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Prevention of esophageal lesions during atrial fibrillation catheter ablation using esophageal temperature monitoring: A systematic review and meta-analysis

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Abstract

Introduction: The use of esophageal temperature monitoring (ETM) for the prevention of esophageal injury during atrial fibrillation (AF) ablation is often advocated. However, evidence supporting its use is scarce and controversial. We therefore aimed to review the evidence assessing the efficacy of ETM for the prevention of esophageal injury.

Methods: We performed a meta-analysis and systematic review of the available literature from inception to December 31, 2022. All studies comparing the use of ETM, versus no ETM, during radiofrequency (RF) AF ablation and which reported the incidence of endoscopically detected esophageal lesions (EDELs) were included.

Results: Eleven studies with a total of 1112 patients undergoing RF AF ablation were identified. Of those patients, 627 were assigned to ETM (56%). The overall incidence of EDELs was 9.8%. The use of ETM during AF ablation was associated with a non significant increase in the incidence of EDELs (12.3% with ETM, vs. 6.6 % without ETM, odds ratio, 1.44, 95%CI, 0.49, 4.22, $p = .51$, $I^2 = 72\%$). The use of ETM was associated with a significant increase in the energy delivered specifically on the posterior wall compared to patients without ETM (mean power difference: 5.13 Watts, 95% CI, 1.52, 8.74, $p = .005$).

Conclusions: The use of ETM does not reduce the incidence of EDELs during RF AF ablation. The higher energy delivered on the posterior wall is likely attributable to a false sense of safety that may explain the lack of benefit of ETM. Further randomized controlled trials are needed to provide conclusive results.

Abbreviations: AEF, atrio-esophageal fistula; AF, atrial fibrillation; EDELs, endoscopic detected esophageal lesion; ETM, esophageal temperature monitoring; LA, left atrium; RF, radiofrequency; UGE, upper gastrointestinale endoscopy.

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KEYWORDS
ablation, atrial fibrillation, esophageal lesion, radiofrequency, temperature probe

1 | INTRODUCTION

A constantly growing demand in atrial fibrillation (AF) ablation has been observed over the last two decades due to more effective ablation procedures and the broadening of indications.[1,2] Efficacy and safety of the procedures have notably improved over the years but one potentially lethal complication remains a matter of major concern: esophageal thermal injury potentially leading to perforation or atrioesophageal fistula (AEF). The risk is commonly estimated to be between 0.1% and 0.25%, with a mortality rate as high as 70%–80%.[3,4]

Various methods to reduce the occurrence of esophageal lesions during AF ablation procedures have been evaluated beyond the reduction of power delivery during ablation on the posterior wall of the left atrium (LA). Among these, esophageal temperature monitoring (ETM) has gained considerable acceptance and is now considered "reasonable" to help guide energy delivery with a class IIa recommendation according to the Consensus Statement on catheter and surgical ablation of AF.[3]

Studies assessing the efficacy of esophageal protection methods have relied on the detection of endoscopically detected esophageal lesions (EDELs) after AF ablation,[4–7] a surrogate marker for the risk of esophageal perforation or fistula. The reported incidence of EDELs ranges from 0 to 47% in patients following pulmonary vein isolation (PVI) procedures. While most lesions resolve with conservative management, more severe lesions, such as deep ulcers, can progress to esophageal perforation and AEF in 4.2% of the cases.[4,5] Two previous meta-analyses investigated with inconclusive results the role of ETM in preventing esophageal damage during radiofrequency (RF) AF ablation.[8,9] Following these publications, the rapid development of high- and very high-powershort-duration (HPSD) ablation strategies has prompted an increased use of ETM, which has been constituently implemented in studies due to safety concern.

The aim of this systematic review and meta-analysis is therefore to incorporate the latest available evidence in order to evaluate the use ETM in the prevention of esophageal lesions during AF ablation procedures.

2 | MATERIALS AND METHODS

This systematic review with meta-analysis follows a prespecified study protocol registered on the PROSPERO international prospective register of systematic reviews (Esophageal Temperature Monitoring for the Prevention of Esophageal Lesions in Atrial Fibrillation Ablation: A Systematic Review and Meta-Analysis; **CRD42023396515**). Results are reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (**PRISMA**) 2020 statement (Table S1).

2.1 | Literature search and selection criteria

A systematic review of the literature was performed using the online databases PubMed/MEDLINE (Medical Literature Analysis and Retrieval System Online), Embase (Excerpta Medica Database) and Cochrane Library, from inception to December 31, 2022, using the search terms: (atrial fibrillation) AND (temperature monitoring) AND (esophageal lesion) (Table S2).

We focused on Medical Subject Headings and key words related to "temperature monitoring" and "esophageal". The search was enriched by previously conducted systematic searches,[8,9] and independently peer-reviewed by two cardiologists (A.S., P.A.). Bibliographies of all included studies were reviewed for other relevant articles.

2.2 | Eligibility criteria and selection process

To be eligible for inclusion, studies had to fulfill the following criteria: (1) randomized or non-randomized controlled trials comparing ETM against no-ETM, (2) patients with AF undergoing RF ablation procedure only, (3) Systematic EDELs assessment with upper gastrointestinal endoscopy (UGE) performed within 7 days after AF ablation procedure, (4) adequate reporting of population characteristics, periprocedural details and outcome (success, other complications). We excluded non-human and non-English studies. The eligibility of studies was independently assessed by two authors (A.S. and P.A.).

The search results were uploaded into an online systematic review management platform (Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia). Articles were independently screened for inclusion by title and abstract by two reviewers (A.S., P.A.), and any discrepancy was resolved with the help of a third reviewer (P.P.).

2.3 | Data extraction and quality assessment

All relevant data were independently extracted by two co-authors (A.S. and P.A.) to obtain the following information from each study: first author's name, year of publication, type of study, number and baseline characteristics of patients, type of AF, peri-procedural ablation details and procedure-related complications.

The methodological quality of each included study was independently assessed by two co-authors (A.S. and H.L.) using the MINOR (Methodological Index for Nonrandomized Trials) tool for prospective cohort studies. The MINOR tool allows for the assessment of

internal validity based on eight criteria for noncomparative studies (clearly stated aim, inclusion of consecutive patients, prospective collection of data, endpoints appropriate for the aim of the study, unbiased assessment of the study endpoint, appropriate follow-up period, loss to follow-up <5%, and prospective calculation of the study size) and four additional criteria for comparative studies (adequate control group, contemporary groups, baseline equivalence of the groups, and adequate statistical analyses).[8,9] Based on these criteria, each category is given a score from 0 to 2.

2.4 | Outcomes

The primary outcome was the incidence of EDELs in patients undergoing AF catheter ablation using RF with the use of ETM or without the use of ETM. Secondary outcomes included the analysis of patients' characteristics, peri-procedural details and the combined incidence of EDELs.

2.5 | Statistical analyses

Data were summarized using descriptive statistics, with medians (interquartile range [IQR]) or means ± standard deviation (SD) for continuous variables, and frequencies with percentages for dichotomous variables. When data were reported as medians with IQR, they were not incorporated into the comparison analyses as they supposedly did not follow a normal distribution. Meta-analyses were performed by combining the results of the published incidence of the predetermined outcomes. The odds ratios (ORs) and their 95% confidence intervals (CIs) were used as summary statistics. The I^2 statistic was used to estimate the percentage of total variation across studies due to heterogeneity rather than chance: intervals of <25%, 25%–50%, and >50% were used to classify heterogeneity as low, moderate, and high. The random-effects model was used to account for population diversity and methodological variation among studies. All *p*-values were two-sided, a value <.05 was used to define statistical significance. The analyses were performed using Review Manager (RevMan, Version 5.4.1 The Cochrane Collaboration, Copenhagen, Denmark) and Stata Statistical Software, Release 17.0 (StataCorp. 2021. College Station, StataCorp LLC, TX, USA).

3 | RESULTS

3.1 | Article selection

Our initial search resulted in 187 potentially relevant articles (78 articles from PubMed, 87 from Embase, 22 from the Cochrane Library), as shown in the PRISMA diagram (Figure 1). A total of 47 duplicate studies were identified and 140 studies were retained for further analysis. A total of 17 studies were reviewed at the full-text level and six studies were excluded due to unsuitable study design or reported outcomes. At the end of the search, 11 eligible articles met all inclusion criteria and were included in the analysis.[10–20]

3.2 | Characteristics of the overall cohort

Overall, 11 studies, published between 2008 and 2022, with a total of 1112 patients (627 with ETM vs. 485 without ETM) were included.[10–20] Four were randomized controlled trials[16,18–20] and seven were prospective non-randomized trials.[10–15,17] Trials' characteristics are summarized in Table 1.

N = 758 out of 1112 patients (68.1%) were male. The mean age of the cohort was 62.3 ± 10.5 years. Regarding the prevalence of cardiovascular risk factors, 67.2% of patients had hypertension, 13.2% diabetes, 6.3% a history of stroke and 19.7% coronary artery disease. Overall body mass index was 28.3 ± 4.9 kg/m^2. There was no significant difference regarding cardiovascular risk factors between the ETM versus no-ETM groups ($p > .05$ for all).

AF was paroxysmal in 34%–85% of patients. The rates of paroxysmal AF between ETM and no-ETM groups were comparable (53.7% vs. 51.8 %, $p = .56$).

With regards to available echocardiographic parameters, mean LA diameter was 42.5 ± 6.4 mm and mean left ventricular ejection fraction was 57.9 ± 9.4%, with no significant difference between ETM and no-ETM groups ($p = .08$ and $p = .41$, respectively). Comparison of baseline characteristics depending on the use of ETM is presented in Table 2.

A total of nine studies reported the use of transesophageal echocardiography (TEE). In seven studies, TEE was performed the day prior to the ablation procedure,[13–17,19,20] while in two studies, TEE was performed on the day of the procedure.[10,11]

3.3 | RF ablation procedural parameters

All interventions consisted in PVI, with two studies including 56 patients with additional ablation performed at the discretion of the operator.[13,18]

RF ablation was performed using conventional, irrigated-tip ablation catheters[10,13–15,17–20] in eight studies, and using a non-irrigated tip catheter in one study. Two studies by Deneke et al. evaluated a multielectrode ablation catheter: one study used a mapping-system integrated irrigated multipolar circular ablation catheter (nMARQ™ catheter, Biosense Webster),[12] and one study used a system delivering duty-cycled phased RF energy (PVAC®, Medtronic).[11]

The maximum ablation temperature and power settings were heterogeneous depending also on the system used, ranging from 43 to 60°C and 10–50 W, respectively. Only one study used HPSD ablation strategy.[17] Similarly, the maximum ablation time per lesion varied from 8.8 to 60 s. All studies used an ETM probe with a cut-off temperature point ranging from 37.5 to 41°C. Total procedure time and total ablation time ranged respectively from 55 to 264 min and from 11.5 to 67 min without significant difference between the ETM and no-ETM groups ($p = .93$ and .52, respectively).

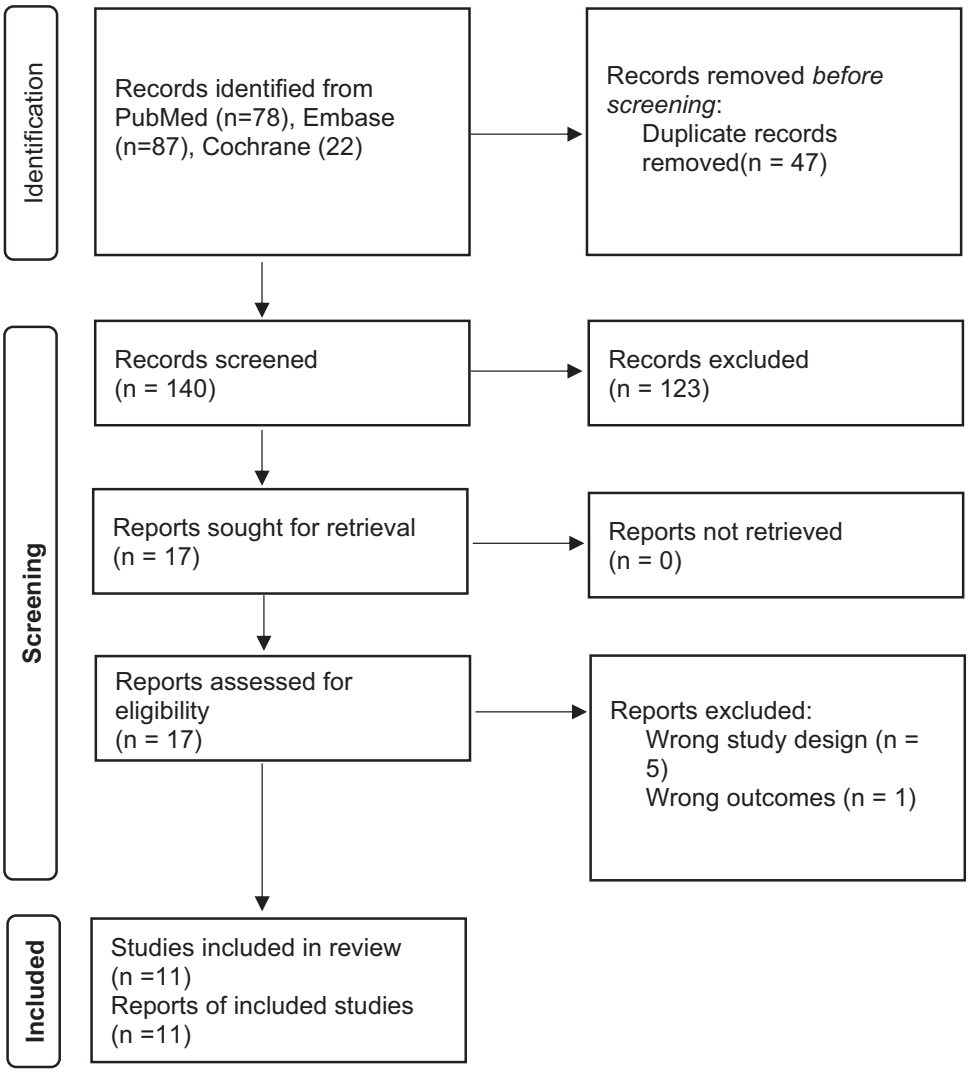

FIGURE 1 Prisma flow diagram.

Interestingly, among the four studies which provided details on the mean power delivered during catheter ablation,[13,16,18,19] a significant difference was observed. Unexpectedly a significantly higher power was delivered in the group with ETM (ETM: 33.0 ± 3.4 W vs. no ETM: 31.3 ± 2.5 W; mean difference, 1.76, 95%CI, 0.34, 3.17, $p = .01$). This difference was driven[16,18,19] by the ablation power delivered specifically on the posterior wall (ETM: 28.6 ± 3.0 W vs. no ETM: 25.1 ± 3.6 W; mean difference 5.13, 95%CI, 1.52, 8.74, $p = .005$).

In five studies, the ablation protocol differed with respect to the energy delivered on the posterior wall, depending on whether ETM was used or not.[14,16,18–20] Power applied in the absence of ETM ranged from 20 to 25 W. On the other hand, in patients with ETM, a 5–10 W higher power was applied per protocol on the posterior wall. Data including contact force monitoring were available for only two studies[17,19] with only one study defining a target ablation index of 400 during posterior wall ablation. Parameters related to the ablation procedure are summarized in Tables 2 and 3.

Multi-sensor (MS) probes were used in nine out of 11 studies, with Sensitherm™ and Circa Scientific™ models being the most prevalent. Intervention were performed under deep sedation in eight studies,[11–15,17–19] general anesthesia (GA) in two studies,[16,20] and one reported the use of either one of the two modalities.[10] ETM probe positioning was performed under fluoroscopic guidance for all procedures. Five studies used a MS, non-deflectable ETM probe (with three or five sensors),.[11–14,18] Four studies used an S-shaped ETM probe with insulated thermocouples (12 sensors).[15,17,19,20] Three studies used a single-sensor (SS), non deflectable ETM probe,[10,16,20] and among those one study used both type of ETM probe.

3.4 | Incidence of endoscopically detected esophageal lesions

The location of the endoscopically detected lesions was specified in eight out of 11 studies[10,11,15–20] and was commonly viewed as being thermally-induced if located on the anterior wall of the mid-esophagus

TABLE 1 Endoscopic studies evaluating the use of esophageal temperature monitoring during AF ablation.

Authors	Year	Design	Number of patient	Paroxysmal AF (in %)	Mean BMI (in kg/m^2)	Ablation type	Ablation strategy	Esophageal temperature monitoring probe	EDEL		
									ETM	No ETM	*p*-value
Singh et al., 2008	2006–2007	Prospective	67/14	42/50	31/28	RF	PVI	SS	4/67	5/14	<.01
Deneke et al.,2011	2011	Prospective	48/42	75/80	NR	RF	PVI	MS	5/48	0/42	<.01
Deneke et al., 2015	2013–2014	Prospective	103/42	58/41	NR	RF	PVI	MS	29/103	0/42	<.001
Muller et al., 2015	NR	Prospective	40/40	65/65	27/28	RF	PVI	MS	12/40	1/40	.0001
Kiuchi et al.,,2016	NR	Prospective	80/80	56/51	24/24	RF	PVI	MS	0/80	6/80	.03
Halbfass et al., 2017	NR	Prospective	40/40	73/54	30/30	RF	PVI	MS	3/40	4/40	NR
De Oliveira et al., 2020	2012–2014	Randomized	15/15	80/73	30/30	RF	PVI	SS	0/15	0/15	NR
Chen et al., 2020	2018–2020	Prospective	60/60	61/ 60	28/27	RF	PVI	MS	2/60	1/60	.99
Schoene et al., 2020	2017–2019	Randomized	90/90	34/42	30/30	RF	PVI	MS	10/90	8/90	.62
Grosse Meninghaus et al., 2021	2018–2020	Randomized	44/42	41/ 43	30/28	RF	PVI	MS	6/44	2/42	.27
Moura et al., 2022	2017–2018	Randomized	40 /20	85/75	28/29	RF	PVI	SS/MS	6/40	5/20	NR

First numbers refer to the ETM group and the second to the no-ETM group.
Abbreviations: EDEL, endoscopically detected esophageal lesion; MS, multi-sensor; NR, not reported; ETM, esophageal temperature monitoring; PV, posterior wall; PVI, pulmonary vein isolation; RF, radiofrequency; SS, single sensor.

or adjacent to the LA region. Lesions located outside this region of interest were not reported in the analysis.

Only two studies performed routine UGE before AF ablation in order to assess pre-existing esophageal lesions at baseline.[16,19] The evaluation by post-intervention UGE ranged from 1 to 5 days after catheter ablation. Most studies defined EDELs as erythema, erosion or ulcer, but only one study differentiated between a small and a large ulcer based on the Kansas City classification.[19]

The overall incidence of EDELs after AF catheter ablation was 9.8% ranging from 0 to 37.5%. No significant difference in the incidence of EDELs was found between procedures performed with (12.3%) or without ETM (6.6%) (OR, 1.44, 95%CI, 0.49, 4.22, $p = .51$; Figure 2). Significant heterogeneity was present among studies ($I^2 = 72\%$) with one study favoring ETM,[10] two studies favoring no-ETM[12,13] and eight studies[11,14–20] finding no significant difference between ETM and no-ETM. No patient included in the studies developed AEF or esophageal perforation.

Five studies documented the type of esophageal lesions and the incidence of esophageal ulcers.[10,17–20] The overall incidence of esophageal ulcers was 5.1%, ranging from 0% to 37.5%. Similar to EDELs, there was also no significant differences in the incidence of ulcerated lesions with ETM (5%) compared to without ETM (5.3%) (OR, 0.72, 95%CI, 0.17−3.06, $p = .66$, Figure 3). Significant heterogeneity existed among studies ($p = .03$, $I^2 = 62\%$).

3.5 | Quality assessment

The risk of bias in the 11 included studies was low based on the MINOR tool assessment (Table S3). Three studies lost points for the "inclusion of consecutive patients" criterion, one study for lacking "prospective collection of data". Additionally, four studies lost points due to the lack of "baseline equivalence of groups". No study satisfied the "unbiased assessment of the study endpoint" and "prospective calculation of the study size" criteria. Among randomized control trials, points were lost regarding the "unbiased assessment of the study endpoint" criterion, either due to studies being single-blinded or unblinded. Finally, the "prospective calculation of the study size" criterion was only assessed for one study.[18] A funnel plot analysis evaluating publication bias for the use of ETM can be found in Table S4.

4 | DISCUSSION

We performed a systematic review with meta-analysis of the evidence supporting the use of ETM in the prevention of esophageal lesions during AF ablation procedures. The major findings of this study are: (1) the use of ETM during RF AF ablation is not associated with a decrease in the incidence of EDELs. Evidence of harm were even observed in two studies; (2) the overall incidence of EDELs after AF ablation remains high and is observed in about 10% of the patients; (3) the use of ETM was associated with a significant increase in the RF energy delivered on the LA posterior wall.

TABLE 2 Comparison of baseline characteristics and procedural data between ETM and no-ETM groups.

Characteristics	Number of studies (references)	ETM	No-ETM	*p*-value
Clinical				
Age (in years)	9[10,11,13–19]	62.5 ± 9.6	62.0 ± 11.5	.91
Male gender, *n* (%)	ALL[10–20]	425 (67.8)	333 (68.7)	.83
BMI (in kg/m^2)	8[10,13–19]	28.65 ± 4.9	27.9 ± 4.9	.10
HTA, *n* (%)	5[14–18]	212 (74.4)	171 (60)	.41
DM, *n* (%)	6[14–18,20]	38 (9.5)	45 (7.9)	.35
PRIOR TIA/STROKE, *n* (%)	3[15,17,18]	11 (5.8)	13 (6.8)	.78
CAD, *n* (%)	3[15,17,18]	39 (14.4)	36 (10.7)	.71
Paroxysmal AF, *n* (%)	ALL[10–20]	337 (53.7)	251(51.8)	.56
Echocardiographical				
LVEF (in %)	7[10,14–19]	58.5 ± 9.5	57.2 ± 9.2	.41
Left atrial diameter (in mm)	6[10,14–17,19]	43.1 ± 6.5	41.7 ± 6.2	.08
Procedural				
Mean. power (in W)	4[13,16,18,19]	33.0 ± 3.4	31.3 ± 2.5	.01
Mean power at LAPW (in W)	3[16,18,19]	28.6 ± 3.0	25.1 ± 3.6	.005
Total procedure time (in min)	6[11,13,16–19]	122.0 ± 32.7	123.9 ± 37.2	.93
Total ablation time (in min)	6[10,11,13,17–19]	35.2 ± 16.9	34.1 ± 16.1	.52

Abbreviations: BMI, body mass index; CAD, coronary artery disease; DM, diabetes mellitus; ETM, esophageal temperature monitoring; HTA, arterial hypertension; LAPW, left atrial posterior wall; LVEF, left ventricular ejection fraction; TIA, transient ischemic attack.

4.1 | Incidence of EDELs

The overall incidence of EDEL was 9.8%. Given the extremely low incidence of AEF, these lesions have been used in all studies as a surrogate marker of the risk of esophageal perforation and AEF. However, this assumption is certainly imperfect considering that more than 99% of the esophageal injuries seen on UGE resolve with conservative management.[21] Furthermore, the absence of preoperative gastroscopy in both groups (ETM vs. no ETM) offsets any potential bias introduced, since presence of any pre-existing lesions would be evenly distributed across the study groups, thereby maintaining the comparative integrity of our findings on the impact of ETM on EDELs. The incidence of esophageal ulcers appears more relevant in terms of risk of AEF considering that about 5%–10%, may progress to perforation or AEF.[5,21] Among studies providing details on the grading of the esophageal lesions, the overall incidence of esophageal ulcers was 5.1%.

Another limitation of using EDELs as a surrogate marker of risk, is the over-estimation of lesions that are actually ablation-induced. Of the two studies[16,19] that performed pre-ablation UGE, one reported their findings[19]: the overall incidence of pre-ablation mucosal erosion or erythema was 4.7%. Moreover, pre- or peri-procedural TEE may also contribute to the incidence of esophageal lesions. Kumar et al. showed that among patients undergoing PVI under GA with TEE, esophageal lesions were observed in 30% of cases, while this proportion was 22% with TEE performed in the absence of LA ablation, and 0% in patients with PVI without TEE.[22] Accordingly, both preexisting lesions and probe-related lesions, may represent a consistent proportion of EDEL. In addition, our meta-analysis incorporates both symptomatic and asymptomatic cases of EDEL, identified through systematic postoperative gastroscopy across all included studies. This approach ensures a comprehensive assessment of EDEL incidence, reflecting the full spectrum of clinical presentations.

4.2 | Studies assessing the role of ETM in the prevention of esophageal lesions

Our meta-analysis shows that the use of ETM is not associated with a reduction in the incidence of EDEL. Though not statistically significant, the incidence of EDELs was nearly twice as high among patients with ETM (12.3% vs. 6.6%, respectively). Significant heterogeneity was present among studies: one study showed a benefit associated with ETM,[10] two studies showed evidence of harm, and the remaining eight studies[11,14–20] showed a neutral effect of ETM. Studies were heterogeneous in terms of ablation catheter types, settings (power, temperature and duration), as well as in terms of esophageal temperature cutoffs that were used, with 39°C being the most often used value. Nevertheless, muti-sensor temperature probes were used in most studies.

The most relevant aspect among studies was the differences in the adopted strategy during posterior wall ablation depending on whether ETM was used or not. Indeed, among the four studies which reported the ablation power delivered,[13,16,18,19] a significantly higher power

TABLE 3 Detailed ablation procedure data.

Authors	Ablation catheter type	Ablation parameters Max Power (LAAW, LAPW) Max Temperature	LAPW ablation protocol modification related to ETM	Max ablation time per lesion (in seconds)	Total procedure time (in minutes)	Total ablation time (in minutes)	Ablation strategy	Esophageal temperature probe type	Esophageal temperature cut-off (in°C)
Singh et al., 2008	3.5-mm externally (Thermocool™, OR 4-mm internally (Chili, Boston Scientific) irrigated catheter	35 W/LAPW 35 W 40°C	None	NR	NR	59 ± 24 67 ± 37	PVI and additional linear lesions the operator's discretion	9Fr Single sensor probe (Vital Temp™, Vital Signs Colorado Inc.)	>38.5
Deneke et al.,2011	Multi-Channel RF (PVAC™)	10 W/LAPW 10 W 60°C	None	60	107 ± 22 94 ± 26	26 ± 9 22 ± 5	PVI only	7 Fr. Three sensor probe (Esotherm™, FIAB SpA, Florence, Italy)	≥39.0
Deneke et al., 2015	nMARQ catheter	25 W/LAPW 25 W 39°C	None	60	112 93	19 15	PVI only	Multiples sensors probe (Sensitherm™, FIAB, Italy)	≥39.5
Muller et al., 2015	Irrigated catheter (ThermoCool ™ Smart Touch catheter)	35 W/LAPW 25 W 43°C	None	NR	119 ± 27 127 ± 40	31 ± 11 30 ± 10	PVI and additional ablations if low voltage. Ablation patterns at the discretion of the operator,	7 Fr, 5 sensors probe (SensiTherm™, FIAB, Firenze, Italy)	≥39.5
Kiuchi et al.,2016	Irrigated catheter (Thermocool™)	30 W/LAPW 20 W 43°C	ETM : 25 W No ETM :20 W	40	264 ± 59 242 ± 91	NR	PVI only	7-sensors probe (SensiTherm™, St. Jude Medical)	≥39.0
Halbfass et al., 2017	Irrigated catheter (ThermoCool SmartTouch™)	35 W/LAPW 25 W 43°C	None	20	NR	NR	PVI only by en-block in a point-by-point fashion	12 sensors probe (S-Cath™)	≥39.0
De Oliveira et al., 2018	Irrigated catheter	50 W/LAPW 30 W 55°C	ETM : Variable * No ETM : 30 W and 20 sec	30	215 ± 38 223 ± 34	NR	PVI only	7 F Single sensor probe (Braile Biomedica)	≥37.5
Chen et al., 2020	Irrigated catheter (ThermoCool, Smart-Touch ™ SF)	50 W/LAPW NR NR	None	8.8	56 ± 7 55 ± 10	11.5 ± 2.3 11.8 ± 2.6	PVI only	12 sensors probe (CIRCA Probe, CIRCA Scientific™, Englewood, CO)	>39.0

(Continues)

TABLE 3 (Continued)

Authors	Ablation catheter type	Ablation parameters Max Power (LAAW, LAPW) Max Temperature	LAPW ablation protocol modification related to ETM	Max ablation time per lesion (in seconds)	Total procedure time (in minutes)	Total ablation time (in minutes)	Ablation strategy	Esophageal temperature probe type	Esophageal temperature cut-off (in°C)
Schoene et al., 2020	Irrigated catheter	40 W/LAPW 30 W 40°C	ETM : 30 W No ETM :25 W	NR	130 ± 42 134 ± 44	35 ± 20 36 ± 20	PVI only	7 Fr 5 sensors probe (SensiTherm™, FIAB, Firenze, Italy)	≥41.0
Grosse Meninghaus et al., 2021	Irrigated catheter (TactiCath, ™ Abbott)	40 W/LAPW 25 W NR	ETM : 25 W† No ETM : 20–25 W	NR	186 ± 43 192 ± 51	65 ± 19 67 ± 19	PVI only	12 sensors probe (S-Cath, Circa Scientific, LLC™, Englewood, CO)	>39.0
Moura et al., 2022	Irrigated catheter (SmartTouch ™ ST-SF 3.5 mm)	30 W/ (LAPW 20 W 43°C	ETM : 30 W No ETM : 20 W	20	NR	32 36	Circumferential PVI additional linear lesions the operator's discretion	7F single sensor probe (Braile Biomédica™) OR 12 sensors probe (Circa S-Cath™	≥37.5

Abbreviations: LAAW, Left atrial anterior wall; LAPW, left atrial posterior wall; NR, not recorded; ETM, esophageal temperature monitoring; PVI, pulmonary vein isolation; RF, radiofrequency.
* Up to 50 W and according to ETM alarms, † was specified to be 25 W in the protocol but mean power was higher in the ETM group for posterior wall (42.2 W with ETM vs. 28.8 W without ETM, *p*-value < .01).

was delivered during ablation in patients monitored with ETM (mean difference 1.76 W, 95%CI, 0.34, 3.17, $p = .01$). One of these studies showed evidence of harm of ETM. This difference was related to an increase in the ablation power delivered specifically on the posterior wall in these patients[16,18,19] (mean difference 5.13 W, 95%CI, 1.52, 8.74, $p = .005$). These findings are obviously counterintuitive considering that the scope of ETM is to limit the energy delivered in case of temperature rise. Energy delivery should therefore be lower, or at best equal, to the non-ETM group. This difference may be explained by a sense of safety that may be felt by operators in the absence of temperature rise alert, potentially leading them to increases power and/or duration of RF. This assumption has been shared by other authors[13,19,23,24] and underlies the fact that in five of the eleven included studies,[10,17–20] the prespecified posterior wall ablation protocol differed whether ETM was used or not (Table 3). In these studies, the protocol set a 5[14,18,19] to 10 W[20] higher ablation power on the posterior wall in patients with ETM in the absence of temperature rise.

Regarding the only study that supported the use of ETM, the study was observational with RF power apparently left at the discretion of the operators. Detailed data on the delivered energy were not provided However, RF power up to 35 W was apparently delivered on the posterior wall in patients without ETM, a value notably higher compared to the other studies. Most importantly, the procedures performed in patients with ETM were far more often performed in general anesthesia compared to patients without ETM (43% vs. 13% with ETM, $p = .01$), which constitutes an important limitation of the study considering that it is a well-known risk factor for esophageal lesions.[25,26] A possible explanation for the higher risk of esophageal lesions with general anesthesia is the diminished motility and lack of swallowing, which prevents focused heat transfer on the same location and physiological cooling. Moreover, the lack of pain feedback by the patient may also contribute, since pain has been shown to be directly related to esophageal warming.[27]

4.3 | Inherent limitations of ETM

The benefit of real-time monitoring of the esophageal temperature is based on some observations showing an increase in EDELs in patients with higher mean[13] or maximal[23] esophageal temperature, or in patients with temperature overshooting ≥42°C after RF cessation.[19] However, one of the limitations of ETM is the fact that the intraluminal temperature underestimates the actual intramural temperature. In-vivo studies have demonstrated that temperatures within the esophageal wall did not necessarily correlate with temperatures measured by intraluminal probes.[24] An additional major limitation lies in the variable proximity of the temperature probe to the site of ablation. While the caudocranial coverage of the esophagus is mostly addressed with multisensory probes, sensing electrodes may be displaced posteriorly and their small size only provides a limited coverage of the esophageal width. Accordingly, their ability to monitor the portion of the esophagus width at risk, close to the posterior wall may

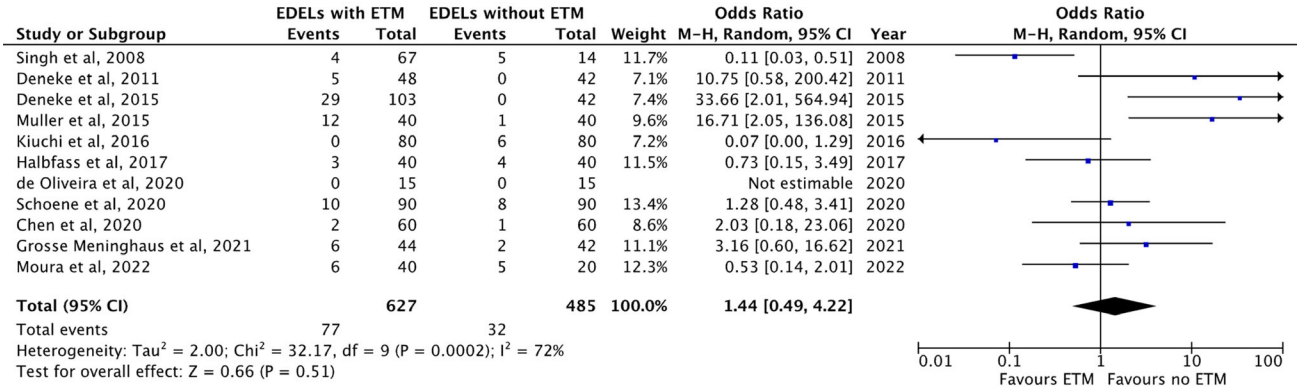

FIGURE 2 Pooled risk of endoscopically detected esophageal lesion according to the use of esophageal temperature monitoring during AF ablation catheter. EDEL, endoscopically detected esophageal lesion; ETM, esophageal temperature monitoring. [Color figure can be viewed at wileyonlinelibrary.com]

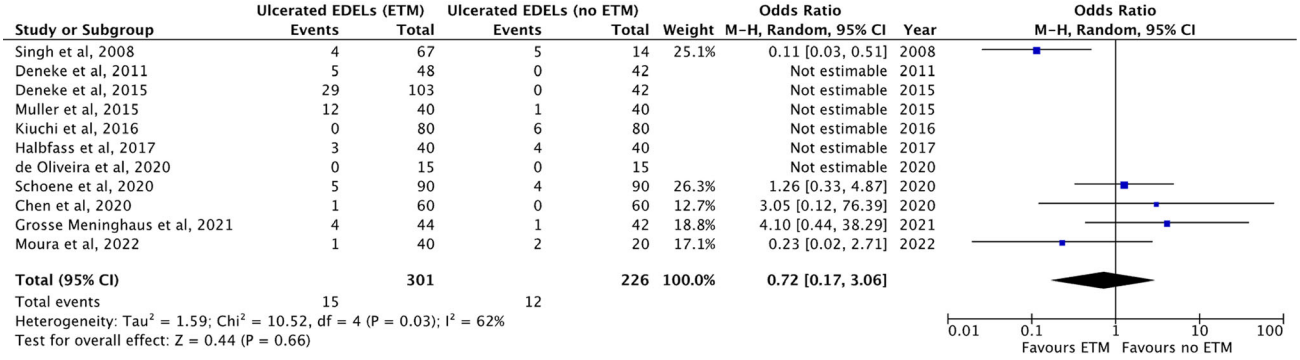

FIGURE 3 Pooled risk of endoscopically detected esophageal ulcerated lesion according to the use of esophageal temperature monitoring during AF ablation catheter. EDEL, endoscopically detected esophageal lesion; ETM. esophageal temperature monitoring. [Color figure can be viewed at wileyonlinelibrary.com]

be limited. Leite et al. showed that, when using a deflectable probe and intracardiac echocardiography guidance to visualize the esophageal-posterior LA wall relationship, a probe deflection was required in more than half of the patients despite adequate craniocaudal placement.[28] Indeed, it has been shown that esophageal temperature increase may be dampened when RF applications are performed as close as a few millimeter from a temperature sensor, and significant temperature increase will be undetected when lesions are >20 mm away from the sensor.[29] Beyond direct thermal injury, RF can also favor EDELs by damaging anterior peri-esophageal arteries and vagal innervation, leading to gastric hypomotility, which is not directly due to temperature rise. It could partially explain the neutral effect of ETM strategy.[30,31]

Because of these technical limitations, esophageal lesions as well as AEF have been observed with maximal temperature lower than 40°C in one quarter to more than one third of patients, or even without detectable temperature rise.[10,15,18,19,23,32] Accordingly, there remains no current consensus regarding the safe maximal temperature cut-off with respect to esophageal injury. Selected temperature thresholds ranged from 37.5 to 41°C in our meta-analysis.[19]

4.4 | The "antenna" effect hypothesis

One of the proposed mechanisms explaining the lack of benefit, or even the paradoxical harm of ETM, is that the esophageal probe itself may act as an "antenna" whereby the metallic component of the probe enhances the transmission of bipolar thermal energy from the RF catheter.[11] The observation of posterior esophageal ulceration with the form and size of the olive-shaped thermocouple has been considered as a possible consequence of the RF-inductive heating of the stainless-steel sensor.[33] Moreover, the possibility of an interaction between the ablation catheter and the probe was raised by Carroll et al. who compared multi-sensor esophageal probes to single-sensor probes. An increased incidence in esophageal injury was found with multi-sensors probes (46% vs. 29%, $p = .021$) despite increased temperature detection rates.[34] On the other hand, two other smaller size studies comparing single-sensor to multi-sensor probe, did not reproduce these findings and found no differences in the rate of esophageal lesions.[35,36] Moreover, in a simulation study using a computational model to assess the electrical and thermal effects of probes with and without metallic surfaces, the minimal electrical

alterations produced by the metallic surface did not appear to be clinically significant.[37] In summary, in the absence of firm evidence or converging data, the "antenna" effect of esophageal temperature probe remains speculative.

4.5 | High-power short-duration ablation

The recent development of high-, or very high-power short-duration ablation has further increased the use of ETM which has been implemented in the vast majority of studies assessing this ablation strategy because of the initial safety concern. Limited and conflicting data have been published regarding the risk of esophageal thermal injury with HPSD, with studies showing an increased risk,[38,39] and others showing a neutral effect.[40] According to a recent study, very high-power short-duration ablation seemed to be associated with a low risk of EDELs.[41] To the best of our knowledge, only one study included in our meta-analysis, compared the use of ETM versus no-ETM in patients who underwent HPSD catheter ablation.[17] Similar to the other studies, no benefit was found with the use of ETM (incidence of EDELs with ETM: 2.5%, without ETM: 3.3%, $p = .99$).[17] It is worth noting that the interpretation of ETM should consider the impact of HPSD on the temperature dynamic profile. Yavin et al.[42] compared the esophageal temperature profile of HPSD and moderate-power moderate-duration ablation. They found that the maximal temperature, time to maximal temperature (mean value about 25 s), and time to return to baseline return (mean value about 110 s), were similar between the two ablation approaches. Accordingly, considering the shorter application time with HPSD, temperature will continue to rise after RF termination (up to 30 s), before slowly decreasing. With shorter intervals between consecutive applications, continuous "stacking" of esophageal temperature may therefore occur, thereby increasing the risk of esophageal lesion despite relatively low peak temperatures.[29,43] This limitation should therefore be kept in mind when using ETM in the setting of HPSD.

4.6 | LIMITATIONS

This meta-analysis is subject to all potential limitations of this kind of analysis. We did not have access to individual patient data, in particular with respect to the ablation power and duration of application on the posterior wall, as well as the contact force applied. As previously discussed, a better knowledge of these data would be key to understand and interpret the results. While all studies were prospectively designed, only four of them were randomized and the overall quality of the studies, according to the MINOR score was variable. Finally, there was a significant heterogeneity between studies in terms of ablation catheter types and ablation settings, as well as in terms of esophageal temperature cutoffs and strategies adopted in case of temperature rise. Similarly, the definitions of EDEL varied among studies and included sometimes only ulcerations. Moreover, the proportion of lesions likely not ablation-related, such as those not facing the atrial wall, were not reported.

4.7 | Clinical implications and future directions

The major implication of our analysis is that ETM should not be considered as a security clearance and should therefore not influence the cornerstone principle of reducing energy delivery on the posterior wall unless the efficacy of other esophageal protection methods has been demonstrated. The use of ETM should be restricted to further reduce, or stop, energy delivery in case of temperature rise. As a corollary, studies evaluating alternative methods of esophageal protection, such as anatomic tracking of the esophageal course through imaging, should not rely on the occurrence of temperature rises as a surrogate marker of the risk of esophageal injury.

Considering the inherent limitations of ETM, particularly the fact that the temperature probe does not cover the width of the esophagus together with the steep dampening of temperature rise with increasing distance between the probe and the ablation catheter, the false impression of safety likely explains the lack of benefit, or even the paradoxical increase in esophageal lesions. This certainly represent a major bias in the interpretation of previous studies since the studied variable, the use of ETM, often influenced the single most relevant factor for esophageal lesion formation, namely RF energy delivery on the posterior wall. Further studies are therefore needed to assess the role of ETM in preventing esophageal injury. These studies should evaluate the same ablation setting and strategy on the posterior wall in both arms. In the ETM arm, ablation line deviation and/or reduced energy, should be restricted to the occurrence of temperature rise.

In order to address the limitations of discrete sensor temperature probes in terms of incomplete spatial coverage and slow temporal response, a promising infrared thermography catheter had been developed. The system allowed non-contact infrared scanning of the entire esophagus surface with high temporal and spatial resolutions, and without the need for precise placement or repositioning. In a first pilot study by Daly et al.,[44] high-resolution mapping of esophageal temperatures was demonstrated with examples highlighting high spatial gradients (where discrete sensor position would be critical), and high temporal rates of change. Esophageal thermal injury was only observed in patients with significantly elevated temperatures (>50°C) for prolonged exposures. These promising findings were confirmed by Deneke et al. showing that in a cohort of 63 patients, a maximal temperature cutoff of 50°C was an excellent binary classifier of patients at risk of EDEL.[45] However, the further development in order to achieve a market release of the product was not pursued because of its economic viability.

5 | CONCLUSIONS

Despite its widespread use, our meta-analysis shows that there is currently no evidence to support the use of ETM to prevent esophageal lesions during AF ablation procedures. Based on our findings, the most plausible explanation for this lack of benefit is the false sense of safety leading to increased energy delivery during RF on the posterior wall, underestimating the inherent limitation of the probe. The use of ETM

should not obviate the need for cautious energy delivery on the posterior wall until further, properly designed, studies assess the use of ETM with the same ablation strategy in both arms.

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CONFLICT OF INTEREST STATEMENT

None declared.

DATA AVAILABILITY STATEMENT

The data supporting the findings of this study are available at https://pubmed.ncbi.nlm.nih.gov due to the study design (meta-analysis).

CLINICAL TRIAL REGISTRATION (PROSPERO)

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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