low	low	low	low	low	low	low
Jan 2018	unclear	unclear	high	low	unclear	low	low
Pokushalov 2013	low	unclear	low	low	low	low	low
Sindby 2018	low	unclear	low	low	unclear	low	high
Sugihara 2018	unclear	unclear	low	low	low	low	unclear
Wang 2014	unclear	unclear	high	low	unclear	low	low

Table A.5
Outline of the included studies divided by type of study.

	RCT			Non-RCT		
Variable	CA (n = 391)	MISOA (n = 418)	p-value	CA (n = 773)	MISOA (n = 652)	p-value
Age, mean (years ± SD)	59.35 ± 8.8	58.1 ± 8.2	0.545	59.2 ± 5.2	59.4 ± 5.8	0.945
Male sex, n (%)	266 (68.0%)	296 (70.8%)	0.390	595 (77.0%)	545 (83.6%)	**0.001**
BMI, mean	29.8 ± 4.6	29.5 ± 5.24	0.823	28.9 ± 3.6	29.0 ± 3.4	0.990
Previous CVA, n (%)	78 (50.3%)	85 (59.4%)	0.114	31 (6.6%)	99 (21.2%)	**<0.001**
CAD, n (%)	15 (13.8%)	10 (10.0%)	0.872	30 (11.7%)	14 (8.3%)	0.250
AF duration, mean (years ± SD)	4.9 ± 4.0	4.8 ± 3.9	0.974	4.7 ± 2.5	4.6 ± 1.9	0.968
LVEF, mean (% ± SD)	58.9 ± 6.7	59.4 ± 6.9	0.842	55.9 ± 5.2	56.0 ± 5.0	0.984
LA diameter, mean (mm ± SD)	43.7 ± 6.1	43.4 ± 6.3	0.817	45.8 ± 4.2	42.7 ± 13.7	0.497
nPAF, n (%)	151 (38.6%)	190 (45.5%)	**0.049**	550 (71.2%)	540 (82.8%)	**<0.001**
Diabetes, n (%)	31 (11.2%)	23 (9.0%)	0.399	87 (13.8%)	60 (10.5%)	0.085
Hypertension, n (%)	155 (47.3%)	199 (55.7%)	**0.026**	305 (39.5%)	202 (31.0%)	**<0.001**
CHA2DS2-VASc, mean ± SD	1.2 ± 1.1	0.9 ± 1.1	0.386	1.6 ± 0.8	1.4 ± 0.5	0.513
Previous ablation, n (%)	78 (50.3%)	85 (59.4%)	0.114	59 (9.8%)	70 (14.4%)	0.235

AF = atrial fibrillation; BMI = body mass index; CAD = coronary artery disease; CVA = cerebrovascular accident; LA = left atrial; LVEF = left ventricular ejection fraction; nPAF = non-paroxysmal atrial fibrillation; SD = standard deviation.

Table A.6
Meta-analysis of the primary and secondary outcomes with absolute values.

Outcome	Group	No. of studies	Estimate (95%CI)	Heterogeneity: I^2, p-value
Postoperative CVA	MISOA	19	2.32% (1.44–3.70)	0%, $p = 0.9010$
	CA		1.22% (0.67–2.23)	0%, $p = 0.9995$
Postoperative PPM	MISOA	10	2.11% (1.21–3.63)	0%, $p = 0.9728$
	CA		1.35% (0.69–2.61)	0%, $p = 0.9892$
Postoperative total adverse events	MISOA	17	22.83% (14.44–34.14)	87.3%, $p < 0.0001$
	CA		7.74% (5.61–10.58)	35.8%, $p = 0.0711$
30-day mortality	MISOA	21	2.39% (1.49–3.83)	0%, $p = 0.6845$
	CA		1.10% (0.61–1.98)	0%, $p = 0.9999$
Late CVA	MISOA	8	0.10%/month (0.05–0.23)	0%, $p = 0.9457$
	CA		0.12%/month (0.06–0.24)	0%, $p = 0.8012$
Late PPM	MISOA	4	0.11%/month (0.03–0.33)	0%, $p = 0.6185$
	CA		0.21%/month (0.10–0.45)	0%, $p = 0.4022$
Late total adverse events	MISOA	4	2.14%/month (1.12–4.09)	81.8%, $p = 0.0009$
	CA		1.02%/month (0.62–1.67)	23.9%, $p = 0.2676$
Late mortality	MISOA	12	0.12%/month (0.06–0.25)	0%, $p = 0.8723$
	CA		0.09%/month (0.05–0.18)	0%, $p = 0.9881$

CI = confidence interval; CVA = Cerebrovascular accident; IR = incidence rate; LAA = left atrial appendage; PER = pooled estimated rate; PPM = permanent pacemaker; SMD = standardized mean difference; SR = sinus rhythm.

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