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Original Article

Trend of Sex Differences and Predictors of Complications of Cardiac Electronic Device Implantations in the Southeast Anatolian Region of Turkey: An Observational Study

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ABSTRACT

Objective: The comparison of complications after cardiac implantable electronic device procedures has not been studied adequately between both genders. Here, we examined the effect of gender on complications in the Southeast Anatolian Region of Turkey.

Methods: A total of 1640 patients from 3 centers in the Southeast Anatolian Region of Turkey were randomly selected. We compared major adverse cardiac events (clinically significant hematoma, pericardial effusion or tamponade, pneumothorax, and device infection) between genders. Univariate and multivariate analyses were plotted to identify predictors of outcomes between both genders.

Results: The overall rate of major adverse cardiac events was 3.8% (63 of 1640). Major adverse cardiac events occurred in 4.1% (40 of 983) of the men and 3.5% (23 of 657) in the women groups ($P = .557$). The most complications were device-related infection (2.1%) and pneumothorax (1.3%) in both genders. Single- and dual-chamber pacemakers were more implanted in women than in men (11.7% vs. 6.2% and 32.6% vs. 20.1%, respectively, $P < .001$). On the contrary, single- and dual-chamber implantable cardioverter defibrillators were more implanted in men than in women (38.1% vs. 19.6% and 8.5% vs. 4.1%, respectively, $P < .001$). Additionally, warfarin treatment and history of heart failure were found predictors of major adverse cardiac events in multivariable analysis.

Conclusions: This small-scale, real-life patient data revealed no remarkable distinction in terms of complications between both genders. Multinational randomized large-scale cohort trials are required to support our results.

Keywords: Anticoagulants, cardiac devices, cardiac epidemiology, cardiovascular events gender, platelets

INTRODUCTION

In recent years, cardiac implantable electronic device (CIED) procedures with the inclusion of permanent pacemakers (PPM), cardiac resynchronization therapy with pacemaker or defibrillator (CRT-P or CRT-ICD), implantable defibrillator (ICD) have increased exponentially throughout the world.[1] The adverse events due to CIED procedure still remain high despite the improvements in the device or lead technologies and advanced operator experience.[2,3]

Gender differences have been a matter of interest in cardiology lately. In that context, the impact of gender differences was investigated in cardiac procedures such as percutaneous coronary intervention, coronary artery bypass operations, and catheter ablation in atrial fibrillation.[4-6] To date, there are very limited studies that showed the effect of genders on the procedural complications such as rehospitalization, device-related infection, and mortality in CIED implantations.[7-10]

The risk of complications is more likely in women patients because of anatomical barriers such as thinner and smaller vessels, narrower thoracic cavity, and smaller body structure in

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arrhythmia procedures.[11] Also, it has been shown that women have had more complications in ICD procedures.[12]

Here, we present the impact of gender differences on CIED procedures including ICD, PPM implantations, and generator change in the Southeast Anatolian Region of Turkey, and also we explored the incidence of complications of these procedures in a multicenter, small-scale observational study.

METHODS

One thousand six hundred forty patients were randomly selected to reduce selection bias from 3 different hospitals in the Southeast Anatolian Region of Turkey. The study was performed as a retrospective and observational design. De novo implantations of CIED (PPM, CRT-P, CRT-ICD, and ICD) or generator change patients over the age of 18 between January 2010 and 2021 were included. Information about the study was provided both orally and in written form to the patients or their trustees. The study was performed with respect to the Declaration of Helsinki (2013). The study was confirmed by the institution review board (date of approval: March 17, 2022, and number: 74).

Anticoagulation Management

Warfarin therapy was interrupted in all patients until the INR level fell ≤1.7. Surgical procedures were planned if INR fell ≤1.7 in all the centers. Bridging treatment was performed with low molecular weight heparin (LMWH) or unfractional heparin (UFH) if the INR level fell ≤2. Unfractional heparin treatment was interrupted before 4 hours in all procedures and reinitiated 12 hours after implantation. The last dosing of LMWH was performed 12 hours before implantation and reinitiated 12 hours after the implantation. Unfractional heparin or LMWH was given with warfarin until INR ≥2. Additionally, warfarin treatment was continued in patients with previous prosthetic valve thrombosis and a history of ischemic events. In this population, target INR level was maintained between 2 and 3.5.

Non-vitamin K-dependent oral anticoagulants (NOACs) were routinely discontinued 24 hours before the procedure to prevent bleeding. Dabigatran treatment was adjusted according to the patients estimated glomerular filtration rate (eGFR). Non-vitamin K-dependent oral anticoagulant treatment was restarted in the evening of the day of the procedure. Any prior antiplatelet treatment was routinely continued during the perioperative period.

Main Points

- Little is known about the impact of gender on clinical outcomes throughout the pacemaker's surgery.
- The effect of gender difference on clinical outcomes has been a matter of interest in cardiology lately.
- The risk of complications is more likely in women patients because of the anatomical barriers.
- We present the impact of gender differences on cardiac implantable electronic device (CIED) procedures in the Southeast Anatolian Region of Turkey.
- This small-scale, real-life patient cohort of CIED implantation revealed no significant differences in terms of complications between both genders.

Definitions

Clinically significant hematoma (CSH) was defined as hematomas that cause significant swelling and pain at the generator site, cause discontinuation of oral anticoagulant therapy, require the evacuation of the hematoma due to severe pressure, or require a blood transfusion. Pneumothorax, pericardial effusion, and cardiac tamponade were documented by chest x-ray film, computed tomography, or echocardiography as indicated. Pocket infections, lead-endocarditis, and positive blood cultures in 1 or more cultures were considered device-related infections. Infections were described in accordance with previously published guidelines.[13] Cardiovascular disease diagnoses are coded accordingly to the 10th Revision Codes of the International Classification of Diseases (Supplementary Table S1).

Implantation Technique

The punctures were routinely performed with an axillary approach, and the device generator was implanted in the subpectoral fascia. The puncture was planned with subclavian venography under fluoroscopy if the punctures were unsuccessful 3 times. Sandbags were applied to all cases for an hour. A pressure bandage was applied to the patients with signs of swelling and hematoma in the pocket area, and they were kept for at least 1 night. A prohemostatic agent was not applied in any case. Antibiotics were administered to all patients before the procedure to prevent surgical site infections.

Follow-up and Study Outcomes

Demographic data, clinical history, medications, device implantations, complications, and laboratory data were obtained from electronic hospital records or social security institution registry system. Primary endpoint was accepted as major adverse cardiac events (MACE) with the inclusion of composite of CSH, pericardial effusion or tamponade, pneumothorax and infection related to the device system. Secondary outcomes included each component of MACE. Details of study enrollment (follow-up, outcomes) and study flow chart are shown in Figure 1.

Statistics

The Statistical Package for the Social Sciences for Windows version 25.0 (IBM Corp., Armonk, NY, USA) was used to perform statistical analysis. The distribution of continuous variables was assessed by Kolmogorov–Smirnov test. Continuous variables were indicated as mean ± standard deviation or median (interquartile range). Categorical variables were indicated as percentages and were compared using chi-square test or Fisher's exact test as appropriate. Continuous variables between 2 independent groups were analyzed by Student's *t*-test or Mann–Whitney *U* test as appropriate. Univariable and multivariable analyses for predictors of MACE were applied and also were plotted in a graph. Variables with a $P < .05$ were assumed significant.

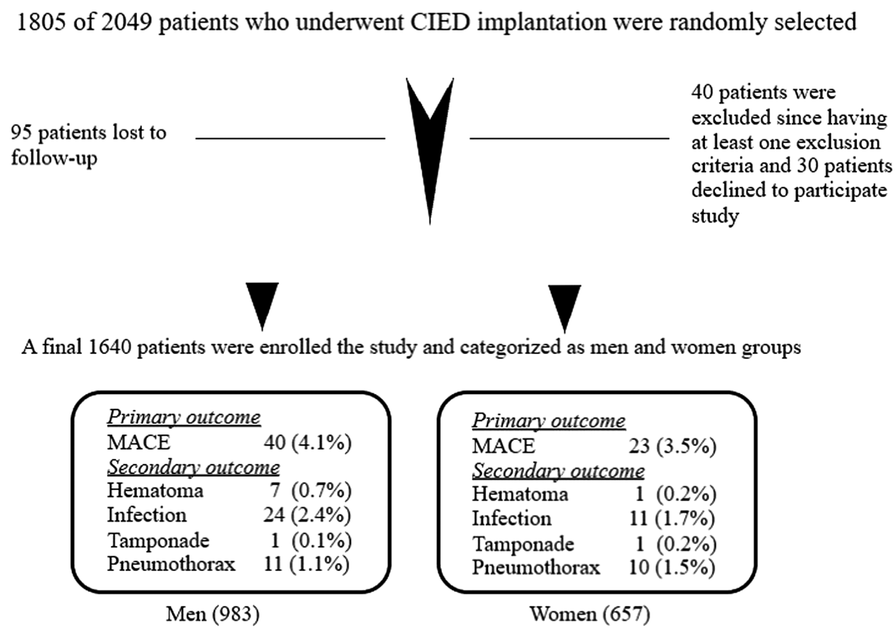


Figure 1. Study flow chart.

RESULTS

The study enrolled 1640 patients who underwent CIED procedures from 3 different hospitals in the Southeast Anatolian Region of Turkey. The ratio of women in the total population was 40% (657 of 1640).

We noticed substantial differences in patient baseline clinical characteristics and medications among genders in the whole population (Table 1). Mainly, women were older and had a significantly higher prevalence of Hypertension (HT) and Diabetes mellitus (DM). On the contrary, women had a lower previous history of Coronary artery disease (CAD) and Heart failure (HF). Additionally, antiplatelet drug treatment was more likely higher in men than in women. In contrast to this, edoxaban and dabigatran treatment was more likely higher in women than in men as shown Table 1.

The operation details and procedural complications between genders are shown in Table 2. While single-lead pacemaker, dual-lead pacemaker, and CRT-ICD were more implanted in women, on the contrary, single-lead ICD and dual-lead ICD were less implanted in women. Overall, the MACE occurred in 63 of 1640 patients (3.8%). This was mostly driven by device-related infection (1.3%) and pneumothorax (2.1%). The MACE occurred in 40/983 (4.1%) patients in men as compared to 23/657 (3.5%) women ($P = .557$, Table 2). There were no differences among genders with regard to CSH, pericardial effusion or tamponade, pneumothorax, and device-related infection.

The periprocedural laboratory parameters of patients are represented in Table 3. The men group was positively associated with higher periprocedural white blood cell count, hematocrit, hemoglobin, platelet, urea, creatinine, eGFR, and INR levels and were negatively associated with lower serum albumin, total cholesterol, and triglyceride levels (Table 3).

In the univariable logistic regression analysis, hemoglobin level, receiving warfarin therapy and HF, was found to be predictors of MACE (Table 4). However, gender difference was not a predictor of MACE. In multivariate analysis, HF and warfarin therapy were found to be the predictors of MACE. Moreover, being on warfarin treatment increased approximately 3-fold the risk of MACE (Figure 2).

DISCUSSION

In this multicenter, observational study, we investigated the effect of gender on complications in CIED procedures over an 11-year horizon. According to the results of the study, PPMs are more commonly implanted in women, while ICDs are more commonly implanted in men. The most complications were device-related infection (2.1%) and pneumothorax (1.3%) in both genders, respectively. However, our data demonstrated no remarkable difference in point of procedural complications between the genders.

The management of CIED implantation in women is different from that in men, as women are less likely to undergo a dual-chamber pacemaker and have ICD implantation, even when clinically appropriate. This can be explained by the smaller body structure of the women, co-morbidities, patient preference, and more avoidance of aggressive treatment by female patients.[11]

The number of studies is limited in the literature that indicates the efficacy of gender differences in CIED procedures in a heterogeneous patient cohort with both ICD and PPMs implants. In addition, data relating to gender effects onto pacemaker

Table 1. Clinical Characteristics and Medications of the Patients at Baseline

	Total (n=1640)	Men (n=983)	Women (n=657)	*P*
Age (IQR)	66 (56-73)	65 (55-73)	66 (58-73.5)	***.004***
Body mass index kg/m^2, IQR	24 (22-25)	24 (22-25)	24 (21-26)	.482
Hypertension, n (%)	719 (43.8)	386 (39.3)	333 (50.7)	***<.001***
Diabetes mellitus n (%)	389 (23.7)	202 (20.5)	187 (28.5)	***<.001***
Atrial fibrillation or flutter, n (%)	148 (9)	84 (8.5)	64 (9.7)	.407
Coronary artery disease, n (%)	1126 (68.7)	748 (76.1)	378 (57.5)	***<.001***
Heart failure, n (%)	1008 (61.5)	677 (68.9)	331 (50.4)	***<.001***
Mechanical prosthesis valve, n (%)	39 (2.4)	25 (2.5)	14 (2.1)	.591
Ejection fraction %, IQR	35 (25-60)	30 (25-60)	50 (30-60)	***<.001***
Time to discharge (days), IQR	4 (3-5)	4 (3-5)	4 (3-5)	.874
HAS-BLED score[a], IQR	2 (1-2)	2 (1-2)	2 (1-3)	.674
Medications, n (%)				
Antiplatelet	997 (60.8)	673 (68.5)	324 (49.4)	***<.001***
ASA	956 (58.3)	637 (64.8)	319 (48.6)	***<.001***
Clopidogrel	183 (11.2)	149 (15.2)	34 (5.2)	***<.001***
Prasugrel	2 (0.1)	2 (0.2)	0	.519
Ticagrelor	12 (0.7)	10 (1)	2 (0.3)	.139
Warfarin	84 (5.1)	52 (5.3)	32 (4.9)	.706
NOAC	119 (7.3)	62 (6.3)	57 (8.7)	.070
Rivaroxaban	81 (4.9)	49 (5)	32 (4.9)	.917
Edoxaban	4 (0.2)	0	4 (0.6)	***.026***
Apixaban	7 (0.4)	5 (0.5)	2 (0.3)	.709
Dabigatran	27 (1.6)	8 (0.8)	19 (2.9)	***.001***
Unfractioned heparin	4 (0.2)	1 (0.1)	3 (0.5)	.308
LMWH	65 (4)	40 (4.1)	25 (3.8)	.788
Bridge therapy	68 (4.1)	41 (4.2)	27 (4.1)	.951

Data are n (%), median (IQR).
[a]HAS-BLED score is an index of the risk of bleeding in patients with atrial fibrillation. HAS-BLED score ≥3 indicating a great risk of bleeding.
ASA, acetylsalicylic acid; LMWH, low molecular weight heparin; NOAC, non-vitamin K oral anticoagulants; IQR, interquartile range.

Table 2. Operative Details and Procedural Complications

	Total (n=1640)	Men (n=983)	Women (n=657)	*P*
Pacemaker, n (%)				
Single-chamber	138 (8.4)	61 (6.2)	77 (11.7)	***<.001***
Dual-chamber	412 (25.1)	198 (20.1)	214 (32.6)	***<.001***
ICD, n (%)				
Single-chamber	504 (30.7)	375 (38.1)	129 (19.6)	***<.001***
Dual-chamber	111 (6.8)	84 (8.5)	27 (4.1)	***<.001***
CRT	454 (27.7)	250 (25.4)	204 (31.1)	***.013***
Generator change	37 (2.3)	27 (2.7)	10 (1.5)	.102
MACE[a], n (%)	63 (3.8)	40 (4.1)	23 (3.5)	.557
CSH, n (%)	8 (0.5)	7 (0.7)	1 (0.2)	.155
Pericardial effusion or tamponade, n (%)	2 (0.1)	1 (0.1)	1(0.2)	1
Pneumothorax, n (%)	21 (1.3)	11 (1.1)	10 (1.5)	.507
Device-related infection, n (%)	35 (2.1)	24 (2.4)	11 (1.7)	.292

[a]MACE included the composite of all clinically significant hematoma (CSH), pericardial effusion or tamponade, pneumothorax, and infection related to the device system.

implantation are hesitant. In the study by Nowak et al.[10] procedural complications were compared in patients who had PPMs implanted. According to the results of this trial, single lead pacemakers were more implanted in women than in men; however, dual lead pacemakers were more implanted in men. In addition, women were more complicated by adverse events such as pneumothorax and pocket hematoma. In our study, sex differences were compared in a more heterogeneous patient population with both ICD and PPMs implants. No significant difference was found regarding the pneumothorax and CSH between both genders, which was quite different from the trial by Nowak et al. Mohammad et al[8] compared the 30-day rehospitalization for cardiac and non-cardiac causes and complications in CIED procedures between both genders. There was no difference between the sexes in terms of all-cause rehospitalization, but cardiac rehospitalization and device-related complications were more common in women. Similar to our study, infections were not significantly different between genders over a 6-year period. In another study, Mohammed et al[7] investigated the difference in complications between genders with all types of CIED procedures. They indicated that women were at an overall higher risk of complications compared with men; however, mortality rates were not found meaningful among genders in a national cohort. In our study, although women are at a higher odds of pneumothorax than men, it was not significant between genders [odds ratio: 1.36 (0.57-3.23), $P=.479$].

Unlike the prior studies, our data certainly indicate that gender is not related to an increased risk of MACE. These differences

Table 3. Perioperative Laboratory Parameters of the Patients

	Total (n=1640)	Men (n=983)	Women (n=657)	*P*
White blood cell count (×10³ µL)	8.8 ± 2.9	9 ± 3	8.7 ± 2.8	***.034***
Hematocrit (%)	41.2 ± 10.5	42.4 ± 12.3	39.3 ± 5	***<.001***
Hemoglobin (g/dL)	13.5 ± 3.8	13.8 ± 1.8	12.9 ± 5.3	***<.001***
Platelets (×10³ µL)	237 ± 76	229.7 ± 76.7	249.5 ± 72.6	***<.001***
Serum albumin, g/dL, IQR	3.7 (3.4–4)	3.7 (3.4–3.9)	3.7 (3.5–4)	***.011***
Urea, mg/dL, IQR	44 (33–57)	45 (35–59)	42 (32–56)	***.001***
Creatinine, mg/dL, IQR	0.92 (0.77–1.15)	0.99 (0.83–1.23)	0.81 (0.7–1)	***<.001***
eGFR (mL/min/L,73m²), IQR	85 (65–101)	88 (67–105)	82 (63–96)	***<.001***
Glucose, mg/dL	137 ± 66	135.7 ± 66.7	140.2 ± 74.3	.198
Preoperative INR, IQR	1.05 (0.99–1.17)	1.07 (1–1.19)	1.03 (0.98–1.12)	***<.001***
Total cholesterol, mg/dL	175 ± 42	167.8 ± 40.8	185.3 ± 43.1	***<.001***
Triglyceride, mg/dL	151 ± 95	147.7 ± 97.4	159.3 ± 101	***.023***
HDL, mg/dL	41.6 ± 11.7	39.7 ± 10.8	44 ± 12.4	***<.001***
LDL, mg/dL	104.5 ± 40.5	100.6 ± 43.6	110.4 ± 33.7	***<.001***

Data are expressed as mean ± standard deviation, or as median (interquartile range) as appropriate. eGFR, estimated glomerular filtration rate; HDL, high-density lipoprotein; LDL, low-density lipoprotein; INR, international normalized ratio; IQR, interquartile range.

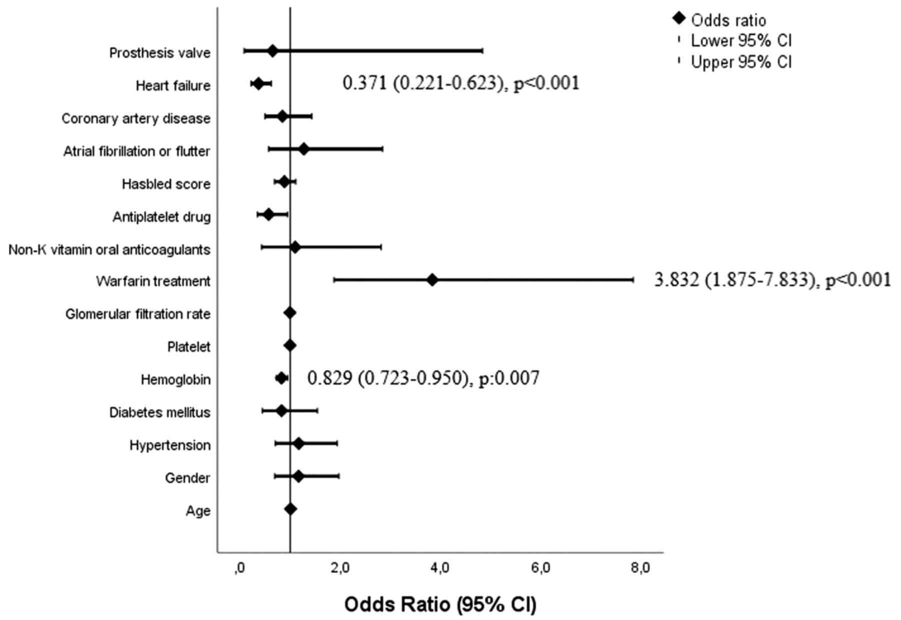
can basically be explained with the ethnicity as with other variables such as body mass index (BMI), anatomical variations, and operator experience. Most of the previous studies have been conducted on the American, European, and Australian populations.[7-10] As far as we know, the present study is one of the original studies to investigate the trends of sex differences and predictors of complications following CIED surgery in the Asian population. Lee et al[14] investigated the temporal trends of CIED procedures in the Asian population. Also, Aktoz et al[15] investigated the effect of gender-specific differences and patient demographics on a cardiac device and pacing mode selection. However, neither of these studies compared the procedural complications between genders. In that context, our study was unique in the Asian population. Another important factor that

Table 4. Predictors of MACE[a] in Univariate and Multivariate Logistic Regression Analysis Model

	Univariate Model		Multivariate Model	
	OR (95% CI)	*P*	OR (95% CI)	*P*
Age	1.019 (0.999–1.040)	.065	1.012 (0.993–1.031)	.214
Gender	1.169 (0.693–1.972)	.558		
Hypertension	1.172 (0.708–1.940)	.538		
Diabetes mellitus	0.830 (0.446–1.545)	.558		
Hemoglobin	0.829 (0.723–0.950)	***.007***	0.870 (0.756–1.001)	.051
Platelet	1.001 (0.998–1.004)	.483		
eGFR	0.998 (0.989–1.007)	.628		
Warfarin	3.832 (1.875–7.833)	***<.001***	3.069 (1.436–6.560)	***.004***
NOAC	1.106 (0.435–2.813)	.832		
Antiplatelet drug	0.573 (0.346–0.948)	.030		
HAS-BLED score	0.887 (0.689–1.141)	.349		
Atrial fibrillation or flutter	1.273 (0.569–2.846)	.556		
Coronary artery disease	0.845 (0.498–1.434)	.533		
Heart failure	0.371 (0.221–0.623)	***<.001***	0.420 (0.248–0.713)	***.001***
Mechanical prosthesis valve	0.653 (0.088–4.835)	.677		

[a]MACE included the composite of all clinically significant hematoma, free wall rupture, pneumothorax, and infection related to the device system.
eGFR, estimated glomerular filtration rate; OR, odds ratio; NOAC, non-vitamin K oral anticoagulants.

Figure 2. Forest plot graph of predictors of complications.



contributes to CIED complications is BMI. Previous studies have indicated that a lower BMI was related to a higher risk of complications.[16] In the present study, BMI was not significantly different between both genders. Furthermore, Eberhardt et al[17] demonstrated that operation time and complication rate increased with operator experience. Although the experience of one-on-one operators was not evaluated in our study, implantation procedures are mostly performed by experienced electrophysiologists in the existing centers.

As in any study, specific design limitations are also available in the present study. First, our study data does not include details on the indication for CIED procedure and operator experience, and for this reason, we were unable to regulate the differences in these covariates among both genders. Second, we have only focused on major complications and not on all subtypes of complications such as minor bleedings, pericardial effusion without hemodynamic collapse, mild pleural effusion, modest superficial wound infection, and uncomplicated arrhythmias. In summary, minor complications that did not require intervention were excluded. Finally, the study was observational and there is a possibility of unmeasured confounding, and indeed baseline demographic characteristics, medications that are not homogeneous between both genders.

CONCLUSION

This small-scale, real-life patient data revealed no remarkable distinction in terms of complications between both genders. Multinational, randomized, large-scale cohort trials are required to support our results.

Data Availability Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of Dicle University School of Medicine (Date: March 17, 2022, Decision No: 74).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

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Declaration of Interests: The authors declare that they have no competing interest.

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