AUTHORS' CONTRIBUTIONS

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CONFLICTS OF INTEREST

The authors declare no conflict of interests.

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REFERENCES

1. Marques A, Sarmento H, Martins J, Saboga Nunes L. Prevalence of physical activity in European adults - Compliance with the World Health Organization's physical activity guidelines. *Prev Med.* 2015;81:333–338.
2. Conn VS, Hafdahl AR, Mehr DR. Interventions to increase physical activity among healthy adults: meta-analysis of outcomes. *Am J Public Health.* 2011;101:751–758.
3. García-Ortún F, Jaén A, Solá L, González-Gil L, Garreta R, de la Sierra A. Physical training program for people at risk of cardiovascular disorders in the primary care setting: A randomized clinical trial. *Med Clin (Barc).* 2022. http://dx.doi.org/10.1016/j.medcli.2022.01.020.
4. Laaksonen DE, Lindstrom J, Lakka TA, et al. Physical activity in the prevention of type 2 diabetes: the Finnish diabetes prevention study. *Diabetes.* 2005;54:158–165.
5. Martín-Borràs C, Giné-Garriga M, Puig-Ribera A, et al. PPAF Group. A new model of exercise referral scheme in primary care: is the effect on adherence to physical activity sustainable in the long term?. A 15-month randomised controlled trial. *BMJ Open.* 2018;8:e017211.
6. Harber MP, Kaminsky LA, Arena R, et al. Impact of Cardiorespiratory Fitness on All-Cause and Disease-Specific Mortality: Advances Since 2009. *Prog Cardiovasc Dis.* 2017;60:11–20.

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Impact on early patient mobilization of the use of a single vascular closure device in patients undergoing leadless pacemaker implantation

Impacto en la movilización precoz con el uso de un único dispositivo de cierre vascular en pacientes tratados con implante de marcapasos sin cable

To the Editor,

Leadless pacing has become a safe alternative to conventional pacing. This has led to an increase in its use in clinical practice, particularly in elderly individuals.[1] The only leadless pacing device currently available is the Micra transcatheter pacing system (TPS, models MC1VR01 and MC1AVR1; Medtronic plc, United States), which is implanted via the femoral vein using a large-bore introducer (27 Fr). Despite the caliber of the system, the clinical experience indicates a low risk of vascular complications. Nonetheless, the standard manual compression-mediated hemostasis necessitates 24-hour postimplantation resting of the lower limbs, which delays patient mobilization.

Vascular closure devices represent an alternative to manual compression-mediated hemostasis and permit early patient mobilization. However, their use with the Micra device is infrequent. The reported experience is based on a technique involving 2 such devices for the closure of a single vascular access site.[2] In this scientific letter, we report our experience with the use of a single vascular closure device for hemostasis of the puncture site after Micra implantation.

In June 2021, we began to systematically use the Perclose system (ProGlide/ProStyle, Abbott, United States) in our center for femoral hemostasis during Micra implantation. The Perclose device comprises a percutaneous vascular closure system involving a pretied polypropylene monofilament suture.

All procedures were performed according to the guidelines of the institutional research ethics board of Sant Pau Hospital, and all patients provided written informed consent. Direct oral anticoagulant therapy was withdrawn 24 hours before the procedure, as well as vitamin K antagonists until an INR $\leq$ 2 was achieved. Implants were performed according to the standard technique and with conscious sedation.[3] Femoral venous access was achieved using ultrasound-guided puncture. The access site was predilated with an 8-Fr introducer and the Perclose device was deployed while the polypropylene filaments were retained. Through the Perclose, a conventional metal guidewire was introduced to once again advance the 8-Fr introducer and this wire was then exchanged for an extra-stiff guidewire. Serial dilatation was performed with a single 18-Fr dilator, followed by a 27-Fr introducer for the implantation. If considerable tortuosity was encountered while the implant material was being advanced toward the heart, iliofemoral venous angiography was performed, although this was rare. The 27-Fr introducer and the release system were constantly perfused with heparinized serum, without the administration of additional anticoagulant. After removal of the 27-Fr introducer, the vascular closure was finalized by advancing the propylene filament knot. Once hemostasis was confirmed, the access site was covered with a dressing, without compression. Patient mobilization was recommended 6 hours after implantation.

Table 1
Baseline characteristics of the study population

Patients, No.	62
Age, y	85.6 ± 6.5
Male sex	27 (43.5)
Hypertension	53 (85.5)
Diabetes mellitus	16 (25.8)
Chronic kidney disease	18 (29.0)
Heart disease	33 (53.2)
LVEF, %	0.54 ± 0.09
Heart failure	22 (35.5)
Atrial fibrillation	33 (53.2)
Atrial fibrillation at implantation	28 (45.2)
Stroke	12 (19.4)
Peripheral vascular disease	3 (4.8)
Oral anticoagulation	28 (45.2)
Direct anticoagulation	18 (29.0)
Vitamin K antagonists	10 (16.1)
Preimplant INR if administered vitamin K antagonist	1.50 ± 0.29
Pacing indication	
Atrioventricular block	46 (74.2)
AF with a slow ventricular response	13 (21.0)
Sinus node dysfunction	5 (8.1)
Pacemaker model	
Micra VR	37 (60.0)
Micra AV	25 (40.0)

AF, atrial fibrillation; AV, pacemaker with atrioventricular synchrony; INR, international normalized ratio; LVEF, left ventricular ejection fraction; VR, single-chamber pacemaker.
Values are reported as mean ± standard deviation or No. (%).

The objective of the current study was to evaluate the hemostatic effectiveness of the closure device, patient mobilization 6 hours after the procedure, and vascular access complications in the first postimplantation month.

Percutaneous vascular closure was performed using a single Perclose device in 62 patients implanted with the Micra device. Patients' clinical characteristics are shown in table 1. The mean patient age was 85.6 ± 6.5 years and 16 of the patients (25.8%) were ≥ 90 years old; 28 patients (45.1%) were receiving chronic anticoagulation.

Table 2 shows the implant characteristics. Complete hemostasis was achieved in 59 of the 62 patients (95.2%). Early mobilization 6 hours after implantation was accomplished in 45 of the 59 patients (76%) successfully managed with the Perclose system. In the 14 remaining patients, early mobilization failure was considered to be due to nonimplantation-related factors: 3 patients with implantation immediately after transcatheter aortic valve implantation, 1 in the subacute phase of stroke, 1 with intense back pain due to vertebral fracture, and 9 with cognitive decline/drowsiness. The 3 patients with partial device effectiveness were at the start of the series. In these 3 patients, hemostasis was effectively achieved by adding an external "figure-of-8 suture" with a 3-way stopcock. No vascular access-associated complications were seen in the peri-implantation period or in the first 30 postimplantation days.

Table 2
Implantation characteristics

Patients, No.	62
Successful implantation	62 (100)
Procedure time, min	32.7 ± 10.2
Percutaneous closure device effectiveness	59 (95.2)
Early mobilization (6 h, if percutaneous closure device was effective)	45 (76.3)
Complications (peri-implantation and 30 d after implant)	
Major complications	0
Vascular access complications	0

Values are reported as mean ± standard deviation or No. (%).

Based on our outcomes, we conclude that the use of a single Perclose vascular closure device during implantation of the Micra leadless pacemaker is highly safe and effective and permits the early mobilization of the vast majority of patients.

Early mobilization is a particularly relevant aspect for the profile of patients receiving pacemakers, who are typically elderly and with comorbidity. Our research group had previously proven the safety and effectiveness of the Micra device in elderly patients.[1] Nonetheless, the need for a prolonged postimplantation recovery period related to the vascular access had limited the early mobilization of these patients. This restriction additionally represented a clear disadvantage vs conventional transvenous pacemakers, which allow safe same-day discharge.[4] Kiani et al. has proposed the same-day discharge of patients receiving a leadless pacemaker, using femoral hemostasis with a "figure-of-8 suture". However, the restriction of the early discharge to highly selected patients and the nonnegligible risk of vascular complications limited the standardized use of the figure-of-8 suture for systematic early discharge strategies.[5] The use of a vascular closure device overcomes this limitation classically associated with leadless pacemakers and permits consideration of a safer same-day discharge after implantation. The ability of the device to reduce the length of hospital stay remains to be assessed, although it is a real possibility with an undoubted potential impact at both clinical and economic levels.

The closure device was also safe and effective in chronically anticoagulated patients with the standard temporary peri-implantation adjustment/interruption protocol. The use of a device with a strategy that maintains full peri-implantation anticoagulation has not yet been evaluated.

The good safety and effectiveness profile of the Perclose system has already been reported for Micra implantation in younger patients and using the dual-device preclosure technique.[2] However, the use of a single device simplifies the vascular closure technique and shows a similar safety and effectiveness profile, even in elderly patients.

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AUTHORS' CONTRIBUTIONS

All authors contributed significantly to the current work. All authors participated in the data collection and drafting of the scientific letter, made critical revisions, and approved the final submitted document.

CONFLICTS OF INTEREST

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REFERENCES

1. El Amrani A, Campos B, Alonso-Martín C, et al. Performance of the Micra cardiac pacemaker in nonagenarians. *Rev Esp Cardiol.* 2020;73:307–312.
2. Deshmukh A, Ghannam M, Cunnane R, Liang JJ. Double ProGlide preclose technique for vascular access closure after leadless pacemaker implantation. *J Interv Card Electrophysiol.* 2022;63:341–343.
3. Ritter P, Duray GZ, Steinwender C, et al. Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study. *Eur Heart J.* 2015;36:2510–2519.
4. Trongtorsak A, Kewcharoen J, Thangjui S, Worapongsatitaya P, Yodsuwan R, Navar-avong L. Same-day discharge after implantation of cardiac implantable electronic devices: A systematic review and meta-analysis. *Pacing Clin Electrophysiol.* 2021;44:1925–1933.
5. Kiani S, Black GB, Rao B, et al. The Safety and Feasibility of Same-Day Discharge After Implantation of MICRA Transcatheter Leadless Pacemaker System. *J Atr Fibrillation.* 2019;12:2153.

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Association between in-hospital glycemic control and neurological outcome at 6 months of follow-up in survivors of out-of-hospital cardiac arrest

Asociación entre el control de la glicemia intrahospitalaria y el pronóstico neurológico a 6 meses en supervivientes a una parada cardiaca extrahospitalaria

To the Editor,

Hyperglycemia is common in survivors of out-of-hospital cardiac arrest (OHCA). It is associated with increased mortality and worse neurological outcomes. Current guidelines advise its treatment,[1] but the optimal blood glucose level for this population has not been evaluated in randomized clinical trials.

To determine whether in-hospital glycemic control is associated with neurological outcome at 6 months, we performed an ambispective observational study of a cohort of OHCA survivors admitted to the acute cardiac care unit of our center between May 2019-April 2021. The study was approved by the ethics committee and all patients/relatives signed the informed consent form. The inclusion criterion was being admitted for an OHCA and remaining comatose after return of spontaneous circulation (ROSC). The exclusion criteria were refusal to provide informed consent and being lost to follow-up. As part of in-hospital standard management, intravenous or subcutaneous basal-bolus insulin regime treatment protocols were applied for all patients as per treating physician discretion. Point of care glycemia measurements were performed before the morning, afternoon, evening meals, and at midnight during the basal-bolus insulin regime, or hourly during intravenous treatment. The insulin dose was modified, with the goal of maintaining blood glucose levels between 100-180 mg/dL over the entire hospitalization. For each patient, the values retrieved were: first blood glucose, mean blood glucose during hospitalization (BGOH), blood glucose in the morning, afternoon, evening and night, maximum blood glucose, and percentage of blood glucose values within the 100-180 mg/dL target. Insulin doses could not be retrieved from the system properly.

Evaluation of neurological outcome was structured, multimodal and multidisciplinary. Withdrawal of life-sustaining therapy was decided in consensus with the entire the team, concluding the patient had poor neurological outcome. Neurological outcome at 6 months was evaluated according to the cerebral performance category (CPC) score. Patients were divided into 2 groups: "good" (CPC 1–2) or "poor" (CPC 3–5) neurological outcome. Patients who died were included in this last group.

Univariate analysis was performed between the 2 groups. A stepwise logistic regression model was performed to determine covariates independently associated with neurological outcome.

After an initial screening log of 50 patients, 45 patients were included in the final analysis (3 were lost to follow-up and 2 did not sign the informed consent form). Median age was 60.1 [interquartile range, 50.9-70.6] years, most were male (86.7%), 22 (48.9%) patients had good neurological outcome (CPC 1-2) and mortality at 6 months was 46.7% (most deaths—85.7%—occurred during hospitalization and were the consequence of neurological injury and/or withdrawal of life-sustaining therapy). Demographic and clinical characteristics were similar between the 2 groups: 76% had a first shockable rhythm and an acute coronary syndrome was the cause in 58%. All patients required mechanical ventilation and were treated with active targeted temperature management in agreement with current guidelines.[1] Most of them (89%) received vasopressor/inotrope support. Blood glucose, lactate, APACHE-II, and SOFA scores were higher in patients with CPC 3-5 (table 1). A total of 3190 blood glucose determinations were performed during hospitalization. Patients with good neurological outcome had lower BGOH mg/dL (130 [124-138] vs 166 [131-187], $P < .01$), lower glycemia at all time slots (figure 1), and a higher percentage of glycemic controls within the 100-180 mg/dL target (83.8% vs 64.8%; $P < .01$). Moreover, maximum glycemia was lower in patients with good neurological outcome (218 [180-259] vs 278 [232-420]; $P < .01$). As expected, BGOH was lower in nondiabetic individuals (132 [124-138] vs 185 [130-217]; $P < .01$). However, we found no interaction between glycemic control variables and diabetes status in the association with neurological outcome. In the logistic regression analysis, only BGOH (odds ratio, 1.03; 95% confidence interval, 1.006-1.07) and APACHE-II (odds ratio, 1.34; 95% confidence interval, 1.10-1.64) were independently associated with neurological outcome (area under the curve of the model 0.879, $P < .01$).

In this observational study of comatose survivors of OHCA, lower average blood glucose values during hospitalization, irrespective of diabetic status, were associated with better neurological outcome at 6 months. Previous studies found consistent results. A multicenter analysis[2] determined that in survivors of OHCA, glycemia between 70-140 mg/dL was associat-