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ORIGINAL RESEARCH

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The role of negative pressure wound therapy in the treatment of poststernotomy mediastinitis in Asians: A single-center, retrospective cohort study

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Abstract

Introduction: Poststernotomy mediastinitis (PSM) is a critical and life-threatening complication that can arise after cardiac surgery. The aim of this study was to evaluate and compare the outcomes of negative pressure wound therapy (NPWT) and conventional methods in the management of mediastinitis following heart surgery with a focus on Asian populations.

Methods: For this retrospective study, we included and evaluated a total of 34 patients who had undergone cardiac operations between January 2011 and September 2021 and developed PSM. The patients were divided into two groups, the NPWT group ($n = 16$, 47.1%) and the conventional treatment group ($n = 18$, 52.9%), and compared.

Results: The two groups showed no significant differences in terms of patient characteristics, PSM wound classification based on the El Oakley classification, and wound closure methods, but there was a higher incidence of diabetes mellitus in the NPWT group. With regard to mediastinal cultures, a higher prevalence of *Staphylococcus epidermidis* was observed in the NPWT group. However, we found no significant differences between the two groups regarding the time interval from diagnosis to wound closure, hospitalization duration, and re-exploration rate. Notably, the NPWT group exhibited a significantly higher in-hospital mortality rate than the conventional treatment group ($p = 0.024$).

Conclusions: Our findings suggest that the use of NPWT might not lead to improved medical outcomes for patients with PSM when compared to conventional treatment methods. As a result, it becomes imperative to exercise great care when choosing patients for NPWT. To obtain more definitive and conclusive results and identify the most appropriate cases for NPWT, conducting larger randomized clinical trials is necessary.

KEYWORDS

conventional treatment, negative pressure wound therapy, poststernotomy mediastinitis

1 | INTRODUCTION

Median sternotomy is a commonly employed incision for various heart surgeries.[1,2] However, it comes with the risk of surgical site complications (SSCs), such as poststernotomy mediastinitis (PSM), defined as deep sternal wound infections with sternal osteomyelitis with or without infected retrosternal space,[3] which may occur in approximately 0.2%–8% of cases. Furthermore, sternal dehiscence can be observed in 0.06%–12.50% of instances.[4–6] Failing to address these SSCs can lead to perioperative mortality rates soaring as high as 47%. Hence, proper attention and management of potential complications are vital for patients undergoing median sternotomy procedures.[7]

The recommended approach to address sternal defects arising from PSM involves reconstruction, which has the potential to lead to improved patient outcomes, especially when prompt closure is achieved. The Treatment for PSM usually involves a combination of antibiotic therapy,[8] incision and drainage of the wound, multiple debridement procedures, rewiring if necessary,[9] closed irrigation, early closure (unless instability is a concern),[10,11] and omental[12] or myocutaneous flap reconstruction.[13] This comprehensive treatment strategy aims to effectively manage PSM and promote successful healing of sternal wounds. In the past, traditional wet-to-dry dressings were used, creating a sterile and moist environment while removing excessive wound drainage. However, these dressings required frequent changes and caused discomfort during removal. To overcome these issues, Obdeijn et al.[14] suggested the utilization of negative pressure wound therapy (NPWT) after debridement of PSM wounds. This approach facilitates the healing and stabilization of the sternotomy wound. Recent studies have provided evidence of the safety and effectiveness of NPWT, showcasing its ability to accelerate the formation of granulation tissue in the wound, promote enhanced wound closure, and reduce the frequency of dressing change as compared with open packing.[15,16]

Despite the availability of research on the efficacy of NPWT and traditional standard treatments, there is a lack of specific studies comparing their effectiveness in Asian populations. Thus, our study aimed to address this gap and investigate the impact of NPWT on patients with PSM. We focused on key variables such as the time required for wound closure, duration of hospital stay, mortality rate, and occurrences of other morbidities. By doing so, we aimed to contribute valuable information regarding the effectiveness of NPWT in managing this condition in Asian patients.

2 | METHODS

2.1 | Patients

Between January 1, 2011, and September 31, 2021, a retrospective evaluation was performed. During this period, a total of 34 patients who had undergone cardiac operations involving median sternotomy were identified as having developed mediastinitis after the surgery. The patients who experienced postoperative mediastinitis were divided into two groups, namely, the NPWT group ($n = 16$, 47.1%) and the conventional treatment (CoT) group ($n = 18$, 52.9%).

The diagnosis of PSM was established using at least one of the following criteria outlined by the Centers for Disease Control and Prevention[17]: (i) identification of microorganisms in the cultures of mediastinal tissue or fluid drainage during surgery or needle aspiration, (ii) observation of mediastinitis on gross abatomic or histopathologic exam during the operation, or (iii) chest pain, presence of sternal instability, a fever (>38°C), and purulent discharge from the mediastinum, along with the isolation of microorganisms in the blood/mediastinal drainage cultures.

2.2 | Pre- and postoperation antibiotics use

Our standard prophylactic antibiotic regimen consisted of cefazolin sodium, starting on the day of surgery and continuing for the first and second postoperative days. For the patients diagnosed with PSM, when Gram-positive microorganisms were detected in their tissue cultures, we typically initiated intravenous antibiotic therapy with teicoplanin, taking into account renal function, as coagulase-negative staphylococci and *Staphylococcus aureus* are commonly identified as the prevailing pathogens in PSM according to existing literature.[18,19] The duration of antibiotic treatment was typically extended until the results of the tissue cultures were available. Subsequently, the antibiotic therapy was adjusted based on bacterial sensitivity and the specific strain identified.

2.3 | The CoT of PSM

Upon detection or confirmation of sternal infection by osteomyelitis scans, our approach involved initiating treatment by opening the wound incisions and removing the sternum wires of the patients diagnosed with PSM, following strict aseptic protocols. Aggressive debridement of sternal and surrounding tissues was then performed in both groups. Subsequently, in the CoT group, a protocol involving irrigation with povidone-iodine and saline solutions, as well as open packing, was administered three to four times daily. In the conventional group, following three consecutive negative tissue cultures, we performed sternum revision and rewiring. Additionally, we assessed the clinical appearance of the wound and ensured the satisfactory development of granulation tissue within the wound before proceeding with wound closure.

2.4 | The NPWT treatment of PSM

In the NPWT group, the PSM patients underwent aseptic wound incisions and removal of sternum wires. Subsequently, thorough debridement of the sternum and surrounding tissue was performed. In this group, a specialized system consisting of polyurethane foam

and a computer-controlled pump unit was utilized. The polyurethane sponge was carefully inserted into the wound beneath the sternum, while additional foam pieces were placed between the sternal edges and the subcutaneous layer. To facilitate the treatment, an adhesive, a semipermeable drape, was applied over the wound and connected to the therapy unit. A continuous negative pressure mode of the therapy unit ranging from −125 mmHg was maintained. In parallel with the CoT group, the NPWT group also underwent sternum revision and rewiring. This occurred once three consecutive negative tissue cultures were confirmed, along with the presence of satisfactory granulation tissue in the wound and favorable clinical appearance. The decision regarding the use of NPWT or not was entirely reliant on the individualized clinical judgment, experiences, and preferences of the operators.

2.5 | Outcomes

The evaluation of patient outcomes encompassed several factors, including mainly the period of time required for wound closure, duration of hospital stay, all-cause mortality, and other related morbidities.

2.6 | Statistical analysis

In our study, the El Oakley classification system was employed to categorize the severity of PSM cases.[20] We also utilized the European System for Cardiac Operative Risk Evaluation (EuroSCORE),[21] a widely recognized scoring system, to assess the severity of cardiac disease in our study population and predict mortality in cardiac surgery. The distribution of continuous variables was evaluated using the Kolmogorov–Smirnov test. Normally distributed continuous variables were presented as the mean ± standard deviation, while nonnormally distributed continuous variables were described using the median and minimum–maximum values. Nominal variables were reported as numbers and percentages. The χ^2 test was employed to compare categorical variables, while the Student's *t*-test or Mann–Whitney *U* test was used to compare continuous variables. A paired-samples *t*-test was utilized for comparing repeated measures. A *p*-value of less than 0.05 was considered statistically significant. The data were analyzed using SAS software (version 9; SAS).

3 | RESULTS

There were minimal notable differences observed in the baseline characteristics of the two groups, as presented in Table 1. In the NPWT group, the average age of the patients was 63.3 ± 13 years, while it was 63.8 ± 10.8 years in the CoT group ($p = 0.1$). Among the NPWT group, 3 patients were female (18.7%) and 13 were male (81.3%), whereas in the CoT group, 3 patients were female (16.7%) and 15 were male (83.3%). The numbers of patients with a body mass index ≥30 were three (18.7%) in the NPWT group and three (16.7%) in the CoT group. Other characteristics, such as smoking habit, history of hypertension, chronic obstructive pulmonary disease (COPD), end-stage renal disease, ongoing immunosuppressive therapy, history of pulmonary hypertension, left ventricular ejection fraction, and the EuroSCORE, were comparable between the NPWT and CoT groups. However, it is worth noting that the incidence of diabetes mellitus (DM) was higher in the NPWT group ($n = 11$, 68.7%) than in the CoT group ($n = 6$, 33.3%, $p = 0.0.39$).

TABLE 1 Baseline characteristics of the study population.

	NPWT group ($n = 16$)	CoT group ($n = 18$)	*p* Value
Age (years)	63.8 ± 10.8	63.3 ± 13.0	0.890
Gender			0.549
Male, *n* (%)	12 (75.0)	15 (83.3)	
Female, *n* (%)	4 (25.0)	3 (16.7)	
Obesity (BMI ≥ 30), *n* (%)	3 (18.7)	3 (16.7)	0.771
Smoking, *n* (%)	8 (50)	10 (55.6)	0.928
Diabetes mellitus, *n* (%)	11 (68.7)	6 (33.3)	0.039
Hypertension, *n* (%)	13 (81.3)	12 (66.7)	0.094
Chronic pulmonary obstructive disease, *n* (%)	6 (37.5)	7 (38.9)	0.246
End-stage renal disease, *n* (%)	7 (43.7)	5 (27.8)	0.331
Immunosuppressive therapy, *n* (%)	2 (12.5)	1 (5.5)	0.508
Pulmonary hypertension, *n* (%)	6 (37.5)	2 (11.1)	0.200
LVEF (%)	49.8 ± 14.3	50.1 ± 9.6	0.955
EuroSCORE value	9.2 ± 7.3	6.1 ± 4.0	0.163

Note: Continuous variables are presented as mean ± standard deviation, and nominal variables are reported as numbers and percentages.

Abbreviations: BMI, body mass index; CoT, conventional treatment; EuroSCORE, the European System for Cardiac Operative Risk Evaluation; LVEF, left ventricular ejection fraction; NPWT, negative pressure wound therapy.

There were no significant statistical differences observed between the groups regarding the indications for sternotomy, which included valve replacement, coronary artery bypass graft surgery, ventricle-assist devices, pericardiectomy, redo operations, and total operation duration (Table 2).

Table 3 presents the identified PSM pathogens confirmed by cultural testing. Among the microorganisms analyzed in the microbiological examinations and cultures of both the NPWT and CoT groups, *Staphylococcus* strains were the most prevalent. However, there was no significant distinction between the two groups in terms

TABLE 2 The different indications for sternotomy in cardiac surgery.

	NPWT group ($n = 16$)	CoT group ($n = 18$)	p Value
Valve replacement, n (%)	9 (56.3)	8 (44.4)	0.492
CABG, n (%)	6 (37.5)	9 (50)	0.464
VAD, n (%)	2 (12.5)	3 (16.7)	0.887
Pericardiectomy, n (%)	5 (31.2)	3 (16.7)	0.852
Emergency surgery, n (%)	7 (43.7)	7 (38.9)	0.774
Re-do surgery, n (%)	7 (43.7)	6 (33.3)	0.533
Operation duration (min)	308.8 ± 114.9	359.7 ± 140.9	0.274

Abbreviations: CABG, coronary bypass graft; CoT, conventional treatment; NPWT, negative pressure wound therapy; VAD, ventricular assist device.

TABLE 3 Culture-verified poststernotomy mediastinitis pathogens.

Infection pathogens	Total ($n = 34$)	NPWT group ($n = 16$)	CoT group ($n = 18$)	p Value
Staphylococcus aureus	13 (38.2)	6 (37.5)	7 (38.9)	0.934
Staphylococcus epidermidis	3 (8.8)	2 (12.5)	1 (5.6)	0.037
Klebsiella pneumoniae	1 (2.9)	1 (6.3)	0 (0)	0.282
Corynebacterium	1 (2.9)	1 (6.3)	0 (0)	0.282
Enterobacter cloacae	2 (5.8)	1 (6.3)	1 (5.6)	0.932
Enterobacter hormaechei	1 (2.9)	1 (6.3)	0 (0)	0.282
Enterococcus faecium	1 (2.9)	1 (6.3)	0 (0)	0.282
Candida albicans	2 (5.8)	1 (6.3)	1 (5.6)	0.932
Salmonella	1 (2.9)	0 (0)	1 (5.6)	0.339

Abbreviations: CoT, conventional treatment; NPWT, negative pressure wound therapy.

of microbiological agents, except for a higher occurrence rate of *Staphylococcus epidermidis* in the NPWT group ($n = 2$ in the NPWT group, $n = 1$ in the CoT group, $p = 0.037$).

Upon conducting a comparison of the two groups utilizing the El Oakley classification, we observed no significant distinctions between them concerning the El Oakley PSM severity beyond Type IV, as shown in Table 4. However, in terms of less severe classifications, Types I and II, the CoT group exhibited a higher prevalence (25% in the NPWT group compared with 44.4% in the CoT group, $p = 0.236$), while Type III was more commonly observed in the NPWT group (50% in the NPWT group vs. 27.8% in the CoT group, $p = 0.183$), although this difference had no statistical significance.

TABLE 4 Poststernotomy mediastinitis according to the El Oakley classification system.

	NPWT group ($n = 16$)		CoT group ($n = 18$)		p Value
Type I, n (%)	1 (6.2)	4 (25%)	1 (5.6)	8 (44.4%)	0.236
Type II, n (%)	3 (18.8)		7 (38.8)		
Type IIIA, n (%)	2 (12.5)	8 (50%)	0 (0)	5 (27.8%)	0.183
Type IIIB, n (%)	6 (37.5)		5 (27.8)		
Type IVA, n (%)	1 (6.2)	4 (25%)	1 (5.6)	5 (27.8%)	0.855
Type IVB, n (%)	0 (0)		0 (0)		
Type V, n (%)	3 (18.8)		4 (22.2)		

Abbreviations: CoT, conventional treatment; NPWT, negative pressure wound therapy.

TABLE 5 Comparisons of wound closure methods between the negative pressure wound therapy and conventional treatment groups.

	NPWT group ($n = 16$)	CoT group ($n = 18$)	p Value
Secondary healing	1 (6.3)	3 (16.7)	0.68
Primary closure	2 (12.5)	6 (33.3)	0.30
Local flap	5 (31.3)	0 (0)	0.08
Pectoralis major flap	6 (37.5)	8 (44.4)	0.68
Rectus abdominis flap	1 (6.3)	1 (5.6)	0.51

Abbreviations: CoT, conventional treatment; NPWT, negative pressure wound therapy.

In terms of wound closure methods, the utilization of local flaps was more prevalent in the NPWT group, although it did not reach statistical significance. Regarding other closure approaches, such as secondary healing, primary closure, or the use of a pectoralis major flap or rectus abdominis flap, there were no discernible differences between the NPWT and CoT groups, as indicated in Table 5.

The two groups did not show any significant differences in terms of hospital stay, re-exploration, time to wound closure, and death related to pneumonia, sepsis or intracranial hemorrhage ($p = 0.688$, 0.915, 0.394, 0.233, 0.282, respectively). Although there was a slightly higher incidence of death attributed to wound infection in the NPWT group than in the CoT group, the difference was not

TABLE 6 Outcomes of poststernotomy mediastinitis in our population.

	NPWT group ($n = 16$)	CoT group ($n = 18$)	p Value
Hospital stay (days)	109.1 ± 55.0	101.4 ± 52.1	0.688
Re-exploration, n (%)	4 (25)	9 (50)	0.915
Time to wound closure (days)	21.3 ± 19.1	31.1 ± 41.6	0.394
Expired during hospitalization, n (%)	7 (43.7)	1 (5.6)	**0.024**
Causes of death			
Sepsis (pneumonia), n (%)	3 (18.7)	1 (5.6)	**0.233**
Sepsis (wound), n (%)	3 (18.7)	0 (0)	**0.054**
Intracranial hemorrhage, n (%)	1 (6.3)	0 (0)	**0.282**

Abbreviations: CoT, conventional treatment; NPWT, negative pressure wound therapy.

statistically significant ($p = 0.054$). However, contrary to previous reports, the NPWT group had a significantly higher in-hospital mortality rate ($p = 0.024$) (Table 6).

4 | DISCUSSION

To the best of our knowledge, this retrospective cohort study conducted at a single center was the first of its kind to examine the effects of NPWT in an Asian population. In contrast to previous studies, NPWT was found to carry a higher risk of in-hospital mortality. There are several possible explanations for this discrepancy. First, the NPWT group had a higher incidence of high-degree PSM wounds, based on the El Oakley classification, while the CoT group mostly had less severe Type I and Type II PSM wounds. Additionally, the NPWT group showed a greater prevalence of DM, a recognized risk factor for infection and impaired wound healing. Furthermore, *S. epidermidis*, a prominent pathogen associated with sepsis, was more commonly found in the NPWT group. These factors likely contributed to the heightened severity of the wounds; consequently, there was a higher rate of in-hospital mortality despite the implementation of NPWT. These findings emphasized the importance for clinicians to carefully consider the individual wound conditions and patient characteristics when deciding to initiate NPWT.

Infection of the sternotomy area after heart surgery is a severe and often deadly complication. Previous studies have identified various risk factors associated with this type of infection, including advanced age, obesity, smoking, DM, COPD, renal dysfunction, and the use of immunosuppressive therapy.[22] In this study, we also examined these factors in our patient population and found a higher prevalence of DM in the NPWT group. The incidence of sterile wound dehiscence was higher than that of PSM. Among patients who experienced wound complications after median sternotomy, 60% developed sterile wound dehiscence.[23] Gram-positive bacteria are the most commonly identified microorganisms in cases of PSM, with *S. aureus* or *S. epidermidis* accounting for 70%–80% of such infections.[20,24,25] In line with these findings, similar results were manifested in our study, revealing a higher prevalence of *S. epidermidis* in the NPWT group.

The utilization of NPWT in cases of PSM has demonstrated beneficial effects, such as increased blood flow in the parasternal area, reduced bacterial load, and accelerated wound healing with the formation of granulation tissue. Several studies, providing level 3 evidence, have highlighted the role of NPWT in managing PSM.[26,27] In a comprehensive review spanning 12 years, Lonie et al.[28] reported that NPWT was associated with a decreased need for flap reconstruction and a lower incidence of postoperative complications requiring reoperation after definitive wound closure. Notably, none of the patients treated with NPWT in their study required sternum rewiring, indicating an additional benefit in sternum stabilization. A prior systematic review also demonstrated favorable outcomes when comparing negative pressure wound care with other wound management techniques for PSM, including a shorter hospital stay, reduced reinfection rate, and decreased early mortality.[29] Akbayrak et al.,[15] in a recent study, found statistically significant reductions in the total treatment duration, time from diagnosis to negative culture, hospitalization duration, and in-hospital mortality in their NPWT group as compared with the CoT group. However, our study has presented conflicting findings, and we need a larger sample size to gain a clearer understanding of the indication of NPWT and relationship between mortality and morbidity in patients with PSM.

As mentioned earlier, in terms of wound infections, the risk for patients with DM is higher compared with that for non-DM patients, possibly because of more frequent postoperative hyperglycemia.[30,31] Additionally, preoperative[32] and perioperative[33] glycemic control has also been linked to a higher risk of PSM after cardiac surgery. To mitigate the risk of PSM, the Society of Thoracic Surgeons (STS),[34] Spanish Society of Cardiovascular Infections (SEICAV), the Spanish Society of Thoracic and Cardiovascular Surgery (SECTCV), and Biomedical Research Center Network for Respiratory Diseases (CIBERES)[3] currently recommend maintaining perioperative glucose levels below 180 mg/dL in patients undergoing cardiac surgery.

Regarding the evidence of prognostic factors for PSM, there remain limited findings. Dessap et al.[35] have indicated that early-onset PSM (occurring within 14 days of the initial operation) is a

significant and independent risk factor for both 1-year and overall mortality. Other studies have suggested that factors such as age older than 65 years, a longer stay in the intensive care unit,[36] PSM caused by methicillin-resistant *S. aureus*,[37] co-infection, like mechanical ventilator-associated pneumonia following PSM,[38] and a longer primary operation time,[39] can reduce survival in patients with PSM. We were unable to explore additional predictors of mortality in our study due to a small cohort size.

Vascularized tissue flaps are an alternative treatment option for patients with PSM, particularly in cases where there is a significant soft tissue deficit. In 1976, Lee et al.[40] introduced the use of an omentum flap for sternal closure, while Jurkiewicz et al.,[41] in 1980, initially described the utilization of pectoral flaps for the same purpose. The implementation of NPWT has decreased the need for complex interventions to close the sternum in PSM patients as compared with traditional methods, allowing for simpler and more cost-effective techniques to suffice.[29,42] Within our study, 21 patients underwent flap procedures, with no significant difference observed in the requirement for pectoral muscle flaps between the CoT group and the NPWT group. Furthermore, the NPWT group exhibited no disparities in terms of primary closure or secondary healing when compared with the CoT group. Once again, our study emphasized the importance of individualized selection of NPWT for each PSM case.

Effective collaboration among various members of the multidisciplinary team is crucial to achieve favorable outcomes in patients with PSM, a complication that is greatly feared following cardiac surgery. This collaborative team typically includes cardiothoracic surgeons, plastic surgeons, intensivists, infectious disease specialists, and clinical microbiologists. The optimal surgical technique for managing mediastinitis after open-heart surgery remains a subject of debate. However, the routine use of NPWT has gained popularity in many clinics due to its safety and reliability. NPWT has been increasingly employed in cardiac surgery. While there are numerous studies available on the outcomes of NPWT in the literature, our study has provided valuable insights to guide more careful selection of NPWT, thereby maximizing its benefits and improving patient outcomes.

5 | LIMITATIONS

Our study had several limitations. First, the retrospective design introduced selection bias, limiting the robustness of our conclusions. Second, the heterogeneity resulting from variations in protocols, surgeons' experience levels, and treatment approaches among different surgical teams may have influenced our results. Third, there is a potential limitation related to excluding patients who sought treatment in their local cities instead of coming to our center, which could have led to missed postoperative mediastinitis cases. Fourth, we were unable to conduct a comparative analysis between NPWT and another similar therapeutic intervention, standard of care (SOC)—intermittent antimicrobial irrigation and sterile gauze dressing, due to the unavailability of NPWT with the instillation in Taiwan currently. Fifth, another notable limitation is the small sample size, which hindered a comprehensive analysis to understand the underlying reasons for the inferior outcomes observed in the NPWT group. Specifically, we were unable to ascertain whether the higher mortality incidence was linked to prolonged NPWT use, pneumonia, wound infection, or other factors. Moreover, our study lacked the ability to establish the most appropriate criteria for the application of NPWT, necessitating further investigation and research in this area. We were unable to assess the long-term outcomes of the patients, which could have provided valuable insights into the sustained effects of the treatments. To validate and reinforce our findings, a blinded, prospective, randomized, multicenter study is indispensable. Such an approach will enable us to attain more reliable and definitive conclusions regarding the role and effectiveness of NPWT in managing PSM after cardiac surgery.

6 | CONCLUSION

In conclusion, our retrospective analysis indicates that NPWT may not provide superior medical outcomes for patients with PSM when compared to CoT techniques. However, it is crucial to acknowledge that NPWT still serves as a safe and effective bridging treatment option for PSM after cardiac surgery, with acceptable levels of morbidity and mortality. Nonetheless, the selection of patients for NPWT should be approached with careful consideration.

To obtain more definitive insights into the role of NPWT and to draw conclusive findings, larger randomized clinical trials are warranted. Such studies will help further elucidate the potential benefits and limitations of NPWT in managing PSM effectively.

AUTHOR CONTRIBUTIONS

Wei-Ting Wang: Conceptualization; data curation; formal analysis; investigation; methodology; software; writing—original draft; writing—review & editing. **Jui-Min Lee**: Data curation; formal analysis; methodology; writing—review & editing. **Kuan-Ju Chiang**: Methodology; writing—review & editing. **Shih-Hwa Chiou**: Supervision; writing—review & editing. **Chin-Tien Wang**: Supervision; writing—review & editing. **Szu-Hsien Wu**: Conceptualization; data curation; investigation; project administration; supervision; validation; writing—review & editing. All of the authors have read and approved the final version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

As participants did not consent for their data to be publicly shared, even anonymized, the data would be made available only to potential collaborators with ethical approval after they submitted a research proposal to the Bureau of the NHI (https://nhird.nhri.org.tw/). The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The study was approved by the Institutional Review Board (IRB) of Taipei Veterans General Hospital. Consent to participate and consent to publish are not applicable.

TRANSPARENCY STATEMENT

The lead author Szu-Hsien Wu affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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