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Impact of COVID-19 infection among patients hospitalized for conventional pacemaker implantation: Analysis of the Nationwide Inpatient Sample (NIS) 2020

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Abstract

Introduction: The cardiac pacemaker is indicated for treating various types of bradyarrhythmia, providing lifelong cardiovascular benefits. Recent data showed that COVID-19 has impacted procedure numbers and led to adverse long-term outcomes in patients with cardiac pacemakers. However, the impact of COVID-19 infection on the in-hospital outcome of patients undergoing conventional pacemaker implantation remains unclear.

Method: Patients aged above 18 years who were hospitalized for conventional pacemaker implantation in the Nationwide In-patient Sample (NIS) 2020 were identified using relevant ICD-10 CM and PCS codes. Multivariable logistic and linear regression models were used to analyze pre-specified outcomes, with the primary outcome being in-patient mortality and secondary outcomes including system-based and procedure-related complications.

Results: Of 108 020 patients hospitalized for conventional pacemaker implantation, 0.71% (765 out of 108 020) had a concurrent diagnosis of COVID-19 infection. Individuals with COVID-19 infection exhibited a lower mean age (73.7 years vs. 75.9 years, $p = .027$) and a lower female proportion (39.87% vs. 47.60%, $p = .062$) than those without COVID-19. In the multivariable logistic and linear regression models, adjusted for patient and hospital factors, COVID-19 infection was associated with higher in-hospital mortality (aOR 4.67; 95% CI 2.02 to 10.27, $p < .001$), extended length of stay (5.23 days vs. 1.04 days, $p < .001$), and linked with various in-hospital complications, including sepsis, acute respiratory failure, post-procedural pneumothorax, and venous thromboembolism.

Conclusion: Our study suggests that COVID-19 infection is attributed to higher in-hospital mortality, extended hospital stays, and increased adverse in-hospital outcomes in patients undergoing conventional pacemaker implantation.

KEYWORDS
conventional pacemaker, COVID-19 infection, epidemiology, National In-patient Sample

1 | INTRODUCTION

Cardiac pacemakers are the treatment of choice for various types of bradyarrhythmia, such as symptomatic sinus node dysfunction and high-grade atrioventricular block.[1] Despite the advanced innovative development of pacemakers, a conventional pacemaker has noticeably been carried a low risk of notable complications, affecting approximately one sixth of patients.[2] Most complications are related to the ventricular pacing lead and device pocket, including lead-associated thrombosis, device-related infections, pneumothorax, hematoma, and cardiac perforation.[2,3] As it significantly contributes to a patient's quality of life, preventing these complications necessitates close and vigilant monitoring.

Since COVID-19 emerged, these concerns have accelerated. Recent data indicates a significant decrease in elective and urgent pacemaker implantations during pandemic.[4] Furthermore, numerous studies highlight the negative impact of COVID-19 on patients with pre-existing cardiac conditions,[5] These encompass, but are not limited to, an increased risk of new-onset arrhythmia and deterioration of conduction disease, subsequently increasing the risk of mortality.[6] Interestingly, prior studies have gradually addressed the adverse effects of COVID-19 on individuals hospitalized for cardiac implantable electronic device (CIED) implantation.[7] The COVID-19 infection imposed a higher rate of other infections, significant pocket hematoma, pneumothorax, vascular bleeding with hemorrhagic shock, and a higher mortality rate on these vulnerable patients after the CIED procedure.[7] However, there is a paucity of data on the impact of active COVID-19 infection on in-hospital outcomes of patients undergoing conventional pacemaker implantation.

Therefore, our study aims to explore the association between COVID-19 infection and in-hospital outcomes of conventional pacemaker implantation, including mortality, system-related complications, and procedure-related complications.

2 | METHOD

2.1 | Data source

We utilized the Health Care Utilization Project National Inpatient Sample (HCUP-NIS) database in 2020. In brief, the NIS is funded by the Agency for Healthcare Research and Quality (AHRQ) and is the largest publicly accessible all-payer inpatient database in the United States. It employs a survey design database comprising discharge data from inpatient hospital care in non-federal, non-rehabilitation, acute care, and short-term hospitals. Moreover, it represents approximately 20% of hospital admissions and discharges, offering national estimates regarding the characteristics of patients, diagnoses, and hospital-based procedures conducted in US acute-care hospitals. In addition, all hospital discharges from the sample are recorded and weighted to ensure national representativeness.

2.2 | Study population

Patients aged 18 and older who were hospitalized for the conventional pacemaker implantation, both single-chamber and dual-chamber pacemakers, from January to December in 2020 were identified on the database. Patients who are age <18 or have a history of prior CIED implantation were excluded from the study. We utilized the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Procedure Coding System (ICD-10 PCS) to identify eligible discharge records and stratify patients into those with and without COVID-19 infection (see Table S1 for ICD-10-CM and PCS codes used in this study and Figure S1 for a study flow diagram illustrating the inclusion and exclusion criteria, along with the final number of records included in the analysis).

2.3 | Outcome measurements

Our primary outcome was aimed at exploring inpatient mortality among patients hospitalized for conventional pacemaker implantation, considering the presence or absence of COVID-19 infection. For secondary outcomes, in-hospital-related parameters and complications were evaluated, focusing on the following: length of hospital stay (LOS), total hospital charges (THC), acute myocarditis, sepsis, acute kidney injury (AKI), acute respiratory failure (ARF), acute pulmonary embolism (PE), deep venous thrombosis (DVT), renal replacement therapy (RRT), utilization of mechanical ventilation, pericardial complication, device-related complication, post-procedural bleeding and anemia, post-procedural pneumothorax, and in-hospital pericardiocentesis.

2.4 | Statistical analysis

The data were analyzed using Stata BE 18.0 (StataCorp, College Station, Texas). The NIS database employs a complex sampling design with stratification, clustering, and weighing for nationally representative results, variance estimates, and *p*-values. Continuous variables were presented as mean and standard deviation while categorical variables were presented as number and/or percentages. Proportions were compared using the chi-square test, and continuous variables were compared using the student *t*-test. Multivariable survey logistic and linear regression analyses were employed to calculate adjusted odds ratios (aORs) for primary and secondary outcomes. Outcomes were adjusted for patients and hospital-related confounders, including age, gender, race, Charlson comorbidity index, median income, hospital bed size, hospital location, teaching status, insurance type, and comorbidities. A *p*-value of <.05 was considered statistically significant.

2.5 | Ethical considerations

The NIS database lacks specific identifiers for patients and their corresponding hospitals, making this study exempt from Institutional Review Board (IRB) approval. Still, the study adhered to ethical standards for human subjects as outlined by the responsible institution and the Helsinki Declaration.

2.6 | Data availability statement

NIS is a publicly available, large, all-payer inpatient database, containing hospitalization data for more than 7 million hospital stays. Therefore, this database offers advantages in terms of a large sample size, ideal for assessing national and regional estimates, while also enabling analysis of rare conditions, uncommon treatments, and special populations. The NIS database is available at: https://www.hcup-us.ahrq.gov.

3 | RESULTS

3.1 | Baseline patient characteristics

A total of 108020 patients hospitalized for conventional pacemakers who met our inclusion criteria were identified. Of these, 0.71% (765 out of 108020) had concurrent COVID-19 infection. Notably, those with COVID-19 infection had a younger mean age (73.7 vs. 75.9, $p=.027$). The proportion of females was comparable between both groups (39.87 vs. 47.60, $p=.062$). The majority of both groups were Caucasian, comprising 57.93% in the COVID-19 cohort and 79.39% in the non-COVID-19 counterpart. Interestingly, in the COVID-19 group, the subsequent ethnic breakdown was Hispanic at 18.62%, African American at 11.03%, and others at 12.42%. In contrast, among those without COVID-19, African Americans accounted for 8.07%, followed by Hispanic at 7.03%, and others at 5.51%. Furthermore, the hospitalized patients with COVID-19 had a significantly lower proportion of elective hospitalization than those without COVID-19 (3.92% vs. 14.30%, $p<.001$). Table 1 displays the baseline characteristics of both cohorts.

Regarding patients' comorbidities, the COVID-19 cohort had a notably lower percentage of individuals with a smoking history compared to those without (25.49% vs. 35.98%, $p<.001$). However, for other comorbidities, there were not significant differences in proportions of Charlson comorbidity index, percentage of patients that received transvenous temporary cardiac pacing therapy (TV-TP), and the majority of chronic conditions, including hypertension, hyperlipidemia, diabetes mellitus, obesity (BMI ≥30), chronic obstructive pulmonary disease (COPD), chronic kidney disease (CKD) stage 1–4, end-stage renal disease (ESRD), coronary artery disease (CAD), history of percutaneous intervention (PCI) and history of coronary bypass graft (CABG). In addition, both groups had comparable proportions of patients admitted based on location, primarily in the southern region, followed by the midwest, west, and northeast. Moreover, 76%–77% of patients from both cohorts were admitted to teaching hospitals (Table 1).

3.2 | Primary outcome

The inpatient crude mortality rate was significantly higher in the COVID-19 cohort than those without COVID-19 (5.23% vs. 1.04%, $p<.001$). After adjusted for confounders, the inpatient mortality aOR was 4.67 (95% CI: 2.02 to 10.72, $p<.001$). Table 2 displays in-hospital outcomes for patients hospitalized for conventional pacemakers with and without COVID-19.

3.3 | Secondary outcomes

3.3.1 | Resource utilization

Resource utilization was assessed from LOS and utilization of procedures, such as mechanical ventilation, RRT, and pericardiocentesis. Subsequently, patients admitted for conventional pacemakers with COVID-19 had a significantly longer mean LOS than those without COVID-19 (12.4 days vs. 5.5 days, $p<.001$). After adjusted for confounders, COVID-19 patients spent 6.65 more days in hospitals than their counterparts (β_{LOS} 6.65, 95% CI: 4.45 to 8.85, $p<.001$). An increased use of mechanical ventilation was noted in those with COVID-19 (11.1% vs. 3.82%) with an aOR of 2.56 (95% CI: 1.50 to 4.39, $p=.001$). In addition, the use of RRT and pericardiocentesis in the index admission was, although not statistically significant, more frequent in the COVID-19 cohort (Table 2).

3.3.2 | Total hospitalization charges

Total hospitalization charges reflects the total amount of financial resources billed to payers. Patients with COVID-19 had higher mean THC compared to those without COVID-19 ($215811 vs $135103,

TABLE 1 Baseline characteristics of patients hospitalized for conventional pacemaker implantation with and without COVID-19.

Patient characteristics	With COVID-19 infection (%)	Without COVID-19 infection (%)	*p*-value
Number of patients	765 (0.71)	107 255 (99.29)	
Age at index admission (years)	73.7	75.9	**.027**
Women (%)	39.87	47.60	.062
Racial distribution			
Caucasian	57.93	79.39	**<.001**
African American	11.03	8.07	
Hispanic	18.62	7.03	
Others	12.42	5.51	
Charlson comorbidity index score			
0	16.99	18.66	.762
1	22.88	21.07	
2	15.69	18.26	
3	44.44	42.01	
Insurance type			
Medicaid	79.33	81.71	.087
Medicare	7.33	3.61	
Private	13.33	13.57	
Uninsured	0	1.11	
Elective Hospitalization	3.92	14.30	**<.001**
Median annual income in patient's zip code (USD)			
1–43 999	28.95	25.70	.182
44 000–55 999	30.92	27.18	
56 000–73 999	24.34	24.37	
≥74 000	15.79	22.75	
Hospital characteristics			
Hospital region			
Northeast	15.69	19.18	.170
Midwest	18.30	22.36	
South	47.71	38.82	
West	18.30	19.64	
Hospital bed size			
Small	17.65	16.89	.825
Medium	26.80	29.09	
Large	55.56	54.02	
Location and teaching status of the hospital			
Rural	5.88	5.51	.930
Urban non-teaching	17.65	17.40	
Urban teaching	76.47	77.09	
Comorbidities			
Hypertension	83.01	82.78	1.000
Hyperlipidemia	58.17	62.93	.240
Diabetes Mellitus	41.18	36.84	.275
Obesity	18.95	19.62	.919
Smoking history	25.49	35.98	**.007**
COPD	22.22	22.05	.922
CKD, stage 1–4	22.88	27.68	.204
ESRD	4.58	2.88	.217
CAD	44.44	39.66	.246
Hx of PCI	1.96	1.81	.758
Hx of CABG	3.27	1.93	.226
Hx of TV-TP during index hospitalization	11.11	11.78	.900
Device Type			
Dual-chamber PM	94.12	91.30	.250
Single-chamber PM	5.88	8.78	

Abbreviations: CABG, coronary artery bypass graft; CAD, coronary artery disease; CKD, chronic kidney disease; COPD, chronic pulmonary obstructive disease; COVID-19, coronavirus disease 2019; ESRD, end stage renal disease; Hx, history; PCI, percutaneous coronary intervention; PM, pacemaker; TV-TP, transvenous temporary cardiac pacing therapy.

Bold values indicate *p*-value < .05.

$p<.001$). Then, when compared to patients without COVID-19, those with COVID-19 displayed an additional mean THC of $66 762, after adjusted for confounders (β_{THC} $66 762, 95% CI: $22 053 to $111 473, $p=.003$; Table 2).

3.3.3 | In-hospital complications

Among individuals with COVID-19, there were significantly increased odds of in-hospital complications in comparison with their counterparts: acute myocarditis (aOR 11.24, 95% CI 3.02 to 41.84, $p<.001$), sepsis (aOR 4.04, 95% CI 1.76 to 9.25, $p=.001$), acute respiratory failure (aOR 2.56, 95% CI 1.63 to 4.02, $p<.001$), pulmonary embolism (aOR 5.87, 95% CI 2.06 to 16.70, $p=.001$), deep vein thrombosis (aOR 4.60, 95% CI 1.71 to 12.40, $p=.003$), and post-procedural pneumothorax (aOR 3.02, 95% CI 1.39 to 6.58, $p=.005$). Although not statistically significant, elevated odds of acute kidney injury, post-procedural bleeding and anemia, device-related complications, and pericardial complications were observed (Table 2). We performed a subgroup analysis to assess the risk of bacterial infection according to the severity of COVID-19 among patients who underwent conventional pacemaker implantation. Severe infection was characterized by COVID-19 with acute respiratory failure features. Our results indicated a progressive increase in the risk of bacterial infection among patients who underwent pacemaker implantation: 9.68% in severe COVID-19 cases, 3.85% in non-severe COVID-19 cases, and 0.89% in non-COVID-19 cases ($p<.001$).

TABLE 2 Displays in-hospital outcomes for patients hospitalized for conventional pacemaker implantation with and without COVID-19.

Outcome	With COVID-19 infection (%)	Without COVID-19 infection (%)	aOR (95% CI)	*p*-value
Number of patients (n)	765 (0.71)	107 255 (99.29)	–	–
Inpatient mortality	5.23	1.04	4.67 (2.02, 10.72)	**<.001**
Mean length of stay (days)	12.4	5.5	6.65 (4.45, 8.85)[a]	**<.001**
Mean total hospital charge (USD)	215 811	135 103	66 762 (22 053, 111 473)[a]	**.003**
Acute myocarditis	1.96	0.10	11.24 (3.02, 41.84)	**<.001**
Sepsis	5.23	0.87	4.04 (1.76, 9.25)	**.001**
Acute kidney injury	32.68	25.71	1.46 (0.95, 2.23)	.083
Acute respiratory failure	20.26	8.23	2.56 (1.63, 4.02)	**<.001**
Venous Thromboembolism				
Acute pulmonary embolism	2.61	0.47	5.87 (2.06, 16.70)	**.001**
Deep venous thrombosis	2.61	0.49	4.60 (1.71, 12.40)	**.003**
Procedural-related complication				
Post-procedural bleeding and anemia	11.76	6.58	1.52 (0.86, 2.66)	.146
Post-procedural pneumothorax	4.58	1.80	3.02 (1.39, 6.58)	**.005**
Device-related complications[b]	3.92	2.14	1.53 (0.61, 3.84)	.367
Pericardial complications[c]	1.31	2.00	0.62 (0.15, 2.62)	.507
Pericardiocentesis Performed	0.65	0.43	1.93 (0.26, 14.19)	.518
RRT	4.58	2.59	1.44 (0.54, 3.86)	.464
Mechanical ventilation	11.11	3.82	2.56 (1.50, 4.39)	**.001**
Pneumonia requiring mechanical ventilation	1.31	0.57	1.79 (0.40, 8.03)	.446

Abbreviations: aOR, adjusted odds ratio; CIED, cardiac implantable electronic device; RRT, renal replacement therapy.

[a]Beta-coefficient from multivariable linear regression model.

[b]Device-related complications: device thrombus, CIED-related complication, infection and inflammation of cardiac device, and other mechanical complications.

[c]Pericardial complications: pericarditis, pericardial effusion, hemopericardium, cardiac tamponade, and unspecified pericardial complications.

Bold values indicate *p*-value < .05.

4 | DISCUSSION

To the best of our knowledge, this is the first study aimed at utilizing the NIS sample database to address whether COVID-19 infection imposes a risk of in-hospital complications on individuals undergoing conventional pacemaker implantation. Our findings found that the cohort with COVID-19 infection encountered a higher risk of in-patient mortality, prolonged hospital stays, increased expenditures, and various adverse events, such as acute myocarditis, sepsis, acute respiratory failure, mechanical ventilation use, venous thromboembolism (VTE), and post-procedural pneumothorax.

The population in our study were predominated elderly with a mean age more than 70 years, align with another study showing an upward trend in pacemaker implantation in the aging population.[8,9] In terms of racial distribution, a recent meta-analysis by Mude et al. addressing whether there are racial disparities in COVID-19 patients indicated that Hispanic and Black populations had a higher pooled prevalence ratio of 1.78 and 1.79-fold, respectively, compared to the White population.[10] Notably, our findings reproduce this trend by demonstrating that Caucasians were the majority of both groups, and, in the COVID-19 cohort, there were higher percentages of Hispanic (18.62% vs. 7.03%) and African American (11.03% vs. 8.07%) populations compared to the non-COVID-19 group. Therefore, our study highlights certain racial disparities in patients undergoing pacemaker implantation with COVID-19 infection. Addressing these issues could provide benefits, and further research is needed to determine if racial disparities can impact to the outcomes of pacemaker implantation.[11]

We found a significant 4.67-fold increase in in-hospital mortality risk among patients hospitalized for conventional pacemaker implantation with COVID-19 compared to those without. Consistently, Tovia-Brodie et al., who explored data across 13 countries on four continents since the pandemic's inception until April 2021, reported a high 30-day mortality rate of 9.6% for patients hospitalized for cardiac implantable electronic devices (CIEDs)—including conventional or leadless pacemakers and intra-cardiac defibrillation (ICD)—during active COVID-19 infection.[7] In addition, accumulated evidence has corroborated whether perioperative complications markedly rise in patients with active COVID-19 infection undergoing various types of surgery, such as thoracic, gynecological, abdominal, and vascular surgery.[12,13] Given that the present study focuses on the in-patient outcomes of patients hospitalized for conventional pacemaker insertion, we further contribute to this perspective by demonstrating similar trends of higher in-hospital mortality among individuals with COVID-19 than non-COVID-19 patients (5.23% vs. 1.04%). Moreover, as the usual in-patient mortality for urgent or elective patients undergoing pacemaker implantation is known to be minimal, with rates up to 1.55% according to the NIS data before the COVID-19 pandemic, the increased overall in-hospital mortality of up to 5.23% among the cohort with COVID-19 in our study warrants serious attention.[8]

The elevated in-hospital mortality rate in COVID-19 patients who were hospitalized for conventional pacemaker implants in our study could be driven by multiple factors, such as direct myocardial injury from COVID-19 infection, procedural-related complications, or worsening of pre-existing cardiac conditions.[14–16] Recent studies have elucidated the pathophysiological mechanisms underlying systemic adverse effects in COVID-19, including uncontrolled cytokine storm and hyperinflammatory states.[17,18] Subsequently, these mechanisms further contributed to various perioperative complications, as evidenced in our study, including an elevated risk of sepsis, venous thromboembolism (VTE) as well as exacerbated acute respiratory failure requiring mechanical ventilators.[19–21] In addition, we found that cohort with COVID-19 had an 11.24-fold risk of acute myocarditis compared to those without. This finding aligns with previous literature on the impact of COVID-19 on incident myocarditis, attributed to its capability of infecting myocytes.[22]

In addition, the increased perioperative risk in patients with COVID-19 infection may result from operators' hurried efforts to reduce exposure to the virus and the elevated psychological stress among operators, leading to higher peri-procedural complications.[7] Our study highlighted an elevated risk of post-procedural pneumothorax in the COVID-19 cohort compared to those without. While the exact mechanisms of post-pacemaker implantation pneumothorax remain uncertain—whether this reflects a true biological phenomenon or confounding from unmeasured covariates—potential explanations exist. First, higher procedural challenges in those with COVID-19 and requirements for personal protective equipment (PPE), particularly considering the unfamiliarity of PPE during the initial phase of the COVID-19 pandemic. These factors likely contributed to observed in-patient mortality and various complications. Moreover, while specific procedural details and PPE utilization data were unavailable from the NIS database, recent studies have emphasized the fatigue experienced by surgeons and the challenges in perioperative communication and other non-technical skills from the use of PPE during the early phase of the COVID-19 pandemic.[23,24] These difficulties may contribute to procedural complexity and potential adverse outcomes, which warrant further investigation for clarification. Secondly, post-procedural pneumothorax could directly result from COVID-19. Recent data showed that patients with severe COVID-19 pneumonia requiring mechanical ventilation are at risk for pneumothorax due to potential alveolar tissue injury and the possibility of alveolar overdistention from mechanical ventilation.[25,26] Surprisingly, our findings revealed no difference in the rate of severe pneumonia requiring mechanical ventilation between the two groups. However, a higher rate of mechanical ventilation due to other causes was observed, which may increase the risk of post-procedural pneumothorax. It is critical to further explore the relationship between the timing of procedures and the onset of complications, such as post-procedural pneumothorax, to better understand and prevent these complications. Before rushing to a conclusion, more extensive longitudinal studies are needed to monitor this trend. Still, our analysis of the current NIS data may only capture a transient situation (January–December 2020), predating the wide availability of vaccines and medications. Yet, operator's decisions regarding postponement of pacemaker implantation solely due to COVID-19 infection should be cautiously made; a comprehensive assessment is needed to balance the benefits and trade-offs of procedure delay.

In contrast to single-center studies, which often face referral bias, utilizing extensive nationwide database provided strength to this current study. It enabled the depiction of patients' characteristics across the United States and allowed the implication of our findings in diverse situations. However, it is essential to acknowledge existing limitations. First, the administrative, cross-sectional nature of the NIS database hampers the gathering of crucial patient-level information in detail—encompassing, for instance, radiographic, echocardiographic, laboratory findings, and specific procedural information, such as the rate of PPE utilization during the procedure as well as the association and duration of TV-TP utilization before conventional pacemaker insertion. Additionally, we were unable to obtain individual procedural times or establish a causation between the dates of the procedure and the onset of complication including post-procedural pneumothorax. These variables hold the potential to confound the outcome and hindered a comprehensive assessment of patient severity in our study. Second, inaccuracies in the ICD-10 coding limited the detailed recording of indications for pacemaker implantation, each of which could introduce unique effects or even confound the impact of COVID-19 on patients' outcomes.[27] Moreover, the release of the COVID-19 ICD-10 code on April 1, 2020, may have resulted in the underreporting of the actual number of cases prior to its clinical implementation. Of note, the NIS database that focuses on in-hospital events does not incorporate endpoint outcomes after hospitalization, thereby being incapable of addressing how in-hospital COVID-19 infection influences long-term mortality and late-onset complications due to pacemaker device-related issues. Altogether, the study's cross-sectional nature limited us from establishing a causal relationship between COVID-19 infection and various adverse outcomes following conventional pacemaker implantation. As such, further evidence from a longitudinal cohort study is required to assess the current observed trend and track long-term complications in individuals with active COVID-19 undergoing pacemaker implantation.

5 | CONCLUSION

Our study demonstrated that patients hospitalized for conventional pacemaker implantation who also had active COVID-19 infection significantly experienced a higher in-patient mortality, longer LOS, and a variety of adverse events, such as acute myocarditis, sepsis, acute respiratory failure, mechanical ventilation use, venous thromboembolism (VTE), and post-procedural pneumothorax. Further epidemiological studies are required to explore the cause-effect relationship and enhance the clinical implications of these findings.

AUTHOR CONTRIBUTIONS

All authors had access to the data and a role in writing the manuscript.

FUNDING INFORMATION

None.

CONFLICT OF INTEREST STATEMENT

All the authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data from the findings of this study were inferred and can be obtained from the author upon reasonable request.

ETHICS APPROVAL STATEMENT

For this type of study, ethics approval is not required.

PATIENT CONSENT STATEMENT

For this type of study, formal consent is not required.

CLINICAL TRIAL REGISTRATION

N/A.

PERMISSION TO REPRODUCE MATERIAL FROM OTHER SOURCES

N/A.

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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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