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The efficacy and safety of cryoballoon atrial fibrillation ablation in patients with heart failure: A systematic review and meta-analysis

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ABSTRACT

Introduction: While atrial fibrillation (AF) ablation has proven beneficial for heart failure (HF) patients, most reports were performed with radiofrequency ablation. We aimed to evaluate the efficacy and safety of cryoballoon AF ablation in patients with HFrEF.

Method: We comprehensively searched the databases of MEDLINE, EMBASE, and Cochrane database from inception to December 2022. Studies that reported the outcomes of freedom from atrial arrhythmia, complications, NYHA functional class (NYHA FC), and left ventricular ejection fraction (LVEF) after Cryoballoon AF ablation in HF patients were included. Data from each study were combined with a random-effects model.

Result: A total of 9 studies observational studies with 1414 HF patients were included. Five studies had only HF with reduced ejection fraction (HFrEF), 1 study with HF with preserved ejection fraction (HFpEF), and others with mixed HF types. Freedom from AA in HFrEF at 12 months was 64% (95% CI 56–71%, I^2 58%). There was a significant improvement of LVEF in these patients with a standard mean difference of 13% (95% CI 8.6–17.5%, I^2 99% $P < 0.001$. The complication rate in HFrEF group was 6% (95% CI 4–10%, I^2 0%). The risk of recurrence of atrial arrhythmia was not significantly different between HF and no HF patients (RR 1.34, 95% CI 0.8–2.23, I2 76%).

Conclusion: Cryoballoon AF ablation is effective in HFrEF patients comparable to radiofrequency ablation. The complication rate was low.

1. Introduction

Catheter ablation (CA) is among the widely accepted atrial fibrillation (AF) rhythm-control strategies. CA has been proven beneficial in AF patients with heart failure (HF), especially in heart failure-reduced ejection fraction (HFrEF). AF CA was shown to mitigate the mortality rates and worsening heart failure in the CASTLE-AF study [1,2]. Meanwhile, in patients with heart failure with preserved ejection fraction (HFpEF), AF CA was associated with reduced heart failure hospitalization compared to pharmacological therapy alone [3]. AF CA in heart failure patients has become a more attractive therapeutic option, with growing evidence supporting its use in this group of patients. However, the majority of those reports were performed with radiofrequency ablation [1,4,5].

Cryoballoon (CB) AF ablation is a technique that uses cryogenic energy applied with a balloon to isolate pulmonary vein antrum with cold temperature [6]. CB has demonstrated comparable efficacy and safety endpoints compared to RF ablation [7]. However, there is still a lack of evidence for using CB ablation in AF patients with heart failure, both HFrEF and HFpEF.

In this study, our primary objective is to evaluate the efficacy and safety of CB AF ablation in heart failure reduced ejection fraction and

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other types of heart failure.

2. Method

2.1. Literature review and search strategy

The protocol for this meta-analysis is registered with PROSPERO (International Prospective Register of Systematic Reviews; no. CRD 42023387762) [8]. A systematic literature search of MEDLINE (1946 to December 2022), EMBASE (1988 to December 2022), SCOPUS (database inception to December 2022), and the Cochrane Database of Systematic Reviews (database inception to December 2022) was conducted. The need for approval from the institutional review board was waived because publicly available cumulative published data were used.

The systematic literature review was undertaken independently by two investigators (R.C. and N.T.) applying search terms of "cryoballoon" OR "cryoablation" combined with "heart failure" AND "atrial fibrillation" OR "AF" provided in supplementary data 1. A manual search for relevant studies was also performed. Only English language studies were included. This study was conducted by the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) [9] and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement [10].

2.2. Selection criteria

Studies reported outcomes of CB AF ablation in heart failure patients, including all types of heart failure (HFrEF, HFmEF, and HFpEF). Eligible studies must be observational studies (cohort, case-control, or cross-sectional) and clinical trials. Inclusion was not limited by study size and was not determined by the generation of CB. Case reports were excluded. We also excluded studies that did not publish the full-length manuscript.

2.2.1. Eligible study

- Study that reported freedom from atrial arrhythmia (AA) after CB AF ablation. Atrial arrhythmia includes atrial tachycardia (AT), atrial flutter (AFL), and atrial fibrillation (AF).
- The study reported major complications after CB AF ablation, including pericardial effusion/pericardial tamponade, atrioesophageal fistula, phrenic nerve injury, vascular complications that required intervention, and bronchial damage.

Table 1
Study characteristic.

Author	Year	Population	HF population	Type of study	Country	AF type	HF type	Ablation technique	Pre ablation LVEF (%)	Post ablation LVEF (%)	Catheter	Freedom from AA at 12 months in CB (%)
Pruszkowska	2018	89	30	Observational	Poland	pAF/peAF	HFrEF	PVI	30	37	2nd Generation Cryoablation Arctic Front (Medtronic)	43.3
Heeger	2019	551	50	Observational	Germany	pAF/peAF	HFrEF	PVI	37	55	2nd Generation Cryoablation Arctic Front (Medtronic)	73.1
Maj	2019	38	38	Observational	Italy	pAF/peAF	HFrEF	PVI	37.3	40.7	2nd Generation Cryoablation Arctic Front (Medtronic)	76.3
Pott	2020	414	113	Observational	Germany	pAF/peAF	HFrEF	PVI	38.4	52.5	2nd Generation Cryoablation Arctic Front (Medtronic)	64.6
Prabhu	2021	76	76	Observational	Australia	pAF/peAF	HFrEF	PVI	32	45	2nd Generation Cryoablation Arctic Front (Medtronic)	70
Rordorf	2021	1303	318	Observational	Asia and Europe	pAF/peAF	HFrEF/HFpEF	PVI	58	NA	Arctic Front Advance Pro (Medtronic)	80.5
Chen	2022	471	216	Observational	China	pAF/peAF	HFpEF/HFmEF/HFrEF	PVI	NA	NA	2nd Generation Cryoablation Arctic Front (Medtronic)	91.6
Yanagisawa	2022	3655	549	Observational	Japan	pAF/peAF	HFrEF/HFpEF	PVI	56.2	59.7	2nd Generation Cryoablation Arctic Front (Medtronic)	80.1
Zylla	2022	102	24	Observational	Germany	pAF/peAF	HFpEF	PVI	57.1	56.3	2nd Generation Cryoablation Arctic Front (Medtronic)	41.6

2.2.2. Primary outcome of the study

- Freedom from atrial arrhythmia (AA) after CB AF ablation in patient with HFrEF
- Complication from CB AF ablation in patients with HFrEF

2.2.3. Secondary outcome

- Freedom from atrial arrhythmia (AA) after CB AF ablation in other heart failure types (HFpEF and HFmEF)
- Comparing risk of atrial arrhythmia in HF and non-HF patients who underwent cryoballoon AF ablation.

The retrieved articles were individually reviewed by the two investigators (W.T. and N.T.). Discrepancies were discussed and resolved by a third researcher (R.C.). The Newcastle-Ottawa quality assessment scale was used to appraise the quality of the study for case-control studies and outcomes of interest for cohort studies [11]. The modified Newcastle-Ottawa scale was used for cross-sectional studies [12]. The risk of bias by Cochrane Collaboration's tool was used for assessing the risk of bias for randomized controlled trials, as shown in Table 1.

2.3. Data abstraction

A structured data collecting form was utilized to derive the following information from each study, including title, year of the study, name of the first author, publication year, the country where the study was conducted, and demographic and characteristic data of patients who underwent CB AF ablation. The primary outcomes, including freedom from atrial arrhythmia and complications, were collected. The secondary outcomes, including left ventricular ejection fraction (LVEF) and New York Heart Association Functional Class (NYHA FC), were also collected, as shown in Table 1.

2.4. Statistical analysis

Analyses were performed using R software version 3.6.3 (R Foundation for Statistical Computing, Vienna, Austria). The raw data for this systematic review is publicly available through the Open Science Framework (URL: https://osf.io/h9qwu/). Adjusted point estimates from each included study were combined by the generic inverse variance approach of DerSimonian and Laird, which designated the weight of each study based on its variance [13]. Given the possibility of

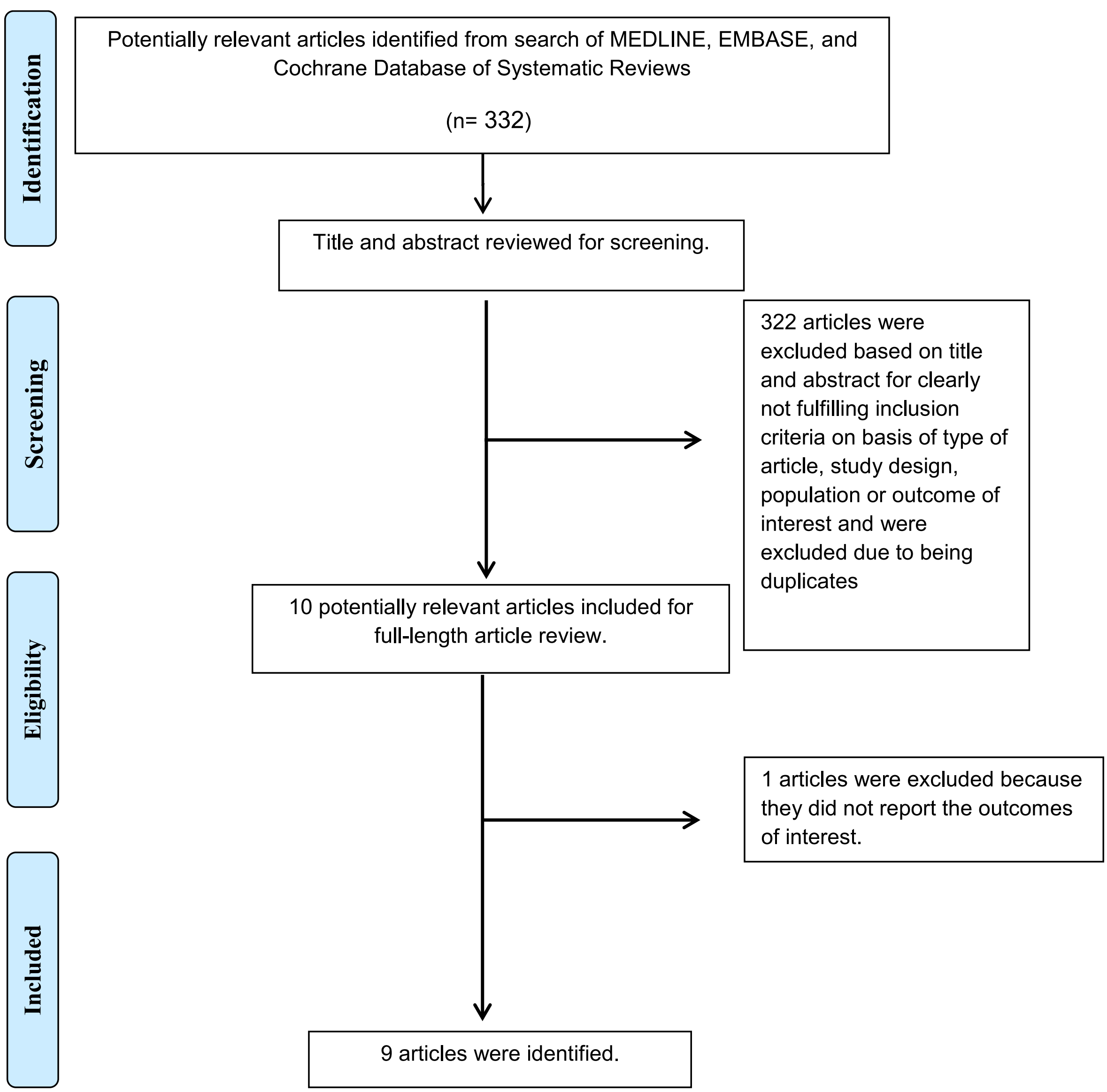

Fig. 1. The literature retrieval, review and selection process.

between-study variance, we used a random-effects model. Cochran's Q test and I^2 statistics were applied to determine the heterogeneity of the analysis. A value of I^2 of 0–25% indicates insignificant heterogeneity, 26–50% low heterogeneity, 51–75% moderate heterogeneity, and 76–100% high heterogeneity [14]. The publication bias was assessed via the Egger test [15]. The sensitivity analysis was done by omitting one study at a time to evaluate the effect of each study.

3. Result

A total of 9 studies [16–24] were included in the analysis after exclusion of duplicate articles, case reports, correspondences, review articles, *in vitro* studies, pediatric patient population, or animal studies. All the included studies were observational.

The total number of participants was 6699. The study consisted of 1414 patients with heart failure who underwent CB AF ablation. The literature retrieval, review, and selection process are illustrated in Fig. 1. The characteristics and quality assessment of the included studies are presented in Table 1.

The sample size of each study ranged from 89 patients to 3655 patients, with no study conducted in the Northern American region. Pulmonary vein isolation was the sole technique performed in all studies. Four out of 9 studies did not compare the success rate of AF ablation between HF and non-HF patients. Eight out of nine studies performed PVI with 2nd generation CB (Arctic Front Advance, Medtronic), and one study performed PVI with 3rd generation CB (Arctic Front Advance Pro, Medtronic).

Five out of 9 studies reported the success rate of the procedure in patients with HFrEF. Three studies reported outcomes in mixed HF (HFrEF, HFpEF and HFmEF). Only one study provided success rate in HFpEF patients and Three studies provided result from mixed heart failure types (HFrEF, HFpEF, and HFmEF).

3.1. Freedom from atrial arrhythmia (AA) in HFrEF

The pooled freedom from AA at 12 months in the study with only HFrEF was 64% (95% CI 56–71%, I^2 58%), with 197 patients from 307 patients remaining in sinus rhythm. Fig. 2 The highest achievable freedom from AA in all studies was 76 %, while the lowest was 43% [16, 18].

3.2. Freedom from atrial arrhythmia (AA) in other heart failure types (HFpEF and HFmEF)

There was only 1 study that reported a success rate of CB AF ablation in HFpEF which reported 41.6% freedom from atrial arrhythmia at 12 months. Five studies compared AA freedom between patients with and without HF, which showed no difference between the two groups (RR 1.34 (95%CI 0.8–2.23, I^2 76%, P 0.19) [17,19,21,23,25] Recurrent AA in the HF group was 149/723 (20.6%) and recurrent AA in no HF was 364/1669 (21.8%), as shown in Fig. 3 The Funnel plots of this outcome were provided in supplementary data 1.

3.3. Complications related to the procedure

The major complication in HFrEF group was 6% (95%CI 4–10%, I^2 0). Fig. 4 Major complication rate from all heart failure types was also 6% (95% CI 4–7%, I^2 17%). Supplementary Data 1 The most common complication was phrenic nerve injury. From 5 studies available for the analysis, we found no significant difference in complication rates between patients with and without HF (RR = 1.38 (95% CI 0.94–2.02, I^2 0%, P 0.07), as shown in Fig. 5. The bronchial injury was found in only a study with a HF patient and three patients without HF [24]. No death related to CB ablation was discovered. The Funnel plots are shown in supplementary data 1.

3.4. Left ventricular ejection fraction (LVEF) and NYHA functional class

Four studies reported pre and post-ablation LVEF in patients with HFrEF [16,19,20,26]. There was a significant improvement of LVEF in these patients with a standard mean difference of 13% (95% CI 8.6–17.5%, I^2 99% $P < 0.001$). Supplementary Data 1 Three out of 4 studies showed improvement in post-ablation LVEF by more than 10% compared to pre-ablation LVEF [19,20,26].

Seven studies out of 9 studies reported pre and post-ablation NYHA functional class. After CB ablation [16,18–21,23,26], NYHA FC was improved significantly with a mean difference of −0.46 (95% CI -0.72, -0.2, I^2 100%, P 0.006) supplementary data 1.

4. Discussion

Our study suggested that CB AF ablation in HFrEF patients was associated with freedom from AA at 12 months 64%. CB ablation is deemed safe in HFrEF patients with major complication rates up to 6%.

From many previous studies, patients with heart failure are more susceptible to developing a recurrence of AF, despite the ablation. One postulated mechanism is an increase in left atrial pressure, which would lead to atrial stretch and further facilitate the initiation of arrhythmia. Other possibilities include dysregulation of the autonomic nervous system, neurohormonal system, and intracellular calcium disruption [27]. Unexpectedly, Freedom from atrial arrhythmia at 12 months in HFrEF with cryoballoon ablation was similar to other CB studies in patients without heart failure [28,29]. The freedom from AA in those studies was approximately 60–70% at 12 months. Our analysis also showed a success rate of CB AF ablation in HFrEF patients with freedom from AA 64% at one year compared to previous studies, in which patients underwent RF ablation the success rate was slightly lower than our analysis (Freedom from AA 40–62% in earlier reports) [30,31]. Better rhythm

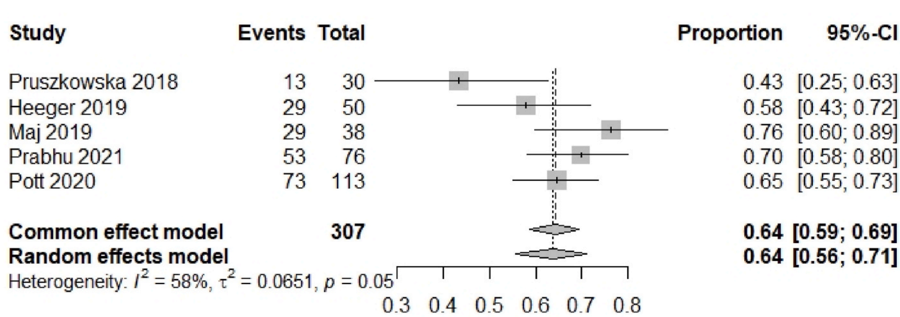

Fig. 2. Pooled freedom from atrial arrhythmia in heart failure reduced ejection fraction (HFrEF) patient. Square data markers represent patient without AA, and horizontal line represent the 95% confidence intervals (CIs) with marker size reflecting the statistical weight of study. A diamond data marker represents overall hazard ratio and 95% confidence interval.

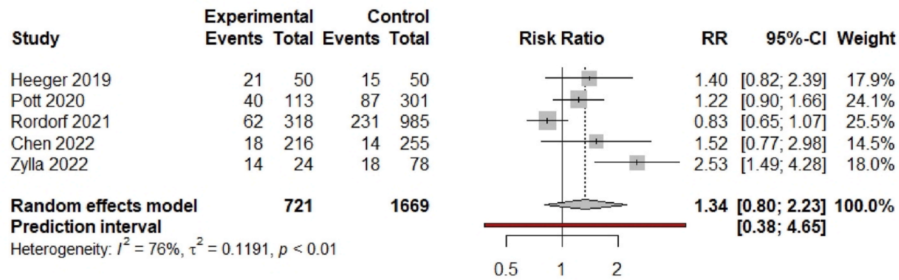

Fig. 3. Freedom from AA between heart failure and no heart failure. Square data markers represent risk ratio (RR), and horizontal line represents the 95% confidence intervals (CIs) with marker size reflecting the statistical weight of study. A diamond data marker represents overall hazard ratio and 95% confidence interval.

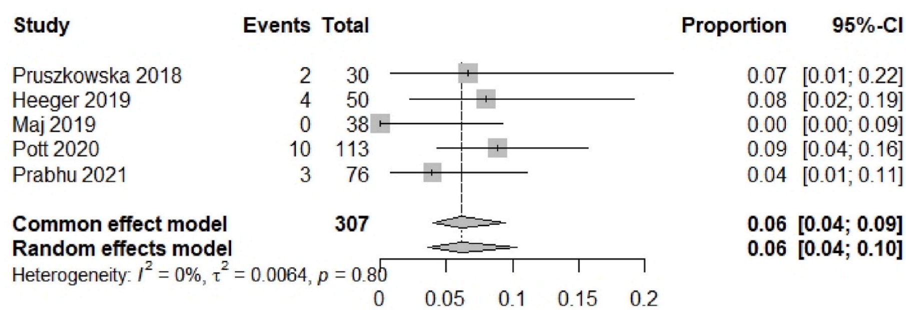

Fig. 4. Pooled major complication rate in HFrEF. Square data markers represent mean complication rate, and horizontal line represents the 95% confidence intervals (CIs) with marker size reflecting the statistical weight of study. A diamond data marker represents overall hazard ratio and 95% confidence interval.

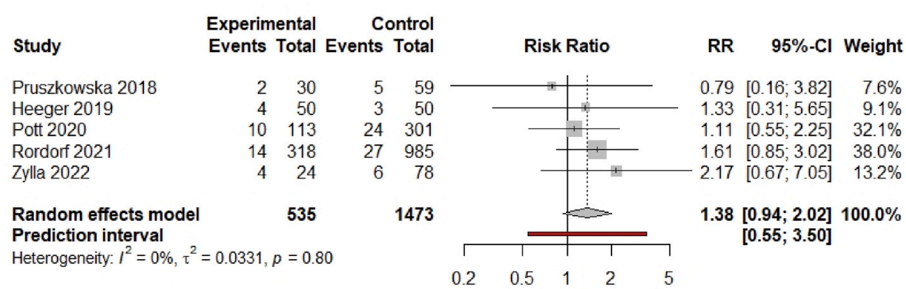

Fig. 5. The complication rate between HF patients and no HF patients. Square data markers represent risk ratio (RR), and horizontal line represents the 95% confidence intervals (CIs) with marker size reflecting the statistical weight of study. A diamond data marker represents overall hazard ratio and 95% confidence interval.

control after ablation may have led to reverse remodeling of the left atrium, thus lowering the AF recurrent rates. This hypothesis has been well supported by our findings, which showed a remarkable improvement in LVEF after the CB ablation. While CB AF ablation is a more recently developed technique than the conventional RF ablation, the success rate with this technique is likely to be better when operators gain more experience [32]. In our opinion, CB should be considered an alternative method to RF ablation in this group of patients.

In previous reports, complications associated with CB AF ablation are similar to RF ablation [33,34]. Atrioesophageal fistula is a deadly complication which may occur in patients who undergo CB ablation, even though at a much lower rate compared to RF ablation [34]. Another potential complication unique to CB AF ablation is a bronchial injury. The long-term consequences of bronchial injury after the procedure remained unknown [35]. The complication rate from our analysis in HFrEF patients was 6% after 12 months follow up with only 1 patient in all studies experiencing bronchial injury and no death related to cryo balloon ablation. Overall complication related to RF ablation was 6% in a worldwide survey from 2005 and decreased to 4.5% from a worldwide survey in 2010 [36,37]. According to the data from RF ablation complication rate tends to be lessening with time with newer technology and more experienced operators.

5. Limitation

There were several limitations in our analysis. The first major limitation is that we did not have enough data to analyze each type of heart failure (HFpEF and HFmEF) separately as each type of heart failure has a different natural course which could lead to inaccuracy of total success rate. We also did not have sufficient data to analyze the success rate according to AF types (paroxysmal, persistent, and longstanding persistent). This also could lead to an inaccurate success rate. The second limitation was the type of study, there were only observational studies included in this analysis. The bias from this type of study was unavoidable. The third limitation of our analysis is the follow up time. The analysis only followed patient for 12 months which is relatively short period. Additionally, the availability of either time or person-years data was limited in the included studies, constraining our ability to provide a more nuanced presentation of follow-up duration. A longer follow-up time is needed to clarify the efficacy of CB AF ablation in heart failure patients. The fourth limitation was the data on antiarrhythmic used post ablation. Most of the studies in our analysis stopped antiarrhythmic drug 3 months after ablation. However, some studies did not stop antiarrhythmic after the procedure and some studies did not mention specifically mention about this protocol. This issue could lead to bias in interpreting the success rate of CB ablation. Finally, this analysis did not include major outcomes such as heart failure hospitalization or mortality due to insufficient data.

6. Conclusion

Cryoballoon AF ablation resulted in good efficacy and safety in patients with HFrEF. However, further study needs to be done to emphasize our findings.

Authors' contributions

All authors had access to the study data, and they played a role in writing the manuscript.

Funding

No funding was received in this study.

Ethical approval

The need for approval from the institutional review board was waived because publicly available cumulative published data were used.

Consent

No inform consent needed due to the type of study.

Clinical trial registry

No clinical trial registry needed due to type of study.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ipej.2024.01.001.

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