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ORIGINAL ARTICLE

Microporous polysaccharide hemospheres for reducing pocket hematomas after cardiac device implantation in patients on antithrombotic therapy

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Abstract

Background: Various surgical procedures have employed microporous polysaccharide hemosphere (MPH) hemostatic agents. However, data regarding their effectiveness in preventing pocket hematomas (PHs) during the implantation of cardiac implantable electronic devices (CIED) among the Asian population are limited. Therefore, this study aimed to investigate the potential benefits of using MPH hemostatic agents during CIED implantations as a preventive measure against post-procedural PHs.

Methods: We conducted a retrospective, single-center, observational study involving 255 consecutive Japanese patients who underwent CIED implantation between November 2017 and April 2021. We compared PH occurrences within 28 days after CIED implantation between patients who received MPH hemostatic agents ($n = 145$) and those who did not ($n = 110$).

Results: PH development was observed in nine (6.2%) patients who received MPH hemostatic agents and in 13 (11.8%) patients without MPH hemostatic ($p = .111$). Kaplan–Meier analysis of PH development revealed no significant difference between the two groups (log-rank $p = .102$). However, utilizing MPH hemostatic agents among patients taking antithrombotic drugs, including antiplatelet medications, direct oral anticoagulants, and warfarin, significantly reduced PH incidence (log-rank $p = .03$). The multivariate Cox proportional hazards model demonstrated that MPH hemostatic agent utilization independently correlated with a decreased PH risk (hazard ratio 0.22, 95% confidence interval 0.08–0.63, $p = .004$).

Conclusions: The findings of this study suggest that the incorporation of MPH hemostatic agents into standard practice may benefit to mitigate PH risk during CIED implantations in patients on antithrombotic therapy. This simple and practical measure may be valuable, especially in high-risk patients, such as those taking antithrombotic medications.

KEYWORDS
cardiac implantable electronic device, hemostatic agents, implantation, microporous polysaccharide hemospheres, pocket hematomas

1 | INTRODUCTION

Over several decades, cardiovascular implantable electronic device (CIED) use, including pacemakers (PM), implantable cardioverter-defibrillators (ICD), and cardiac resynchronization therapy devices with PMs (CRT-P) and defibrillator (CRT-D), have increased exponentially. However, the most common complication of CIED implantations is pocket hematoma (PH). The frequency of PH occurrence may vary, with reported rates as high as 16%.[1–6] PHs can cause severe wound pain, often requiring recompression and the discontinuation of antithrombotic drugs. These adverse events can lead to extended hospital stays and may require re-operation for hemostasis. Furthermore, a meta-analysis reported a potential association between PHs and an increased CIED infection risk (ods ratio 8.46),[7] which can lead to elevated mortality rates and increased healthcare costs.[8] Therefore, efforts to prevent PHs are crucial.

Recently, various surgical procedures have utilized hemostatic agents made of microporous polysaccharide hemospheres (MPHs), which are entirely derived from plants. These agents are non-irritating, non-immunogenic, and bioabsorbable. However, evidence supporting their effectiveness in reducing PHs during CIEDs implantation is limited.[9,10] Moreover, no study has demonstrated their efficacy among the Asian population. Therefore, this study aimed to investigate the advantages of using MPH hemostatic agents during CIED implantations to prevent post-procedural PHs.

2 | METHODS

2.1 | Study design, patient population

The Ethics Committee of the National Hospital Organization Yokohama Medical Center (No. 2022-29) approved this retrospective, single-center observational study. We enrolled patients aged ≥18 years who underwent initial transvenous CIED implantation between November 2017 and April 2022. Additionally, we included patients who underwent index transvenous CIED implantation, specifically PMs, ICDs, CRT-Ps, and CRT-Ds, implanted in the anterior thoracic region. High-power devices include ICDs and CRT-Ds. We excluded cases of leadless PMs and subcutaneous ICDs. All consecutive patients who underwent CIED implantation between November 2017 and November 2019 had CIED procedures without MPH hemostatic agents, while all consecutive patients from December 2019 to April 2022 had CIED procedures with MPH hemostatic agents. We categorized the patients into two groups based on whether MPH hemostatic agents were used (MPH group) or not (No-MPH group) (Figure 1).

2.2 | Data collection

We analyzed patients' data, including age, body mass index (BMI), gender, medical history, and medication use, such as antiplatelet drugs, direct oral anticoagulants (DOACs), and warfarin. Additionally,

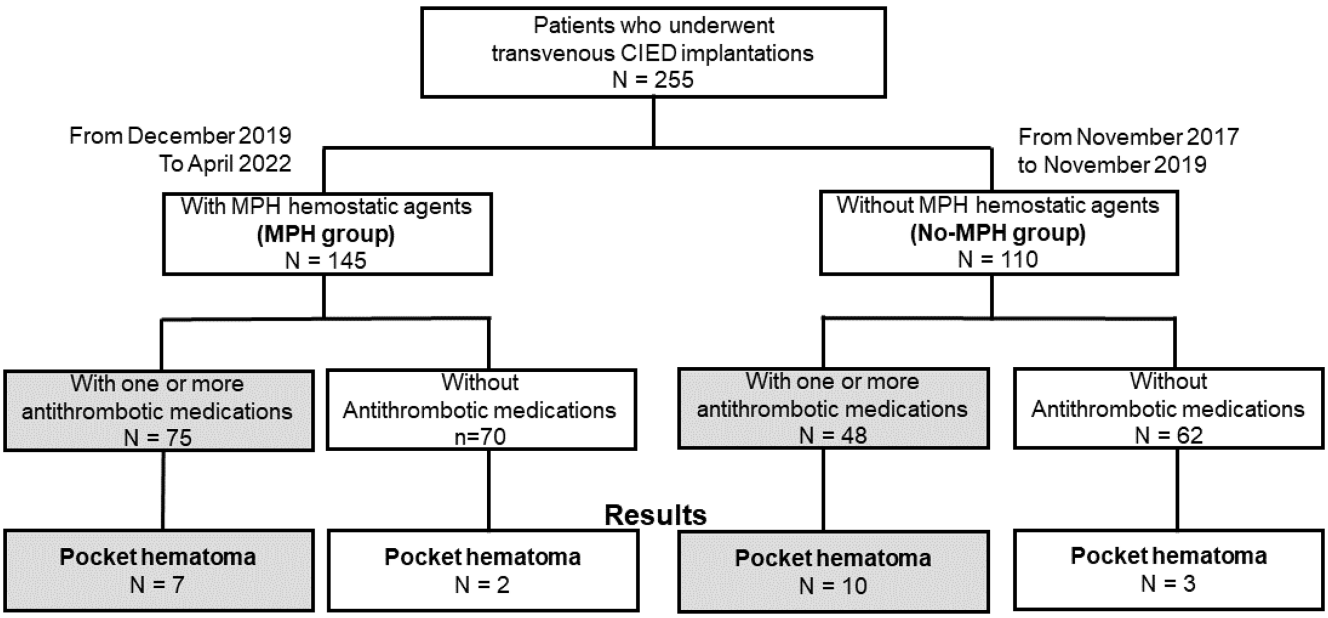

FIGURE 1 Patient flow chart of the study. CIED, cardiovascular implantable electronic devices; MPH, microporous polysaccharide hemospheres.

laboratory findings (including hemoglobin, platelets, activated partial thromboplastin time, prothrombin time-international normalized ratio [PT-INR], creatinine, estimated glomerular filtration rate, hemoglobin A1c [HbA1c], and brain natriuretic peptide [BNP]) upon admission to the hospital before CIED implantation were collected. We also collected data on comorbidities, including hypertension, diabetes mellitus (DM), heart failure, renal dysfunction, old brain infarction, and atrial fibrillation. Hypertension was defined as having a systolic blood pressure ≥140 mmHg for ≥3 days while on antihypertensive medication or during hospitalization. Diabetes mellitus was defined as taking oral hypoglycemic medication or having an HbA1c ≥6.5% within 1 month before or after implantation. Heart failure was defined as a history of hospitalization for heart failure or symptoms of heart failure along with a BNP ≥100 pg/mL on a blood test. We also collected transthoracic echocardiographic parameters, such as left ventricular ejection fraction, left ventricular end-diastolic diameter, left ventricular end-systolic diameter, left atrial diameter, and valvular disease of moderate or greater degree. In addition, we collected information on procedural characteristics, such as device type, number of leads, and duration of compression.

2.3 | Outcomes

The primary endpoint investigated in this study was PH incidence during the initial 28 days after CIED implantation. PH was defined as a palpable mass located anterior to the generator placed in the device pocket that required recompression, extended compression, or antithrombotic discontinuation.

2.4 | Implantation procedures

CIED implantations were conducted following our institutional protocol, which underwent minimal changes during the study period, except for the addition of the MPH hemostatic agent. Venous access was obtained via cephalic cutdown, extra-thoracic, or subclavian vein puncture. CIED generators were routinely placed in the subcutaneous region during the implantation procedure. After connecting the leads and generator and wiping the blood well in the pocket, we evenly spread 1 g dose of MPH hemostatic agent inside the pocket and applied pressure for 40 s in all cases. Following implantation, gauze compression was applied over the pocket, with the duration left to the discretion of the attending physician. Antiplatelet drugs and warfarin were not discontinued during implantation. However, DOACs were discontinued on the morning of implantation and resumed after the procedure. No surgery was conducted under heparin.

2.5 | Statistical analyses

Quantitative data were presented as the median and interquartile range (IQR), whereas categorical data were presented as numbers and percentages. Associations between intervention groups and categorical variables were assessed using the two-sided chi-squared or Fisher's exact test, and continuous variables were compared using the Mann–Whitney *U*-test. Time to outcome between both study groups was analyzed using the Kaplan–Meier survival curve. Hazard ratios (HR) with 95% confidence intervals (CI) were used to estimate and express the treatment effects of both groups, using a univariate Cox proportional hazard model. Multivariate Cox proportional hazards model was used to adjust for covariates. All statistical analyses were conducted using EZR,[11] a modified version of R commander, designed to include statistical functions commonly used in biostatistics. Statistical significance was set at a two-sided p value $< .05$.

3 | RESULTS

3.1 | Patients and procedure characteristics

Overall, 255 patients who met the inclusion criteria were enrolled in the study (Figure 1). Among them, 110 patients underwent CIED implantation without MPH hemostatic agents between November 2017 and November 2019 (no-MPH group). In contrast, 145 patients underwent CIED implantation with MPH hemostatic agents from December 2019 to April 2022 (MPH group). Table 1 presents the characteristics of both groups. The median age of the patients was 70 (IQR: 73–84) years, and 47.5% were women. The median BMI was 22.4 (IQR: 20.1–24.9). Comorbidities in the patient population included hypertension in 60.4%, diabetes in 28.2%, heart failure in 60.4%, old brain infarction in 11.0%, and atrial fibrillation in 35.7%. No considerable differences were observed in age, gender, BMI, comorbidity rates and transthoracic echocardiographic parameters between the two groups. In the MPH group, 23% of the patients received antiplatelet agents, 30% received DOACs, and 3% received warfarin. In the no-MPH group, 16% were on antiplatelet agents, 19% were on DOACs, and 9% were on warfarin. The proportions of patients taking these medications did not vary substantially. Among the patients, 123 (48.2%) were taking at least one antithrombotic medication, and eight (3.1%) were on antiplatelet and oral anticoagulant medication concurrently. Among patients taking warfarin ($n = 15$), the median PT-INR was 1.88 (IQR: 1.61–1.99), whereas the median PT-INR was 1.08 (IQR: 1.03–1.17) in those not taking warfarin. Table 2 presents the procedure characteristics among the two groups. The MPH group had a higher proportion of high-power devices and many leads, and perhaps reflecting this, the median procedure time was also significantly longer in the MPH group, 100 (IQR: 85–110) min compared to 80 (IQR: 70–100) min in no-MPH group. However, the number of compression days did not differ between the groups.

3.2 | Primary outcome

Nine (6.2%) patients in the MPH group and 13 (11.8%) in the no-MPH group experienced PH within 28 days. Among the MPH group,

TABLE 1 Baseline patient characteristics.

	All ($n=255$)	MPH group ($n=145$)	No-MPH group ($n=110$)	p value
Age (years)	79 (73–84)	80 (74–84)	78 (72–84)	0.132
Female (n, %)	121 (47.5%)	64 (44.1%)	57 (51.8%)	0.255
Body mass index (kg/m^2)	22.4 (20.1–24.9)	22.6 (20.2–25.7)	21.8 (20.0–23.9)	0.070
Hypertension (n, %)	156 (61.2%)	89 (61.4%)	67 (60.9%)	1.000
Diabetes mellitus (n, %)	72 (28.2%)	47 (32.4%)	25 (22.7%)	0.094
Heart failure (n, %)	154 (60.4%)	90 (64.8%)	60 (54.5%)	0.121
Renal dysfunction (n, %)	103 (40.6%)	66 (45.5%)	37 (33.9%)	0.070
Old brain infarction (n, %)	28 (11.0%)	16 (11.0%)	12 (10.9%)	1.000
Atrial fibrillation (n, %)	91 (35.7%)	49 (33.8%)	42 (38.2%)	0.510
Hemoglobin (g/dL)	12.9 (11.7–14.2)	12.9 (11.6–14.4)	12.9 (11.7–14.0)	0.779
Platelet (×10^4/μL)	192.0 (259.0–235.0)	200.0 (160.0–245.0)	182.0 (152.3–234.5)	0.186
APTT (s)	31.1 (29.4–33.8)	30.9 (29.2–34.4)	31.3 (29.6–33.6)	0.759
PT-INR				
All	1.08 (1.03–1.19)	1.08 (1.04–1.19)	1.08 (1.02–1.19)	0.589
On Warfarin	1.88 (1.02–2.85) $n=15$	1.62 (1.48–1.99) $n=5$	1.89 (1.74–2.12) $n=10$	0.420
Creatinine (mg/dL)	0.94 (0.74–1.25)	0.96 (0.78–1.24)	0.88 (0.72–1.25)	0.158
eGFR (mL/min/1.73 m^2)	54.2 (41.2–65.3)	52.2 (41.2–61.7)	55.2 (40.9–68.9)	0.224
HbA1c (%)	6.0 (5.7–6.5)	6.1 (5.7–6.6)	5.9 (5.7–6.3)	0.118
BNP (pg/mL)	123.3 (60.0–307.0)	109.5 (51.7–256.7)	148.0 (68.9–339.1)	0.088
LVEF (%)	61.0 (54.0–67.0)	60.5 (50.0–67.0)	62.0 (58.0–66.0)	0.362
LVDd (mm)	36.0 (41.0–50.0)	46.0 (28.0–75.0)	46.0 (32.0–71.0)	0.901
LVDs (mm)	29.0 (26.0–35.0)	29.0 (15.0–57.0)	29.5 (20.0–62.0)	0.496
IST (mm)	10 (8–11)	10 (9–11)	9 (8.8–11.0)	0.322
PWT (mm)	10 (8–11)	10 (9–11)	9 (8–10)	0.300
LAD (mm)	38 (33.8–42.0)	38.0 (34.0–42.0)	37.0 (33.0–43.0)	0.720
Aortic stenosis (n, %)	5 (2.0%)	5 (3.4%)	0 (0%)	0.261
Aortic regurgitation (n, %)	3 (1.2%)	3 (2.1%)	0 (0%)	0.072
Mitral regurgitation (n, %)	10 (3.9%)	6 (4.1%)	4 (3.6%)	1.000
Tricuspid regurgitation (n, %)	16 (6.3%)	8 (5.5%)	8 (7.3%)	0.609
Antiplatelet drug (n, %)	52 (20.4%)	34 (23.4%)	18 (16.4%)	0.209
DOAC (n, %)	62 (25.1%)	43 (29.7%)	21 (19.1%)	0.059
Warfarin (n, %)	15 (5.9%)	5 (3.4%)	10 (9.1%)	0.070
Antiplatelet drug + OAC (n, %)	8 (3.1%)	7 (4.8%)	1 (0.9%)	0.143

Note: Values are expressed as the median (25th, 75th percentile) or n (%).

Abbreviations: APTT, activated partial thromboplastin time; BNP, brain natriuretic peptide; DOAC, direct oral anticoagulant; eGFR, estimated glomerular filtration rate; HbA1c, hemoglobin A1c; LVDd; left ventricular end-systolic diameter; LVDs; left atrial diameter; LVEF, left ventricular ejection fraction, left ventricular end-diastolic diameter; MPH, microporous polysaccharide hemospheres; OAC, oral anticoagulant; PT-INR, prothrombin time-international normalized ratio.

PHs were observed after 4 (IQR: 3–5) days, whereas it was detected after 1 (IQR: 1–2) day in the no-MPH group. Among the patients who developed PH in the No-MPH group, five (38.5%) required recompression, eight (61.5%) required prolonged compression, and four (30.7%) discontinued antithrombotic medication. In the MPH group, four patients (44.4%) required recompression, five (55.5%) required prolonged compression, and one (11.1%) discontinued antithrombotic drugs. No patient required drainage or reoperation because of PHs or treatment for device infection during the follow-up period.

A Kaplan–Meier curve of freedom from PHs revealed no significant difference between the two groups (log-rank $p=.102$) (Figure 2A). Additionally, we analyzed subgroups categorized based on oral antithrombotic drug use, including antiplatelet drugs, DOACs, and warfarin. In the subgroup of patients not taking antithrombotic drugs, five patients (3.8%) experienced PHs. No significant difference was observed in PH incidence between those who used MPH hemostatic agents and those who did not (log-rank $p=.559$) (Figure 2B). In contrast, 17 (13.8%) patients experienced PH among those taking

TABLE 2 Procedure characteristics.

	All ($n=255$)	MPH group ($n=115$)	No-MPH group ($n=110$)	p value
Type of CIED				
PM	229 (87.5%)	115 (79.3%)	108 (98.2%)	<.001
CRT-P	7 (2.7%)	6 (4.1%)	1 (0.9%)	
ICD	16 (6.3%)	16 (11.0%)	0 (0%)	
CRT-D	9 (3.5%)	8 (5.5%)	1 (0.9%)	
High-power device	25 (9.8%)	24 (16.6%)	1 (0.9%)	<.001
Number of leads				
1	2 (0.8%)	2 (1.4%)	0 (0%)	.007
2	237 (92.9%)	129 (89%)	108 (98.2%)	
3	16 (6.3%)	14 (9.7%)	2 (1.8%)	
Procedure time (min)	90 (78–120)	100 (85–110)	80 (70–110)	.002
Days of compression	2 (2–3)	2 (2–3)	2 (2–3)	.844

Note: Values are expressed as the median (25th, 75th percentile) or *n* (%).

Abbreviations: CIED, cardiovascular implantable electronic devices; CRT-D, cardiac resynchronization therapy defibrillators; CRT-P, cardiac resynchronization therapy pacemaker; ICD, implantable cardiac defibrillators; MPH, microporous polysaccharide hemospheres; PM, Pacemaker.

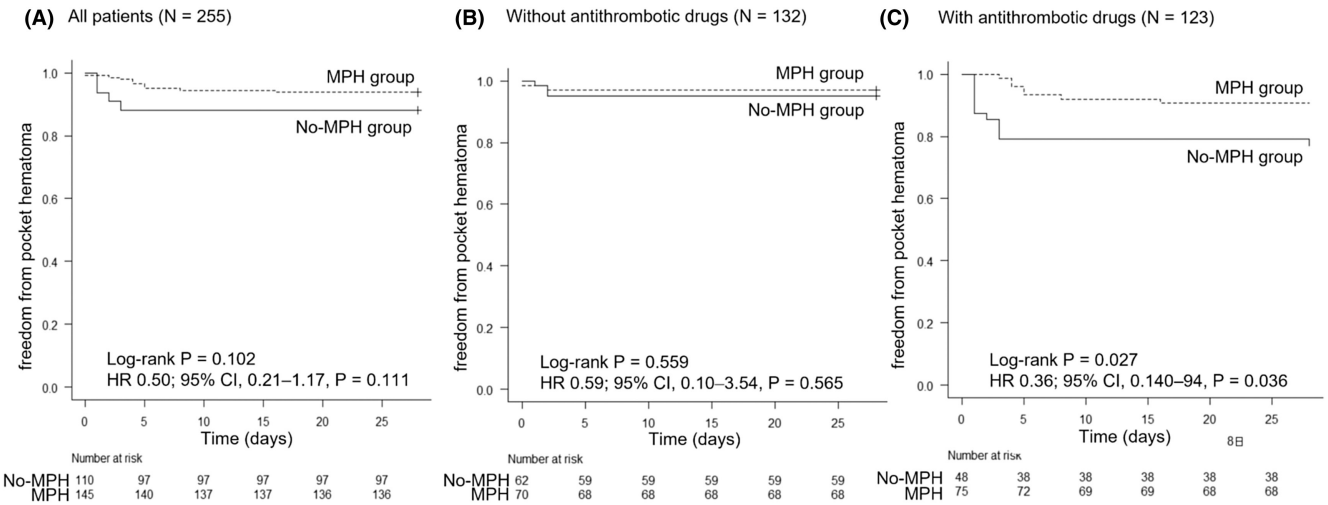

FIGURE 2 Kaplan–Meier curves of the freedom from pocket hematoma within 28 days after the implantation of a cardiac implantable electronic device in the total population (A), in patients not taking any antithrombotic medication (B), and in patients at least one antithrombotic medication (C). The dotted line is the Kaplan–Meier curve for the group that used the MPH hemostatic agent and the solid line is for the group that did not use it. MPH, microporous polysaccharide hemospheres.

antithrombotic drugs. The utilization of MPH hemostatic agents resulted in a significant reduction in PH incidence (log-rank $p=.027$) (Figure 2C).

Two patients in the MPH group experienced PHs after a prolonged period: in one case, an 81-year-old woman with a BMI of 13.9 and creatinine clearance of 31 mL/min, who was taking appropriate dose of apixaban (2.5 mg twice-daily) for atrial fibrillation, underwent implantation with a dual-chamber PM and developed a PH on postoperative Day 8. The PH improved after discontinuing the DOAC and re-applying compression. The patient's PH formation may have been influenced by postoperative delirium, as the patient was agitated and unable to maintain rest. In the other case, a 62-year-old man on a daily dose of aspirin (100 mg) and warfarin (4.5 mg), owing to his history of ventricular aneurysm after coronary stenting, underwent ICD implantation. The patient's preoperative INR was 1.45. The patient underwent postoperative wound compression for 3 days and was discharged on postoperative Day 6. However, on postoperative Day 16, the patient presented to the outpatient clinic with wound swelling, and a PH was identified. The PH improved after the patient discontinued warfarin, and compression was re-applied.

The duration from CIED implantation to discharge was 7 days (IQR: 5–8) in the MPH group and 6 days (IQR: 5–8) in the non-MPH group,

TABLE 3 Multivariable analysis after adjusting for the factors associated with pocket hematoma, using Cox proportional hazards model.

	Univariate analysis				Multivariate analysis			
	HR	95% CI		*p* value	HR	95% CI		*p* value
MPH hemostatic agents	0.50	0.21	1.17	.111	0.22	0.08	0.63	.004
Age	0.99	0.95	1.03	.542	0.99	0.94	1.03	.568
Women	1.62	0.70	3.81	.261	1.86	0.79	4.93	.214
Body Mass Index	0.95	0.84	1.06	.346				
Hypertension	0.93	0.40	2.17	.862				
Diabetes mellitus	0.95	0.37	2.42	.912				
Heart failure	1.78	0.70	4.54	.230				
Renal dysfunction	0.83	0.35	1.99	.683				
Antiplatelet drug	1.47	0.57	3.75	.423	3.62	1.20	10.96	.023
DOAC	4.53	1.94	10.61	<.001	8.01	2.99	21.38	<.001
Warfarin	0.76	0.10	5.45	.733	1.03	0.13	8.52	.973
High-power device	2.03	0.69	6.00	.200	4.75	1.18	20.78	.028

Abbreviations: CI, confidence intervals; DOAC, direct oral anticoagulant; HR, hazard ratios; MPH, microporous polysaccharide hemosphere.

with the former being significantly longer ($p = .019$). Notably, none of the patients required surgical treatment or re-hospitalization for PH.

Univariate and multivariate analysis for the factors associated with PH were shown in Table 3. In univariate analysis, the hematoma occurrence was not affected by the presence of comorbidities such as hypertension, diabetes mellitus, heart failure, and renal dysfunction. In contrast, taking DOAC was significantly associated with increasing risk of hematoma (HR 4.53; 95% CI, 1.94–10.61; $p < .001$). After adjusting for the covariates (use of MPH hemostatic agents, age, gender, antiplatelet drug, DOAC, warfarin, and high-power device), using a multivariate Cox proportional hazards model, the use of MPH hemostatic agents (HR 0.22; 95% CI, 0.08–0.63; $p = .004$), antiplatelet drugs (HR 3.62; 95% CI, 1.20–10.96; $p = .023$), DOAC (HR 8.01; 95% CI, 2.99–21.38; $p < .001$), and high-power device (HR 4.75; 95% CI, 1.18–20.78; $p = .028$) were observed to be independently associated with PH risk.

4 | DISCUSSION

This study is the first to demonstrate the effect of MPH hemostatic agents on PH control during CIED implantations among the Japanese population. The use of MPH hemostatic agents was independently associated with a reduced PH risk. Moreover, MPH hemostatic agents significantly reduced PH incidence among patients taking at least one antithrombotic drug.

The use of MPH hemostatic agents has been reported in various medical fields, including urology and surgery.[12–15] However, only one study investigated their use in CIED implantation.[9] The study was a retrospective observational design involving 283 patients who underwent CIED implantation. The PH incidence was 0.4% in the group with MPH hemostatic agents and 0.9% in the group without MPH hemostatic agents. The study demonstrated that hemostatic agents reduced the incidence of complex endpoints, including PH and infections, with an HR of 2.7. However, we observed several differences between this previous study and our study. The first notable difference lies in the patient background or characteristics of the participants involved in each study. The previous study reported a mean age of 71–72 years, whereas the participants in our study were older, with a mean age of 79 (IQR: 72–84) years. The higher mean age of patients in our study, with a considerable representation of older individuals, reflects a common characteristic in Japan, where a large proportion of the population consists of older patients.[16,17] This demographic trend should be considered when interpreting the study's results and may have implications for healthcare practices in the country.

The difference in the proportion of patients receiving antithrombotic medication is another notable distinction between the two studies. In the previous study, the adherence rate to DOACs was low, with only 2% and 5.2% in the group with MPH hemostatic agents and those without MPH hemostatic agents. Additionally, the previous study did not state the proportion of patients taking antiplatelet medications, such as aspirin. In contrast, our study included patients with a higher utilization rate of antithrombotic drugs, potentially influencing the outcomes and comparisons between the two studies. Among the patients in our study, 48.2% were taking one or more oral antithrombotic drugs, which increased their risk of bleeding complications. PH occurred in 14% of patients who were on at least one antithrombotic drug, indicating a relatively high rate of such complications in this subgroup. This finding highlights the importance of considering the effect of antithrombotic medications on bleeding risk during CIED implantations. Therefore, our research, which included a substantial proportion of patients taking antithrombotic drugs, who inherently have an increased risk of bleeding complications, offers valuable insights into the efficacy of MPH hemostatic agents in this vulnerable population.

Third, the difference in the dose of MPH hemostatic agents used between the previous study and our study is another important

aspect. In the previous study, the dose of MPH hemostatic agents varied between 1 and 5 g at the discretion of the treating physician. However, in our study, a standardized dose of 1 g was consistently used in all cases. This uniform dosing approach in our study enables a more controlled and direct assessment of the specific effects of the MPH hemostatic agents on PH incidence, minimizing potential confounding factors related to varying dosages.

In this study, we followed the protocol of continuing warfarin and discontinuing DOAC. It is important that there is still a lack of evidence and standardized protocol regarding whether to continue or interrupt preprocedural DOAC use. The statement and guideline suggest that the decision should be made at the discretion of the physician.[10,18] In this context, a previous literature on perioperative DOAC management of CIED implantation reported that 96% of patients had their DOAC interrupted 12 h prior to the procedure.[19] We also consider that relatively short half-lives of DOAC compared to warfarin makes it more flexible option for interruption when deemed necessary.

Based on our findings, which demonstrate that using MPH hemostatic agents among the Japanese population was independently associated with a reduction in PH, their utilization in CIED implantation may be a favorable option. Additionally, the findings of our study suggest that MPH hemostatic agents could be an effective and valuable tool to mitigate the PH risk, especially in patients at high risk, such as those on antithrombotic medications. This result emphasizes the potential clinical significance of using MPH hemostatic agents as a preventative measure in patients on antithrombotic medications during CIED implantations. Furthermore, our findings provide valuable insights for healthcare professionals in managing this specific patient population and underscore the potential benefits of using MPH hemostatic agents to improve outcomes in these patients. Whereas MPH hemostatic agents may not be essential in patients without antithrombotic medication, our study may help determine the use of hemostatic agents in consideration of the perioperative risk for PH.

While it was expected that the utilization of MPH hemostatic agents would lead to a shorter duration of hospital stay by improving wound management, our findings revealed that the MPH group had a significantly longer duration from CIED implantation to discharge. When comparing baseline characteristics between the two groups, although not statistically significant, the MPH group tended to have slightly more comorbidities such as DM and renal dysfunction. In light of these observations, longer hospital stays in the MPH group may be because of other factors than the presence of PH may have influenced the duration of hospital stay.

This study had some limitations. First, this study was retrospectively evaluated in a single center in Japan and was therefore subject to selection bias by including a highly selected population. Second, our study was constrained by its overall size. The small sample size may have prevented certain variables (i.e., DM, HF, renal dysfunction, and DOAC use) from reaching statistical significance between the two groups. Moreover, the limited number of patients who reached the study endpoint might reduce the statistical robustness of our multivariable analysis. Therefore, further studies are needed to confirm and extend our findings. Third, the present study, warfarin was not found to be an independent risk for PH, which may include patients with inadequate warfarin control, as indicated by a median PT-INR of 1.88 (IQR: 1.02–2.85). Fourth, the attending physician was left to assess postoperative wounds and make the decision to discontinue the antithrombotic medication or continue compression. Lastly, this study was conducted among the Japanese population limiting its generalizability to individuals from different ethnic backgrounds.

5 | CONCLUSION

The findings of the present study suggest that the use of MPH hemostatic agents may contribute to reducing PH incidence in patients receiving antithrombotic medications. Incorporating MPH hemostatic agents during CIED implantations in such patients may be considered as a valuable addition. This highlights the potential practicality and effectiveness of MPH hemostatic agents in mitigating the risk of complications in these cases. However, it is essential to note that further research is necessary to define the clinical benefit of implementing MPH hemostatic agents during CIED implantation.

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The authors have nothing to report.

FUNDING INFORMATION

None.

CONFLICT OF INTEREST STATEMENT

The authors declare that there is no conflict of interest.

DATA AVAILABILITY STATEMENT

Not applicable.

ETHICS STATEMENT

The Ethics Committee of the National Hospital Organization Yokohama Medical Center (No. 2022-29) approved this retrospective, single-center observational study.

PATIENT CONSENT STATEMENT

Written informed consent for the publication of clinical details and clinical images was obtained from the patient. Permission to reproduce material from other sources.

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