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CLINICAL RESEARCH

Role of oesophageal cooling in the prevention of oesophageal injury in atrial fibrillation catheter ablation: a systematic review and meta-analysis of randomized controlled trials

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Aims

To evaluate the efficacy of oesophageal cooling in the prevention of oesophageal injury in patients undergoing atrial fibrillation (AF) catheter ablation.

Methods and results

Comprehensive search of MEDLINE, EMBASE, and Cochrane databases through April 2022 for randomized controlled trials (RCTs) evaluating the role of oesophageal cooling compared with control in the prevention of oesophageal injury during AF catheter ablation. The study primary outcome was the incidence of any oesophageal injury. The meta-analysis included 4 RCTs with a total of 294 patients. There was no difference in the incidence of any oesophageal injury between oesophageal cooling and control [15% vs. 19%; relative risk (RR) 0.86; 95% confidence interval (CI) 0.31–2.41]. Compared with control, oesophageal cooling showed lower risk of severe oesophageal injury (1.5% vs. 9%; RR 0.21; 95% CI 0.05–0.80). There were no significant differences among the two groups in mild to moderate oesophageal injury (13.6% vs. 12.1%; RR 1.09; 95% CI 0.28–4.23), procedure duration [standardized mean difference (SMD) −0.03; 95% CI −0.36–0.30], posterior wall radiofrequency (RF) time (SMD 0.27; 95% CI −0.04–0.58), total RF time (SMD −0.50; 95% CI −1.15–0.16), acute reconnection incidence (RR 0.93; 95% CI 0.02–36.34), and ablation index (SMD 0.16; 95% CI −0.33–0.66).

Conclusion

Among patients undergoing AF catheter ablation, oesophageal cooling did not reduce the overall risk of any oesophageal injury compared with control. Oesophageal cooling might shift the severity of oesophageal injuries to less severe injuries. Further studies should evaluate the long-term effects after oesophageal cooling during AF catheter ablation.

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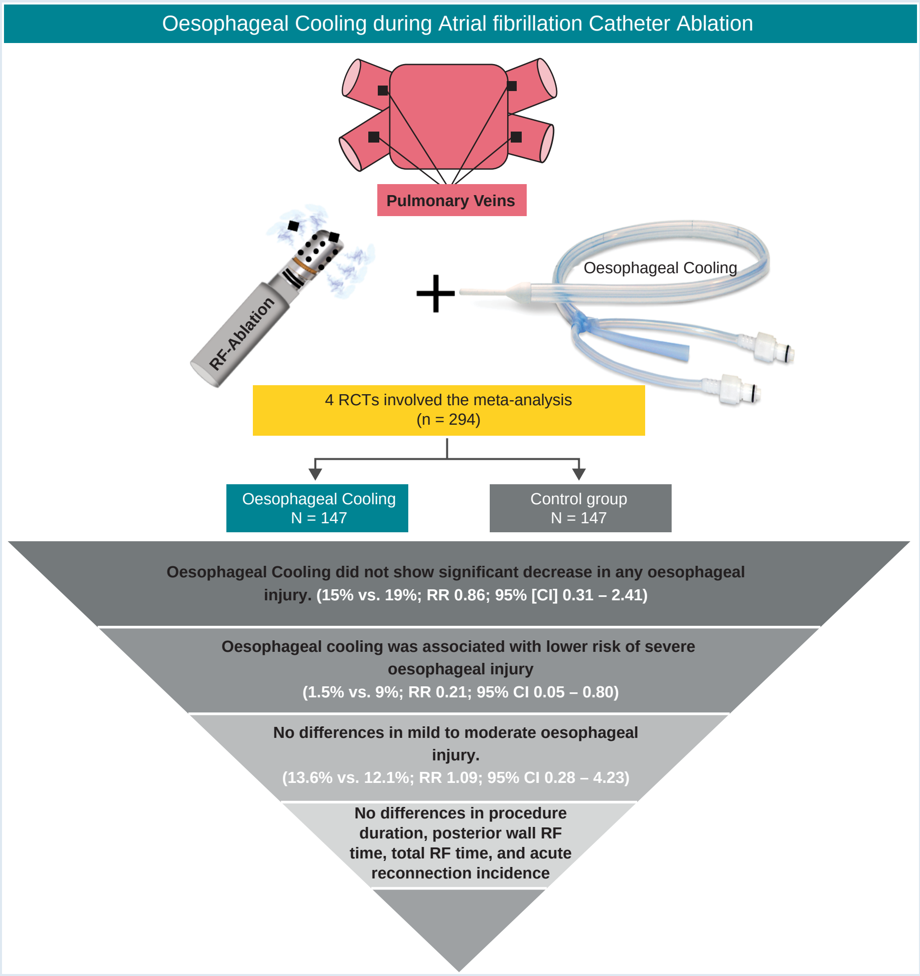
Graphical Abstract



Keywords Atrial fibrillation • Catheter ablation • Radiofrequency ablation • Oesophageal cooling • Oesophageal injury

What's New?

- This current meta-analysis of randomized controlled trials (RCTs) evaluated the role of oesophageal cooling compared with control in the prevention of oesophageal injury during AF catheter ablation.
- Our study demonstrated that oesophageal cooling did not reduce the overall risk of any oesophageal injury compared with control.
- Oesophageal cooling might shift the severity of oesophageal injuries to less severe and non-ulcerous injuries.
- Our findings suggested that oesophageal cooling did not affect the acute outcomes including the duration or success of the ablation process.

Introduction

Atrial fibrillation (AF) is the most common sustained arrhythmia, affecting almost 60 million adults worldwide.[1,2] The role of AF catheter ablation is expanding in this population group, although safety of the procedure is an important consideration. Complications from catheter ablation include stroke, pericardial effusion, cardiac tamponade, oesophageal injury, atrio-oesophageal fistula (AEF), phrenic nerve injury, and vascular complications and usually occur in less than <4% of the cases.[3–5] During both radiofrequency (RF) ablation and cryoablation, energy delivery can extend beyond the myocardium affecting adjacent structures including the oesophagus, which lies next to the left atrial posterior wall. Thermal injury could lead to the development of AEF, a rare yet lethal complication.[6,7] Oesophageal ulceration could be the initial injury that can lead to AEF formation and usually present within hours or days following catheter ablation.[8–10,11] Endoscopic evaluations have reported the incidence of oesophageal lesions to occur in 2–47% of cases post ablation.[12–14] Importantly, clinical data suggest that severe oesophageal injuries are the most concerning, as 9.6% progress to AEF.[9]

Multiple preventive strategies have been introduced including luminal oesophageal temperature monitoring, pre-procedural assessment of oesophagus position, tagging of oesophagus and intra-procedural real-time visualization of its course, mechanical oesophageal displacement, reducing ablation energy to the posterior wall of the left atrium, and gastric acid suppression. Yet, none of these methods have shown efficacy in preventing oesophageal injuries that is a precursor to AEF.[8,11,15–19] Oesophageal cooling for oesophageal protection during

RF ablation has been investigated in a few randomized controlled trials (RCTs), which have yielded mixed results.[20–23] Importantly, these studies were not adequately powered to detect true differences with oesophageal cooling strategies. In this study, we performed a systemic review and meta-analysis of RCTs that assessed the role of oesophageal cooling on the incidence of oesophageal injury and their degree of severity during AF catheter ablation.

Methods

Data sources and search strategy

A comprehensive search of MEDLINE, EMBASE, and Cochrane databases through April 2022 for RCTs evaluating the role of oesophageal cooling compared with control in the prevention of oesophageal injury during AF catheter ablation was performed. The following keywords were used separately and in combination: 'esophageal' OR 'oesophageal' OR 'cooling' OR 'Ablation' OR 'Catheter ablation'. In addition, further screening of Clinicaltrials.gov and prior meta-analyses were performed to retrieve previously published RCTs that did not appear in the initial search. Our study was conducted in accordance with PRISMA (Preferred Reporting Items for Systemic Reviews and Meta-Analyses) guidelines[24] (see Supplementary material online, *Table S1*). Details of the systematic review were submitted for registration in PROSPERO with ID **329145**.

Selection criteria

We included RCTs that compared the protective role of oesophageal cooling vs. control on the prevention of oesophageal injury during AF catheter ablation. We only included studies that assessed oesophageal injury by performing post-ablation endoscopy. The control group in the included studies should have employed oesophageal temperature probes to monitor the oesophageal temperature during RF ablation. We only included studies that were published in English. Conference abstracts, review articles, case reports, case series, case–control, cohort, and non-randomized trials were all excluded.

Data extraction

Data were extracted by two investigators independently (M.H. and S.E.) and included various study features, baseline characteristics, and outcomes. Any disagreements between investigators were settled by consensus.

Outcomes

Our study's primary outcome was the incidence of any oesophageal injury (i.e. irrespective of the severity of oesophageal injury). The secondary outcomes included the incidence of severe oesophageal injury, the incidence of mild to moderate oesophageal injury, procedural duration, posterior wall RF time, total RF time, acute reconnection incidence, and ablation index. The definition of any oesophageal injury and the degree of severity were adopted as per each study. Ablation index, a marker of ablation lesion quality, is a weighted formula that incorporates power, duration, and contact force. These outcomes were reported for the patients with the longest follow-up period till after endoscopic evaluation and on an intention-to-treat basis.

Assessment of the quality of the included studies

The included studies' quality was evaluated using the Cochrane risk assessment for RCTs, which includes various criteria such as random sequence generation and allocation concealment for selection bias, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias. Based on the aforementioned criteria, studies were classified as having a low risk of bias, a high risk of bias, or an unclear risk of bias[25] (see Supplementary material online, *Table S3*).

Statistical analysis

Data were pooled by a random-effects model to overcome anticipated heterogeneity among the included studies. To evaluate statistical heterogeneity between the included studies, we used I^2 statistics; values < 25%, 25% to 50%, and >50% were considered to be a low, moderate, and a high degree of heterogeneity, respectively.[26] For continuous variables, standardized mean difference (SMD) were used, and for categorical variables, risk ratios (RR) were used. Since our meta-analysis included a small number of studies, publication bias was not assessed. The *P*-values for all analyses were considered significant if <0.05. Statistical analyses of the study data were conducted using RevMan 5.0 software (Cochrane Collaboration, Oxford, UK).

Results

Included studies

The study selection process was outlined in *Figure 1*. The final analysis included 4 RCTs which involved a total of 294 patients: 147 in the oesophageal cooling group and 147 in the control group.[20–23] The characteristics of the included studies and patient population appear in *Table 1* and *Table 2*. The weighted mean age was 62.1 years, while the proportion of men was 70.1%. The included studies used various methods of oesophageal cooling. Kuwahara *et al.*[20] used ice water (0°C) that was injected through a gastric tube into oesophagus. Oliveira *et al*. used a catheter balloon filled with cold saline solution and continuously irrigated the oesophageal wall with the catheter balloon.[22] Both Leung *et al.*[21] and Tschabrunn *et al.*[23] used the ensoETM device for oesophageal cooling with oesophageal temperature maintained at 4°C. EnsoETM is an FDA-approved device which is a medical-grade silicone tube through which consistent high volume of distilled water in a closed-loop irrigation system that can be used for cooling or warming.[21,23] All control groups used oesophageal temperature sensor probes (either single sensor or multi-sensor) to monitor oesophageal temperature and ablation was stopped in case of rising temperature in the oesophagus.[20–23] Oesophageal injury was assessed by using endoscopy with different protocols among the included studies. Kuwahara *et al*. used endoscopy 1 day after ablation, while Tschabrunn *et al*. used endoscopy within 48 h after the ablation procedure. In Oliveira *et al.*'s study, endoscopy and endoscopic ultrasound were done within 3 days after the procedure. Leung *et al*. used endoscopy 7 days after the ablation procedure. The definition of oesophageal thermal injury and the degree of severity of thermal injury in the included studies are reported in Supplementary material online, *Table S2*. All involved studies used RF AF catheter ablation and were single-centred studies.[20–23] The quality of the included studies appears in Supplementary material online, *Table S3*. All studies were double-blinded studies except Kuwahara *et al*., which was a single-blinded study as operators were unblinded.[20] The remaining risk of bias was considered to be low among all studies.

Primary outcome

The primary outcome was reported in all included RCTs.[20–23] Oesophageal cooling did not show a significant decrease in any oesophageal injury compared to control [15% vs. 19%; RR 0.86; 95% confidence interval (CI) 0.31–2.41; $I^2 = 63\%$] (*Figure 2*). We performed stepwise sensitivity analyses to evaluate the source of heterogeneity by excluding one study at a time. After excluding the study with the highest contribution to heterogeneity (Leung *et al*.), sensitivity analysis showed similar results (23% vs. 18.4%; RR 1.20; 95% CI 0.67–2.15) although heterogeneity decreased significantly ($I^2 = 0\%$).[20,22,23] Several other sensitivity analyses were conducted as follows: including studies using the most commonly

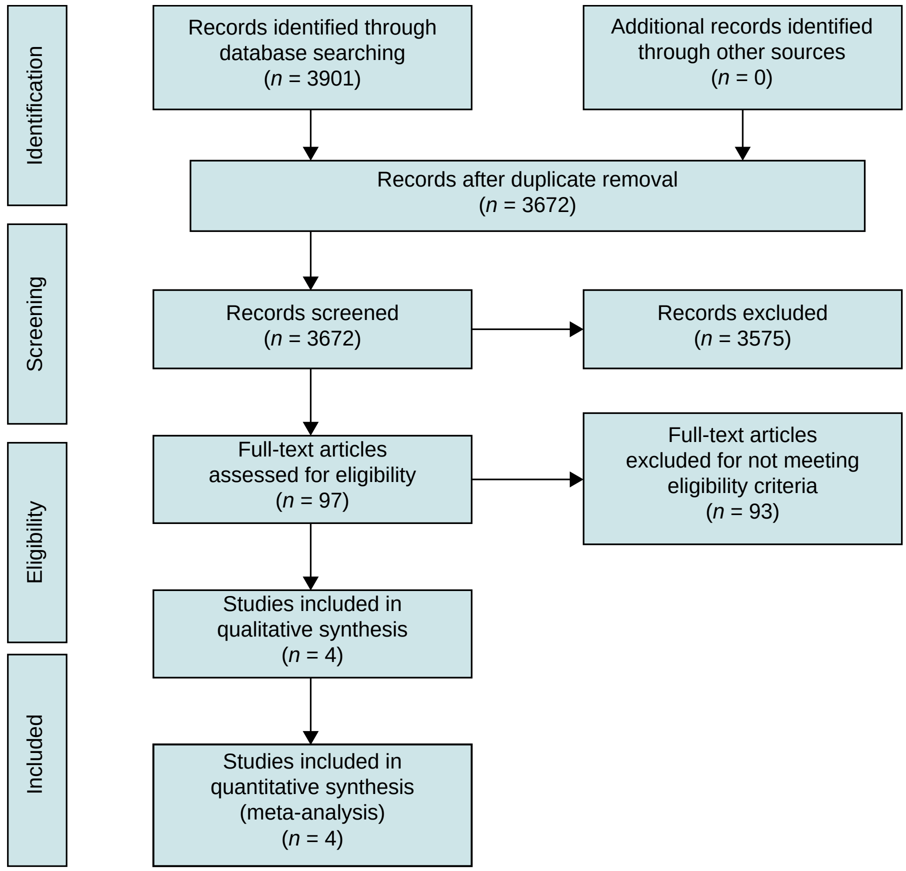


Figure 1 Study flowsheet.

cooling method (i.e. ensoETM device) (RR 0.55; 95% CI 0.05–5.60; $I^2 = 86\%$),[21,23] including studies using consistent temperature monitoring method (i.e. single-sensor probe) (RR 0.90; 95% CI 0.14–5.87; $I^2 = 76\%$)[21–23] and including studies performing endoscopy in the first 3 days after the ablation procedure (RR 1.20; 95% CI 0.67–2.15; $I^2 = 0\%$),[20,22,23] which all showed similar results to the primary analysis (see Supplementary material online, *Figure S1*).

Secondary outcomes

The risk of severe oesophageal injury was reported in 3 studies; however, the definitions varied among these studies (see Supplementary material online, *Table S2*). Oesophageal cooling was associated with a lower risk of severe oesophageal injury (1.5% vs. 9%; RR 0.21; 95% CI 0.05–0.80) with low heterogeneity ($I^2 = 0\%$). Sensitivity analysis excluding the study with the highest contribution to heterogeneity (i.e. Leung *et al.*), demonstrated no significant difference in the rate of severe oesophageal lesions between both groups (RR 0.25; 95% CI 0.04–1.42, $I^2 = 0$) (see Supplementary material online, *Figure S1*). There were no differences among the oesophageal cooling and control groups in mild to moderate oesophageal injury (13.6% vs. 12.1%; RR 1.09; 95% CI 0.28–4.23; $I^2 = 64\%$), procedure duration (SMD −0.03; 95% CI −0.36–0.30; $I^2 = 0\%$), posterior wall RF time (SMD 0.27; 95% CI −0.04–0.58; $I^2 = 0\%$), total RF time (SMD −0.50; 95% CI −1.15–0.16; $I^2 = 61\%$), acute reconnection incidence (RR 0.93; 95% CI 0.02–36.34; $I^2 = 84\%$), and ablation index (SMD 0.16; 95% CI −0.33–0.66; $I^2 = 53\%$). (*Figures 2* and *3*)

Discussion

In this meta-analysis of 4 RCTs, including 294 patients, we evaluated the efficacy and safety of oesophageal cooling in the prevention of oesophageal injuries in patients with AF undergoing catheter ablation. The salient findings of this study are as follows: (i) there was no significant difference in the incidence of any oesophageal injury in patients undergoing oesophageal cooling compared with the control group; (ii) patients undergoing oesophageal cooling might have lower risk of severe oesophageal injury; however, the definition of severe oesophageal injuries varied among included studies; and (iii) there was no significant difference between both groups in mild to moderate oesophageal injury, posterior wall RF time, total procedure duration, total RF time, acute reconnection incidence, and ablation index. Importantly, the current analysis only evaluated the impact of oesophageal cooling on acute efficacy and safety of AF ablation, while there were no data regarding the long-term recurrence risk of AF after oesophageal cooling.

AEF from RF ablation is a rare, but a feared complication as it can be fatal in up to 80% of cases[9–11,15]. Although the mechanism of AEF formation is not well understood, there is general agreement that thermal injury is a precursor.[9] Thermal injury alters the microvasculature of oesophageal tissue leading to ischaemic necrosis of the mucosal

Table 1 Characteristics of the included studies

Study	Publication year	No. of centres	Group 1 (oesophageal cooling)	Group 2 (control)	Oesophageal cooling method	Oesophageal temperature monitoring in control group	Follow-up endoscopy	Type of AF ablation and catheter used	Study objective
Tschabrunn	2022	Single centre	22	22	Active oesophageal cooling (EnsoETM device)	Standard linear and non-deflectable single-sensor probe (Smiths Medical ASD Inc., Keene, NH)	Within 48 h following the ablation procedure	RF (Smart-Touch Surround Flow Thermocool, Biosense Webster Inc.).	Number and percentage of participants with oesophageal thermal injury
Leung (IMPACT)	2021	Single centre	60	60	Active oesophageal cooling (EnsoETM device)	Single-sensor temperature probe (Oesophageal Temperature Probe, Smiths Medical, Minneapolis, MN, USA)	7 days after ablation	RF; using irrigated contact force sensing catheters (STSF or Qdot Micro, Biosense Webster, Johnson and Johnson, Diamond Bar, CA, USA)	The incidence of endoscopically detected oesophageal mucosal lesions and/or gastroparesis
Oliveira	2020	Single centre	15	15	Continuous irrigation of the oesophageal wall with a catheter balloon filled with cold saline solution	Single-thermocouple oesophageal temperature probe (Braile Biomedica)	Endoscopy plus EUS within 3 days after the procedure	RF generator (Stockert EP-Shuttle Generator System; Biosense Webster)	To compare the difference in prevalence of post-AF ablation oesophageal and peri-oesophageal injuries
Kuwahara	2014	Single centre	50	50	Injecting ice water through gastric tube into the oesophagus under oesophageal temperature monitoring	Multi-thermocouple temperature probe (Sensitherm, St. Jude Medical)	One day after the AF catheter ablation session	RF (Thermocool, Biosense Webster Inc.)	To elucidate whether oesophageal cooling with the ice water could prevent the incidence of oesophageal lesions complicating the catheter ablation of AF

EUS, endoscopic ultrasound; AF, atrial fibrillation; RF, radiofrequency.

Table 2 Baseline characteristics of the study population

		Tschabrunn	Leung (IMPACT)	Oliveira	Kuwahara
Age in years (mean ± SD)	Cooling	62.8 ± 9.6	65 ± 10	47.8 ± 13.3	62 ± 9
	Control	63.6 ± 9.3	65 ± 9	53.3 ± 9.4	64 ± 10
Male %	Cooling	64	60	66.7	76
	Control	73	61.7	86.7	84
BMI (kg/m^2)	Cooling	30.5 ± 7.3	28.5 ± 5.3	28.7 ± 4.8	24 ± 3
	Control	31.0 ± 5.1	29.8 ± 6.98	30.4 ± 3.3	24 ± 3
Paroxysmal AF %	Cooling	50	45	86.7	70
	Control	64	50	73.3	58
Diabetes %	Cooling	5	–	0	–
	Control	9	–	13.3	–
Hypertension %	Cooling	55	–	46.7	–
	Control	59	–	66.7	–
EF %	Cooling	54.7 ± 11.4	55 ± 9	63.5 ± 3.9	64 ± 8
	Control	55.8 ± 9.4	52 ± 8	62.9 ± 4.8	64 ± 7
LAD (cm)	Cooling	–	4.1 ± 0.9	4.05 ± 0.48	4.0 ± 0.5
	Control	–	4.2 ± 0.6	4.17 ± 0.37	4.0 ± 0.6

SD, standard deviation; kg, kilogram; m, meter; EF, ejection fraction; LAD, left atrial diameter; cm, centimetre.

layers.[27,28] Importantly, higher-grade thermal injury has a higher risk of progression to AEF.[9]

Few RCTs and multiple observational studies have evaluated the role of oesophageal cooling in AF catheter ablation and shown variable results.[20–23,29–32] Leung *et al*. demonstrated that oesophageal cooling significantly reduces oesophageal thermal injury,[21] while Kuwahara *et al*. and Tschabrunn *et al*. showed that oesophageal cooling did not reduce the incidence of oesophageal injury; however, it could reduce the severity.[20,23] In contrast, Oliveira *et al*. showed a higher incidence of oesophageal injuries in oesophageal cooling relative to control[22], which might have been attributed to the higher RF energy needed in the cooling group. Prior meta-analyses were conducted to evaluate the role of oesophageal cooling on the incidence of oesophageal injury, and their results suggested no significant difference on the incidence of oesophageal injury.[33,34] However, these meta-analyses were mainly comprehensive of observational studies and only one RCT. The current meta-analysis of RCTs demonstrated no significant difference on the incidence of any oesophageal injury. Our study involved a variety of methods used in oesophageal cooling including ice water cooling, cold saline solution, or ensoETM device. Exploratory analysis did not reveal an interaction between the study results and the cooling method used. Importantly, we analysed the different grades of oesophageal injuries in the study groups, to provide deeper insight into the potential degree of oesophageal protection with cooling methods. Severe oesophageal injuries are strongly correlated with the development of AEF and carry significant morbidity and mortality.[9–11,15] However, our analysis was limited by the lack of homogenous definition for the severity of oesophageal injuries among the included studies. In 2 of the 3 studies reporting the severity of oesophageal injuries,[21,23] severe injuries were defined mainly by the presence of ulcerous lesions, while in the last study, severe injuries were qualitatively defined by the colour and extent of the injury.[20] Furthermore, exploratory analysis excluding the study with the highest contribution to heterogeneity showed no significant difference in the risk of severe oesophageal injury among both groups. Our analysis suggests that oesophageal cooling does not reduce the incidence of oesophageal injuries but may shift the severity of injuries to less severe (i.e. non-ulcerous) injuries.

Several ablation techniques and tools could impact the degree of thermal injury with AF ablation procedures. For example, the use of contact force technology can provide real-time feedback for catheter tissue contact and, hence, could contribute to better safety and effectiveness of ablation.[35] Also, the use of techniques such as high-power/short-duration ablation can achieve superior ablation lesions, without increasing the risk of thermal injury.[36,37] Our analysis was limited by the variation in ablation techniques among the included studies, and further clinical trials are warranted to evaluate the role of oesophageal cooling among various ablation techniques. In addition, there was variability in the oesophageal temperature probes among the included studies (i.e. single sensor vs. multi-sensor probes). Prior studies suggested a superior thermodynamic profile with multi-sensor vs. single-sensor probes; however, differences in clinical thermal injuries according to the type of temperature probe are yet to be proven.[11] Relevantly, our exploratory analysis including studies using single-sensor temperature probes only showed consistent results, similar to the primary analysis.

The suggested reduced risk of severe oesophageal injury with cooling methods could be multifactorial. Data suggest that cooling could have a protective effect leading to reduction in lesion thickness.[38] Burn studies suggest that there is a relationship between cooling and thermal injury, as cooling after thermal insults can prevent the progression of thermal injury.[39] Relevantly, although oesophageal cooling might reduce the severity of thermal injuries, it did not alter the ablation process in the acute outcomes, as it did not show any significant difference in the procedure duration, posterior wall duration, total RF time, acute reconnection incidence, or ablation index.[40,41]

This meta-analysis includes the totality of randomized data evaluating the role of oesophageal cooling in AF catheter ablation. Our findings demonstrated that the use of oesophageal cooling in patients undergoing AF catheter ablation had no effect on the incidence of any oesophageal injury. Oesophageal cooling might shift

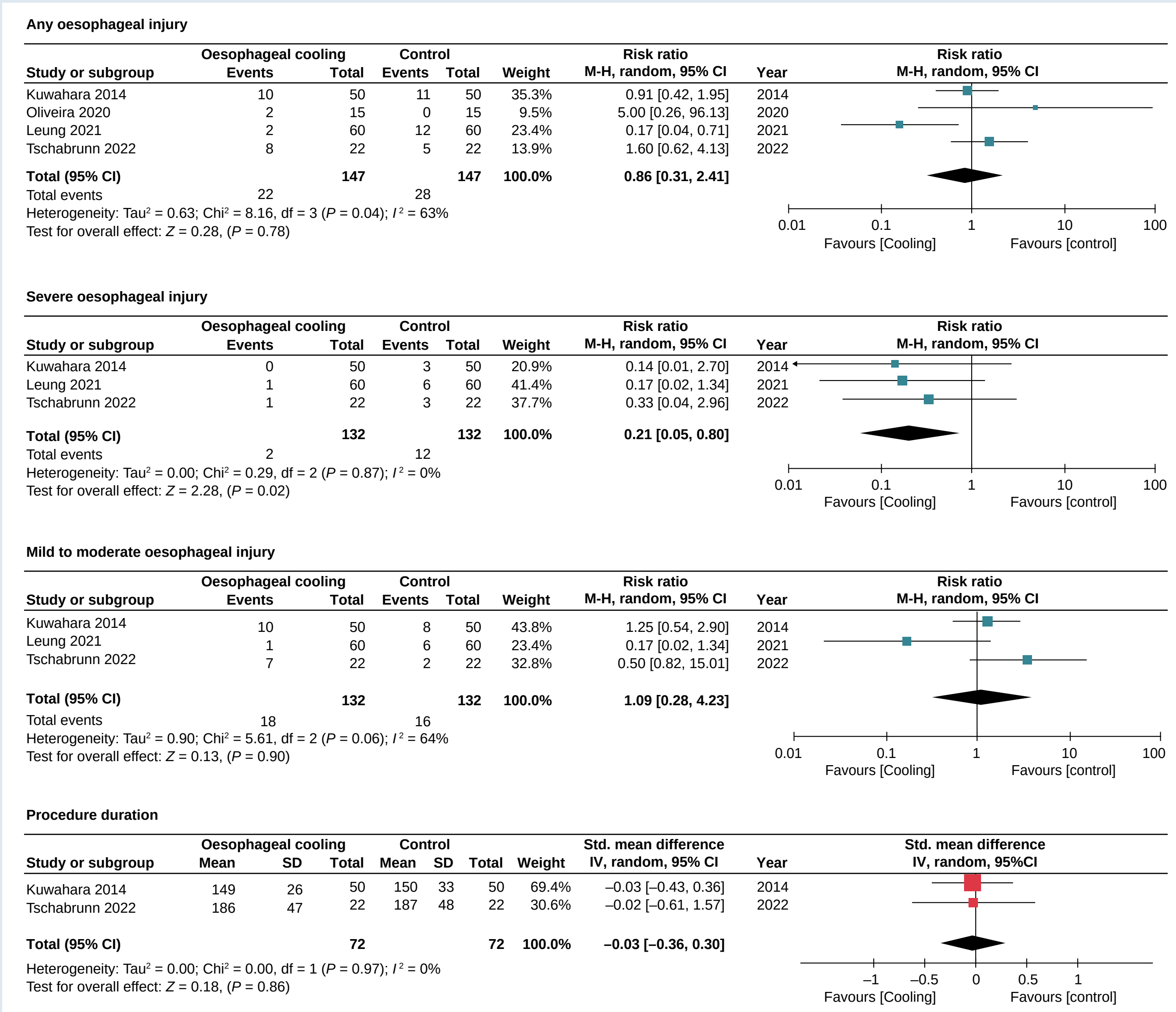


Figure 2 Forrest plot for any oesophageal injury, severe oesophageal injury, mild–moderate oesophageal injury, and procedural duration.

the severity of oesophageal injuries to less severe, non-ulcerous injuries. Yet, given the small sample size of available trials, larger randomized trials are still warranted to further characterize the role of oesophageal cooling in the prevention of oesophageal injuries in patients undergoing AF catheter ablation. Furthermore, standardized definitions for the severity of oesophageal injuries should be adopted in future trials.

Limitations

This meta-analysis had some limitations. First, the few numbers of available RCTs in the study topic have still limited the power of our analysis. Based on the observed rates of oesophageal lesions in both groups, a sample size of 2800 patients would be needed to achieve a study power of 0.80 to answer the hypothesis. Second, some of the study outcomes had a considerable degree of heterogeneity. Moreover, we have employed a random effects model in our analysis to mitigate the between-study heterogeneity. Furthermore, we performed a secondary analysis to explore the sources of heterogeneity in the primary study outcome, and similar results were obtained after excluding the study with the highest contribution to heterogeneity of the primary outcome. Third, there were variabilities among the included studies regarding the oesophageal cooling methods, temperature monitoring methods, the timing of oesophageal endoscopic assessment, and the ablation strategies and tools. To further explore such variabilities, we aimed to perform several exploratory sensitivity analyses for the primary study outcome and demonstrated consistent study results. Fourth, our analysis only evaluated the efficacy of ablation in the acute outcomes with the lack of long-term follow-up regarding arrythmia free data. Fifth, the lack of patient-level data precluded more granular analyses.

Conclusion

In this meta-analysis of randomized trials, oesophageal cooling in patients undergoing AF ablation did not reduce the incidence of

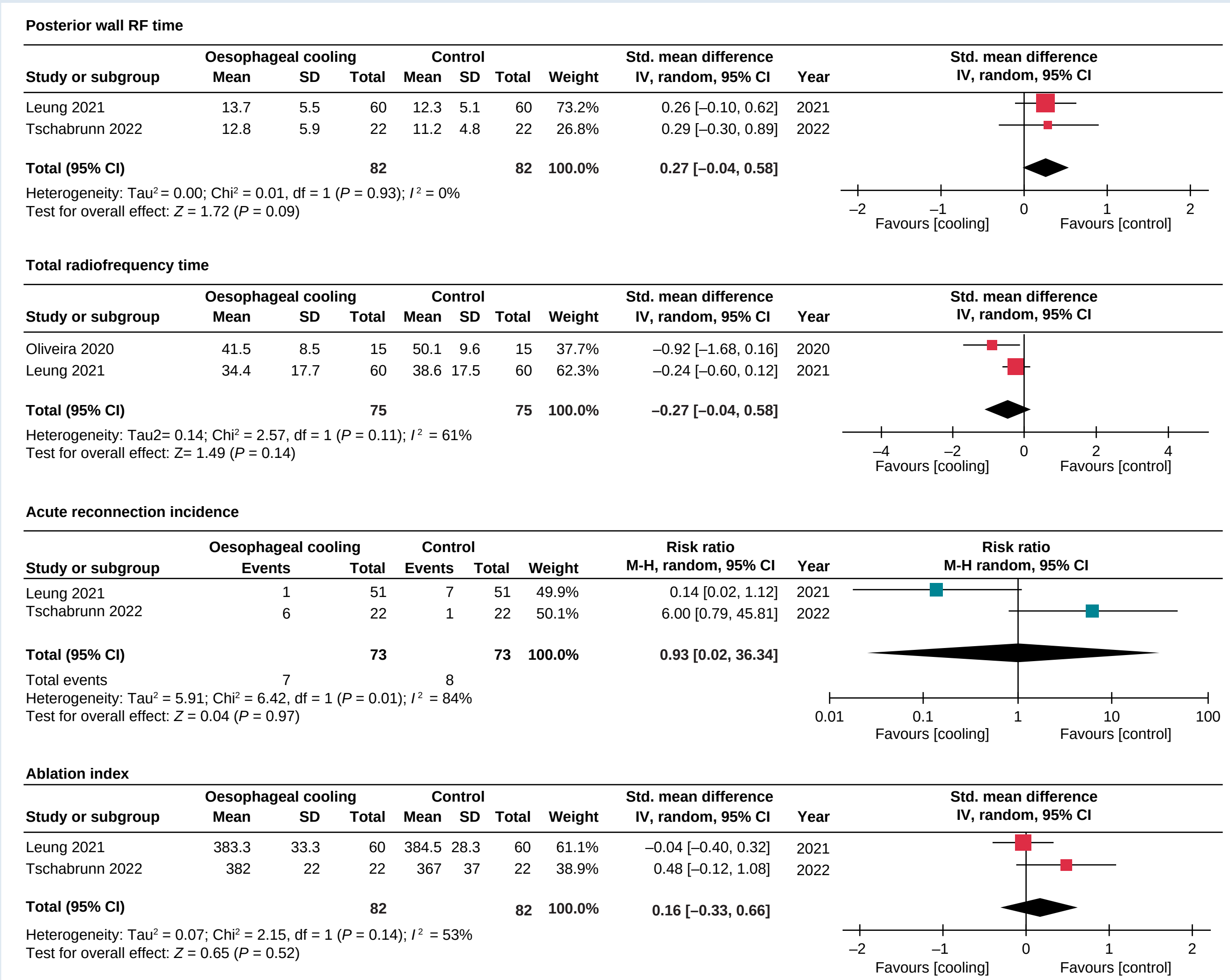


Figure 3 Forrest plot for posterior wall RF time, total radiofrequency time, acute reconnection incidence, and ablation index.

any oesophageal thermal injury, compared with the control. Oesophageal cooling might shift the severity of oesophageal injuries to less severe and non-ulcerous injuries. There were no significant differences between the two groups in the acute outcomes regarding posterior wall RF time, total procedure duration, total RF time, acute reconnection incidence, and ablation index. Further larger randomized trials are needed to better characterize the short- and long-term effects of oesophageal cooling among patients undergoing AF catheter ablation.

Supplementary material

Supplementary material is available at *Europace* online.

Authorship

All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this article, take responsibility for the integrity of the work, and have given their approval for this version to be published.

Author contributions

All authors contributed to the study conception and design, material preparation, data collection, statistical analysis, writing the article, critical revision of the article, and final approval of the article.

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Data availability

The data underlying this article are available in the article and in its online supplementary material.

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