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## Twelve-month effect of a 2-month training program conducted in primary care for patients at cardiovascular risk

### *Efecto a los 12 meses de un programa de entrenamiento de 2 meses realizado en atención primaria para pacientes con riesgo cardiovascular*

**To the Editor,**

Despite the importance of physical activity (PA) for cardiovascular health, only 60% of the European population comply with the World Health Organization's recommendations (at least 150 minutes of moderate PA per week).[1] Effective interventions to encourage PA are urgently needed. The different strategies reported so far have shown a moderate effect for up to 3 to 6 months after the intervention, but there is little evidence from longer follow-up periods.[2] In a clinical trial, our working group on primary cardiovascular prevention previously demonstrated the short-term positive impact on moderate PA of a 2-month training program (TP) delivered in primary care.[3] The aim of the present study was to evaluate whether this effect persisted at 1 year after completion of the program.

The study design and methods have been described previously.[3] Briefly, the program included sedentary patients of both sexes, aged between 35 and 70 years, who were at risk of cardiovascular events: with type 2 diabetes, metabolic syndrome, or hypertension, and at least 1 other cardiovascular risk factor. The control group (CG) and the intervention group (IG) received an

**Table 1**
Baseline values for sociodemographic data, cardiovascular risk factors, and physical exercise for the patients assessed at 1-year of follow-up and between-group differences

| | Control group (n = 55) | Intervention group (n = 56) | *P* |
|---|---|---|---|
| **Demographics** | | | |
| *Age, y* | 59.1 ± 7.9 | 59.8 ± 7.4 | .638 |
| *Male* | 29 (52.7) | 34 (60.7) | .396 |
| *Abdominal circumference, cm* | | | |
| Men | 105.7 ± 10.8 | 110.8 ± 11.5 | .084 |
| Women | 110.0 ± 8.2 | 105.8 ± 13.4 | .189 |
| *Body mass index* | 31.1 ± 4.1 | 30.8 ± 4.7 | .702 |
| *Smokers* | 19 (34.5) | 20 (35.7) | .855 |
| *Educational level* | | | .606 |
| Primary education | 29 (52.7) | 30 (54.5) | |
| Secondary education | 20 (36.4) | 15 (27.3) | |
| Further education | 6 (10.9) | 10 (18.2) | |
| *Live alone* | 10 (18.2) | 4 (7.3) | .151 |
| **Cardiovascular risk factors** | | | |
| *Hypertension* | 44 (80.0) | 50 (89.3) | .174 |
| Systolic blood pressure, mmHg | 139.7 ± 15.7 | 143.9 ± 17.1 | .177 |
| Diastolic blood pressure, mmHg | 89.8 ± 9.1 | 90.4 ± 8.9 | .753 |
| *Dyslipidemia* | 42 (76.4) | 44 (78.6) | .781 |
| Total cholesterol, mg/dL | 208.1 ± 36.7 | 196.4 ± 41.4 | .124 |
| HDL-C, mg/dL | 51.0 ± 11.0 | 51.4 ± 12.2 | .871 |
| LDL-C, mg/dL | 123.6 ± 30.0 | 115.9 ± 30.6 | .227 |
| Triglycerides, mg/dL | 148.7 ± 101.1 | 149.2 ± 81.6 | .979 |
| *Diabetes* | 30 (54.5) | 26 (46.4) | .392 |
| Glycated hemoglobin, % | 6.8 ± 1.1 | 6.7 ± 1.3 | .804 |
| **Physical exercise** | | | |
| *Sufficient amount of exercise* * *(≥ 360 MET-min/week)* | 3 (5.4) | 2 (3.6) | .679 |

HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; MET, metabolic equivalent.
Values are expressed as mean ± standard deviation or No. (%).
* Recorded with international physical activity questionnaire, long version.

**Table 2**
Baseline and final values (at 1-year of follow-up) for physical activity and physical condition and differences between the control and intervention groups

| | Control group (n = 55) | | Intervention group (n = 56) | | β (95% CI)* | *P* |
|---|---|---|---|---|---|---|
| | Baseline | Final | Baseline | Final | | |
| *Physical activity* | | | | | | |
| Total moderate activity,[a] MET-min/wk | 80 [0-360] | 80 [0-540] | 30 [0-210] | 390 [0-1200] | 398 (145; 651) | .002 |
| Total IPAQ,[a] MET-min/wk | 445 [198-891] | 876 [400-1551] | 427 [160-829] | 1473 [702-2085] | 504 (200; 809) | .001 |
| Walking activity,[a] MET-min/wk | 247 [0-742] | 495 [264-1140] | 198 [16-627] | 594 [198-1386] | 130 (−132; 392) | .326 |
| Time spent sitting,[a] min/wk | 2945 [1860-3600] | 2610 [2100-3390] | 2875[2055-3700] | 2575 [2040-3400] | 44.4 (−279;368) | .786 |
| *Physical condition* | | | | | | |
| 6-min walk test, m | 532 ± 65.0 | 542 ± 84.4 | 501 ± 77.2 | 541 ± 96.7 | 21.3 (−4.7; 47.4) | .107 |
| Peak $VO_2$, mL/kg/min | 23.2 ± 5.3 | 23.9 ± 5.5 | 23.5 ± 4.8 | 24.0 ± 5.0 | −0.1 (−1.3; 1.2) | .932 |
| Exercise time, min | 11.0 ± 3.4 | 12.4 ± 3.1 | 11.3 ± 3.0 | 13.2 ± 2.4 | 0.7 (0.1; 1.3) | .018 |
| Peak oxygen pulse,[b] mL $VO_2$/beat | 14.7 ± 3.3 | 14.6 ± 3.2 | 14.7 ± 3.5 | 14.4 ± 3.7 | −0.2 (−0.9; 0.5) | .546 |
| Maximum HR, beats/min | 138.5 ± 18.8 | 138.7 ± 17.1 | 139.6 ± 17.6 | 143.2 ± 16.8 | 3.8 (−1.3;8.9) | .144 |
| Maximum HR, % estimated maximum HR[c] | 85.6 ± 10.6 | 86.2 ± 10.4 | 86.9 ± 10.4 | 89.5 ± 10.3 | 2.6 (−0.6;5.8) | .115 |
| Time to AT, min | 9.8 ± 2.5 | 9.9 ± 2.7 | 9.8 ± 2.6 | 10.7 ± 2.4 | 0.9 (0.2; 1.5) | .007 |
| $VO_2$ at AT, mL/kg/min | 21.1 ± 4.4 | 20.4 ± 3.7 | 21.5 ± 4.4 | 20.0 ± 4.8 | −0.2 (−1.4; 0.9) | .664 |
| $CO_2$ equivalent[d] at AT | 27.1 ± 3.4 | 26.9 ± 2.6 | 26.8 ± 3.0 | 27.8 ± 3.4 | 0.5 (−0.2; 1.2) | .154 |

95% CI, 95% confidence interval; AT, anaerobic threshold; HR, heart rate; MET, metabolic equivalent; $VO_2$, oxygen consumption.
Values are expressed as median [interquartile range] or mean ± standard deviation.
[a] Recorded with the international physical activity questionnaire, long version.
[b] Maximum oxygen pulse: peak oxygen consumption/maximum heart rate.
[c] Estimated maximum HR: 220 – age.
[d] $CO_2$ equivalent: VE (minute volume, mL/min)/$VCO_2$ ($CO_2$ production in mL/min).
[e]Coefficients adjusted for baseline values, age, and sex.

educational talk on heart-healthy habits. The IG participated in an 8-week TP with 3 sessions per week of aerobic exercise and strength training, in groups of 6 supervised by a physiotherapist. The IG received a median [interquartile range] of 22 [20-23] exercise sessions per patient, with 91% [83%-95%] adherence. At the start of the program and at 1 year, PA was assessed with the international physical activity questionnaire (IPAQ) and the brief physical activity assessment tool, and physical condition was assessed with cardiopulmonary exercise testing on a treadmill (modified Bruce protocol) and a 6-minute walk test. The study was approved by the hospital ethics committee, with reference number EO/1220. Written informed consent was obtained from all participants.

Statistical analysis (between-group differences in changes in the variables analyzed) was performed with linear regression analysis, and regression coefficients and their 95% confidence intervals (95% CI) were determined with adjustment for the baseline values of the different outcome variables and for age and sex. Stata S/E v.13 software was used.

Of the 147 patients assessed and randomized at the start of the study (75 in the IG and 72 in the CG), 111 were included in the 1-year analysis (56 in the IG and 55 in the CG). No significant between-group differences were observed in the baseline characteristics for the group evaluated at 1 year (table 1). Cardiopulmonary exercise testing was maximal (maximum respiratory quotient > 1.1) in 62% of the patients at the baseline assessment and in 76.3% at the final assessment, with no differences between groups.

The values at baseline and at 1 year for PA and physical condition, as well as between-group differences, are shown in table 2. At 1 year, the IG had a significantly greater increase than the CG for the overall IPAQ result ($P = .001$), due to a significantly greater increase in moderate PA ($P = .002$). The proportion of patients who at 1 year were doing a "sufficient frequency of physical exercise" (≥ 3 times/wk) was also significantly higher in the IG (41.1% vs 23.6%; $P = .05$). For physical condition, the IG group had significantly greater increases at 1 year than the CG in cardiopulmonary exercise test duration ($P = .018$) and in anaerobic threshold delay ($P = .007$). The results were similar in both age groups (younger and older than 60 years) and sex groups (male and female). Although the improvement in PA was generally somewhat higher in the men and the under 60s, the confidence intervals of the coefficients showed a clear overlap between subgroups (data not shown).

This study demonstrates that the positive effect of the TP on PA persisted at 1 year after its completion, with the notable feature that, unlike other studies,[4] there were no refresher sessions during the follow-up period. In another study that did not involve refresher sessions, the improvements at 1-year follow-up were mostly increased walking time, with no changes in moderate PA.[5] With our TP, the increase in moderate PA of 360 MET-min/wk (90 min/wk) was enough to improve certain physical condition variables, but not enough to significantly affect others, such as the 6-minute walk test and peak oxygen consumption ($VO_2$). Although the 390 MET-min/wk (99 min/wk) of moderate PA recorded in the IG at 1 year after the TP did not meet the recommendatons,[1] small increases in moderate PA are known to be associated with improvements in cardiovascular risk.[4,6]

The main limitation of this study is the self-reporting of PA using a questionnaire, which is known to overestimate accelerometer recordings.

In conclusion, this TP delivered in a primary care center had a positive impact on PA at 1 year. Key to encouraging medium-to-long-term improvements in PA with an effect on cardiovascular health are strategies involving health care professionals, delivered in primary care centers, with individualized assessment and close supervision.

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## AUTHORS' CONTRIBUTIONS

Design and field work: F. García-Ortún, Á. Jaén, L. Solá, L. González-Gil, A. Alvarez Auñon. Statistical analysis and writing first draft: F. García-Ortún, Á. Jaén, A. de la Sierra. All authors: review, writing, editing, reading, and approval of the final version.

## CONFLICTS OF INTEREST

The authors declare no conflict of interests.

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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.