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NATIONAL REGISTRY

# Editor's Choice – Effect of Physical Activity and Tobacco Use on Mortality and Morbidity in Patients with Peripheral Arterial Disease After Revascularisation: A Korean Nationwide Population Based Cohort Study

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**WHAT THIS PAPER ADDS**

The number of patients with peripheral arterial disease (PAD) is highest in the Western Pacific (74.08 million), yet there are few studies in this region. This study included 8 324 patients from the Western Pacific country of Korea with PAD after revascularisation. Physically active patients had substantially lower all cause mortality, major adverse outcome, and major adverse limb events than inactive patients, while current tobacco users had higher rates of those outcomes. Therefore, supervised exercise and tobacco cessation programmes should be promoted to reduce mortality and morbidity rates in patients with PAD after revascularisation in the Western Pacific region.

**Objective:** To investigate the effects of physical activity (PA) and tobacco use on adverse clinical outcomes after revascularisation for peripheral arterial disease (PAD) in the Western Pacific region, where PAD cases and tobacco use are among the highest in the world.

**Methods:** This was a retrospective cohort study using the Korean National Health Insurance Service (NHIS) database and included patients who had received revascularisation for PAD between 2010 and 2015. They were categorised as active or inactive based on the number of days per week they engaged in PA and as current or non-tobacco users (self report). The primary outcome was all cause mortality. Secondary outcomes included major adverse outcome (a composite of all cause mortality, myocardial infarction, and stroke) and major adverse limb event (MALE, a composite of amputation and recurrent revascularisation).

**Results:** The relatively healthy cohort comprised 8 324 patients (mean age 64.7 years; 76.9% male) following revascularisation for PAD. Among them, 32.7% were inactive and 26.4% were tobacco users. Active patients had better outcomes than inactive patients (all cause mortality adjusted hazard ratio [adjHR] 0.766; 95% CI 0.685 — 0.855, major adverse outcome adjHR 0.795; 95% CI 0.719 — 0.878, MALE adjHR 0.858; 95% CI 0.773 — 0.953). Tobacco users had poorer outcomes than non-users (all cause mortality adjHR 1.279; 95% CI 1.124 — 1.456, major adverse outcome adjHR 1.263; 95% CI 1.124 — 1.418, MALE adjHR 1.291; 95% CI 1.143 — 1.458).

**Conclusion:** Even after receiving revascularisation for PAD, a sizable proportion of patients were physically inactive and used tobacco, leading to adverse clinical outcomes such as death, cardiovascular morbidity, and amputation in Korea. These modifiable risk factors should be addressed systematically, and a comprehensive approach including supervised exercise programmes and tobacco cessation is needed in patients with PAD.

**Keywords:** Mortality, Peripheral arterial disease, Physical activity, Tobacco use, Tobacco use cessation
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## INTRODUCTION

Peripheral arterial disease (PAD) is a progressive atherosclerotic disease. There are over 236 million people suffering from PAD worldwide, with the highest number of cases in the Western Pacific region (74.08 million) and lowest in the Eastern Mediterranean (14.67 million) globally.[1] PAD negatively affects quality of life and functional

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status, inducing pain and limitations to walking.[2,3] Moreover, PAD is associated with an increased risk of cardiovascular morbidities, such as myocardial infarction (MI) and stroke,[4] and an increased mortality rate, especially in the case of critical limb ischaemia (CLI).[5,6]

The management of PAD depends on the clinical stage of disease.[7,8] For asymptomatic patients (Fontaine stage I), reduction of cardiovascular risk factors is important, while improvement in pain, walking distances, and quality of life as well as risk factor management is emphasised in patients with intermittent claudication (Fontaine stage II). In patients with more severe CLI (Fontaine stage III or IV), surgery or endovascular procedures for limb preservation should be considered. According to recent guidelines, regular physical activity (PA) is recommended in all patients with PAD,[8] and patients with higher PA showed less functional decline.[9] Additionally, higher levels of PA are associated with reduced mortality, and cardiovascular events.[10] However, patients with PAD often perform lower levels of PA and experience greater functional decline than those without PAD.[11] Moreover, PA still remains low after revascularisation, although the walking ability and quality of life is improved.[12,13] Research on the impact of low PA after revascularisation on mortality or limb events is still lacking, particularly in regions where the PAD burden is high.

Regarding other key health behaviours, tobacco use is closely associated with PAD.[14] Tobacco use increases PAD related hospitalisations and healthcare costs.[15] Tobacco cessation is strongly recommended for all patients with PAD, as it leads to increased walking distance and amputation free survival.[8,16] In a few observational studies, approximately 30% of the patients with PAD were tobacco users, and less than half of the users were able to quit successfully.[17,18] Despite the availability of effective cessation interventions, there are limited real world data on tobacco use in patients with PAD, especially in Asian countries including Korea, Japan, China, and the Philippines where the prevalence and degree of tobacco use are higher than in other countries.[19]

This study aimed to investigate the effects of PA and tobacco use in patients with PAD on clinical outcomes including all cause mortality, MI, stroke, minor and major amputation, and recurrent revascularisation in a large, representative, population based cohort in a Western Pacific country. It was postulated that PA would have a beneficial effect, while tobacco use would have a harmful effect on adverse clinical outcomes. If demonstrated, given that these risk factors are modifiable through proven approaches, efforts to address them could then reduce mortality and morbidity.

## MATERIALS AND METHODS

### *Data source*

The Korean National Health Insurance Service (NHIS) is a single payer organisation covering the entire population. The NHIS reimburses primary and specialty care such as hospitalisations and emergency department visits in Korea. About 97% of citizens are covered by the NHIS, and the remaining 3% with the lowest income are covered by Medicaid (they are included in the NHIS database). Information on sociodemographic characteristics (including socio-economic status), past medical history, and mortality was collected for the NHIS.[20] The database contains information on healthcare claims, including diagnoses as per the International Classification of Diseases, 10th revision, Clinical Modification (ICD−10−CM) codes.[21]

The Korean NHIS provides a biennial health check up for all inhabitants older than 40 years or those who are employed regardless of age. The participation rate of complete health check ups is approximately 77%.[22] Through this programme, height, weight, and blood pressure are measured; laboratory tests including blood cell count and chemistry are completed together with a self administered questionnaire on medical history and health related behaviours.

This study was exempted from review by the Seoul National University Bundang Hospital Institutional Review Board (IRB number X-2001-591-901), complying with the requirements of the Declaration of Helsinki. Data from the Korean NHIS were fully anonymised for analyses, and the need for informed consent was waived.

### *Study cohort*

Records of patients with PAD admitted for revascularisation, from 1 January 2010 to 31 December 2015 were screened (Supplementary Fig. S1). Those who participated in the health check ups after revascularisation within two years were included in the cohort for this study.

Exclusion criteria were as follows: (1) age $<$ 40 years; (2) past medical history of MI and stroke; (3) history of minor and major limb amputation; and (4) occurrence of MI, stroke, recurrent revascularisation, and amputation during the period from the day of revascularisation therapy to the day of health check up (Supplementary Fig. S2).

Interventional codes for revascularisation[23] and amputation and ICD-10-CM codes for MI and stroke are presented in Supplementary Table S1.

### *Measures*

**Physical activity and tobacco use.** A self administered questionnaire on leisure time PA using a seven day recall method was distributed at the time of the health check up (Supplementary Fig. S3). The questionnaire was in Korean and consisted of three items similar to the assessment by Smith *et al.*;[24] the validity and reliability have been established.[25] PA level was classified as “active” or “inactive” based on the number of days per week that patients engaged in PA (Supplementary Fig. S4), similar to previous research.[26]

In addition, PA related energy expenditure (MET min/week) was calculated by summing the multiples of frequency, intensity, and duration of PA. Light intensity (walking), moderate intensity, and vigorous intensity PA thresholds used were 2.9, 4.0, and 7.0 METs, respectively.[27] Then, PA related energy expenditure was categorised into quartiles.

Patients were categorised as current tobacco users or non-users based on the responses to the questionnaire. Additionally, tobacco non-users were further classified as never users or former users, and current tobacco users were classified based on quantity used (i.e., 1 – 19 cigarettes per day, or ≥ 20 cigarettes per day), resulting in four categories.

Finally, further analysis was performed with subgroups based on the combination of PA and tobacco status; inactive tobacco user, inactive non-user, active tobacco user, and active non-user.

**Clinical outcomes.** Adverse clinical outcomes after the health check up were followed in the study population until 31 December 2018. The NHIS database is linked to Korean Statistics, which records the death of all Korean citizens. Death from any cause was considered. MI and stroke were defined as admission with claims and diagnostic codes I21–22 and I60–64, respectively. Major adverse outcome included death, MI, and/or stroke.

Repeat revascularisation and amputation were defined through confirmation of procedural codes, as stated previously for revascularisation therapy, and minor and major amputation, respectively. Major adverse limb event (MALE) was defined as any repeat revascularisation and/or amputation.

**Covariable data.** Details of covariable data are described in the Supplementary material.

### *Statistical analysis*

The characteristics of the study population were described using means with standard deviation, or numbers with percentages. To compare categorical and continuous variables between the "active" and "inactive" groups, the chi square and Student *t* tests were used, as applicable. Cox proportional hazard regression analysis was used to evaluate the effect of PA and tobacco use on adverse clinical outcomes adjusted for age, sex, procedure type, income quartile, rural residence, past medical history, Charlson Comorbidity Index (CCI), medication use, length of hospital stay, days from revascularisation to health check up, and categorised waist circumference, fasting plasma glucose, and low density lipoprotein. The Kaplan–Meier curves were plotted in groups classified by PA and tobacco use. Further analyses were performed including patients who suffered death, MI, stroke, and amputation during a washout period. Statistical analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC, USA). A two sided $p$ value $<$ .050 was regarded as statistically significant.

## RESULTS

### *Cohort characteristics*

A total of 8 324 patients were included in the analysis (Supplementary Fig. S2). The mean age was 64.7 years, and 76.9% were male. They predominantly underwent endovascular procedures (85.0%), followed by open bypass surgery (11.9%), and combined open bypass and endovascular procedures (3.1%).

Days from revascularisation to the health check up are shown in Table 1. In the cohort, 2 721 patients (32.7%) were inactive, and 2 193 (26.3%) were tobacco users (Table 1). Inactive patients were older, mostly female, had lower income, and were more often living in a rural area than their active counterparts. They had more end stage renal disease, greater waist circumferences, more frequent tobacco use, and longer hospital stays. Procedure type and alcohol consumption were notably different in the two PA groups (Table 1).

Tobacco users were younger, were more often male, and had lower income than non-users. Most had diabetes mellitus and dyslipidaemia, higher CCI, and higher low density lipoprotein levels. Moreover, they had less end stage renal disease cases, smaller waist circumferences, and shorter hospital stays. Procedure type and alcohol consumption were notably different between tobacco users and non-users (Table 1).

### *Effect of physical activity and tobacco use on clinical outcomes*

The median and maximum follow up periods were 4.4 and 8.8 years, respectively. During the follow up period there were 1 338 deaths (16.1%), 552 MI and/or strokes (6.7%), and 1 679 recurrent revascularisations and/or amputations (20.2%).

The Kaplan–Meier analysis showed a significant difference in the clinical outcomes by PA (Supplementary Fig. S5). In the Cox proportional hazard regression analysis, active patients had significantly lower death (adjusted hazard ratio [adjHR] 0.766; 95% CI 0.685 – 0.855), major adverse outcome (adjHR 0.795; 95% CI 0.719 – 0.878), and MALE (adjHR 0.858; 95% CI 0.773 – 0.953) (Table 2).

When PA related energy expenditure (MET–min/week) was examined as quartiles, the Kaplan–Meier analysis revealed a difference in clinical outcomes (Fig. 1). The highest MET quartile was associated with lower adjHRs than the lowest quartile (death 0.593; 95% CI 0.505 – 0.696, major adverse outcome 0.636; 95% CI 0.553 – 0.732), MALE 0.859; 95% CI 0.747 – 0.987). The decrease in adjHR based on PA related energy expenditure was statistically significant for death, major adverse outcome, and MALE (Supplementary Table S2).

Current tobacco users had higher death (adjHR 1.279; 95% CI 1.124 – 1.456), major adverse outcome (adjHR 1.263; 95% CI 1.124 – 1.418), and MALE (adjHR 1.291; 95% CI 1.143 – 1.458) (Table 2). The Kaplan–Meier analysis did not show a statistically significant difference in clinical outcomes (Supplementary Fig. S5).

When tobacco use was further classified (tobacco never user, tobacco former user, 1 – 19 cigarettes per day, and ≥ 20 cigarettes per day), the latter two smoking groups showed higher adjHRs than the former two groups (Supplementary Table S3). The group smoking ≥ 20 cigarettes per day showed higher adjHRs than the group of never users (death 1.210; 95% CI 0.989 – 1.481, major adverse outcome 1.226; 95% CI 1.025 – 1.467, MALE 1.354; 95% CI 1.125 – 1.631). There was no statistically significant difference in clinical outcomes between former and never users. The Kaplan–Meier analysis showed a statistically significant difference in death and major adverse outcome, but not in MALE (Fig. 2).

**Table 1.** Sociodemographic and clinical characteristics by physical activity and tobacco use of a cohort of 8 324 patients revascularised for peripheral arterial disease between 2010 and 2015 in Korea

| | Total ($n$ = 8 324) | Physical activity | | | Tobacco use | | |
|---|---|---|---|---|---|---|---|
| | | Inactive ($n$ = 2 721) | Active ($n$ = 5 603) | $p$ | Current user ($n$ = 2 193) | Non–user ($n$ = 6 131) | $p$ |
| Age – y | 64.7 ± 10.5 | 65.9 ± 10.4 | 64.1 ± 10.4 | <.001 | 63.3 ± 9.9 | 65.2 ± 10.6 | <.001 |
| Male sex | 6 403 (76.9) | 1 988 (73.1) | 4 415 (78.8) | <.001 | 2 110 (96.2) | 4 293 (70.0) | <.001 |
| *Procedure type* | | | | .047 | | | .007 |
| Open bypass surgery | 987 (11.9) | 353 (13.0) | 634 (11.3) | | 250 (11.4) | 737 (12.0) | |
| Endovascular procedure | 7 078 (85.0) | 2 276 (83.6) | 4 802 (85.7) | | 1 853 (84.5) | 5 225 (85.2) | |
| Both | 259 (3.1) | 92 (3.4) | 167 (3.0) | | 90 (4.1) | 169 (2.8) | |
| *Income* | | | | <.001 | | | <.001 |
| Medicaid | 483 (5.8) | 181 (6.7) | 302 (5.4) | | 149 (6.8) | 334 (5.5) | |
| 1st quartile | 1 412 (17.0) | 499 (18.4) | 913 (16.3) | | 427 (19.5) | 985 (16.1) | |
| 2nd quartile | 1 336 (16.1) | 469 (17.2) | 867 (15.5) | | 403 (18.4) | 933 (15.2) | |
| 3rd quartile | 2 094 (25.1) | 703 (25.8) | 1 391 (24.8) | | 578 (26.3) | 1 516 (24.7) | |
| 4th quartile | 2 999 (36.0) | 869 (31.9) | 2 130 (38.0) | | 636 (29.0) | 2 363 (38.5) | |
| Rural residence | 4 940 (59.4) | 1 794 (65.9) | 3 146 (56.2) | <.001 | 1 291 (58.9) | 3 649 (59.5) | .60 |
| *Past medical history* | | | | | | | |
| End stage renal disease | 1 056 (12.7) | 386 (14.2) | 670 (12.0) | .004 | 117 (5.3) | 939 (15.3) | <.001 |
| Diabetes mellitus | 3 183 (38.2) | 1 026 (37.7) | 2 157 (38.5) | .49 | 894 (40.8) | 2 289 (37.3) | .005 |
| Hypertension | 5 808 (69.8) | 1 923 (70.7) | 3 885 (69.3) | .21 | 1 513 (69.0) | 4 295 (70.1) | .35 |
| Dyslipidaemia | 5 260 (63.2) | 1 679 (61.7) | 3 581 (63.9) | .050 | 1 504 (68.6) | 3 756 (61.3) | <.001 |
| *Waist circumference – cm* | | | | <.001 | | | <.001 |
| <90 in males, <80 in females | 5 556 (66.8) | 1 730 (63.6) | 3 826 (68.3) | | 1 648 (75.2) | 3 908 (63.7) | |
| ≥90 in males, ≥80 in females | 2 768 (33.2) | 991 (36.4) | 1 777 (31.7) | | 545 (24.8) | 2 223 (36.3) | |
| *Charlson Comorbidity Index* | | | | .71 | | | .012 |
| 0 | 317 (3.8) | 98 (3.6) | 219 (3.9) | | 65 (2.9) | 252 (4.1) | |
| 1 | 969 (11.6) | 311 (11.4) | 658 (11.7) | | 280 (12.8) | 689 (11.2) | |
| ≥2 | 7 038 (84.6) | 2 312 (85.0) | 4 726 (84.4) | | 1 848 (84.3) | 5 190 (84.7) | |
| *Fasting plasma glucose – mg/dL* | | | | .21 | | | .13 |
| <126 | 6 674 (80.2) | 2 203 (81.0) | 4 471 (79.8) | | 1 734 (79.1) | 4 940 (80.6) | |
| ≥126 | 1 650 (19.8) | 518 (19.0) | 1 132 (20.2) | | 459 (20.9) | 1 191 (19.4) | |
| *Low density lipoprotein – mg/dL* | | | | .13 | | | .004 |
| <70 | 2 222 (26.7) | 698 (25.7) | 1 524 (27.2) | | 637 (29.1) | 1 585 (25.8) | |
| ≥70 | 6 102 (73.3) | 2 023 (74.3) | 4 079 (72.8) | | 1 556 (70.9) | 4 546 (74.2) | |
| *Tobacco use* | | | | .001 | | | |
| Non-user | 6 131 (73.7) | 1 944 (71.4) | 4 187 (74.7) | | – | – | |
| Current user | 2 193 (26.3) | 777 (28.6) | 1 416 (25.3) | | – | – | |
| *Alcohol* | | | | <.001 | | | <.001 |
| Non-drinker | 5 831 (70.1) | 2 032 (74.7) | 3 799 (67.8) | | 1 113 (50.8) | 4 718 (76.9) | |
| Mild drinker | 2 119 (25.5) | 554 (20.4) | 1 565 (27.9) | | 875 (39.9) | 1 244 (20.3) | |
| Heavy drinker | 374 (4.4) | 135 (4.9) | 239 (4.3) | | 205 (9.3) | 169 (2.8) | |
| *Medication use* | | | | | | | |
| Lipid lowering agents | 5 126 (61.6) | 1 625 (59.7) | 3 501 (62.5) | .015 | 1 488 (67.9) | 3 638 (59.3) | <.001 |
| Antiplatelet agents, aspirin or clopidogrel | 7 019 (84.3) | 2 288 (84.1) | 4 731 (84.4) | .68 | 5 049 (82.4) | 1 970 (89.8) | <.001 |
| Length of hospital stay – d | 9.1 ± 9.2 | 9.6 ± 9.8 | 8.9 ± 8.9 | .002 | 8.3 ± 8.0 | 9.4 ± 9.6 | <.001 |
| Time from revascularisation to health check up – d | 341.3 ± 196.6 | 343.5 ± 197.3 | 340.3 ± 196.3 | .48 | 347.3 ± 193.2 | 339.2 ± 197.8 | .098 |

Data are presented as $n$ (%) or mean ± standard deviation.

When patients were classified into four groups based on PA and tobacco status, active tobacco non-users had lower adjHRs than inactive tobacco users (death 0.636; 95% CI 0.531 – 0.761, major adverse outcome 0.670; 95% CI 0.569 – 0.789, MALE 0.707; 95% CI 0.590–0.846) (Table 3). The Kaplan–Meier analysis also showed a statistically significant difference in clinical outcomes (Supplementary Fig. S6).

Further analyses were performed including patients who had MI, stroke, recurrent revascularisation, or amputation before the health check up, and outcomes were much the same (Supplementary Table S4).

## DISCUSSION

This population based longitudinal cohort study in the Western Pacific region with the highest number of PAD cases globally revealed that modifiable risk factors were not well controlled after receiving revascularisation; approximately one third of the patients with PAD were physically inactive and a quarter were using tobacco. Moreover, these common health risk behaviours were closely related to adverse clinical outcomes such as all cause mortality, morbidity, and MALE. Active patients had 14% – 23% lower adverse clinical outcomes than inactive patients, and tobacco users had 26% –

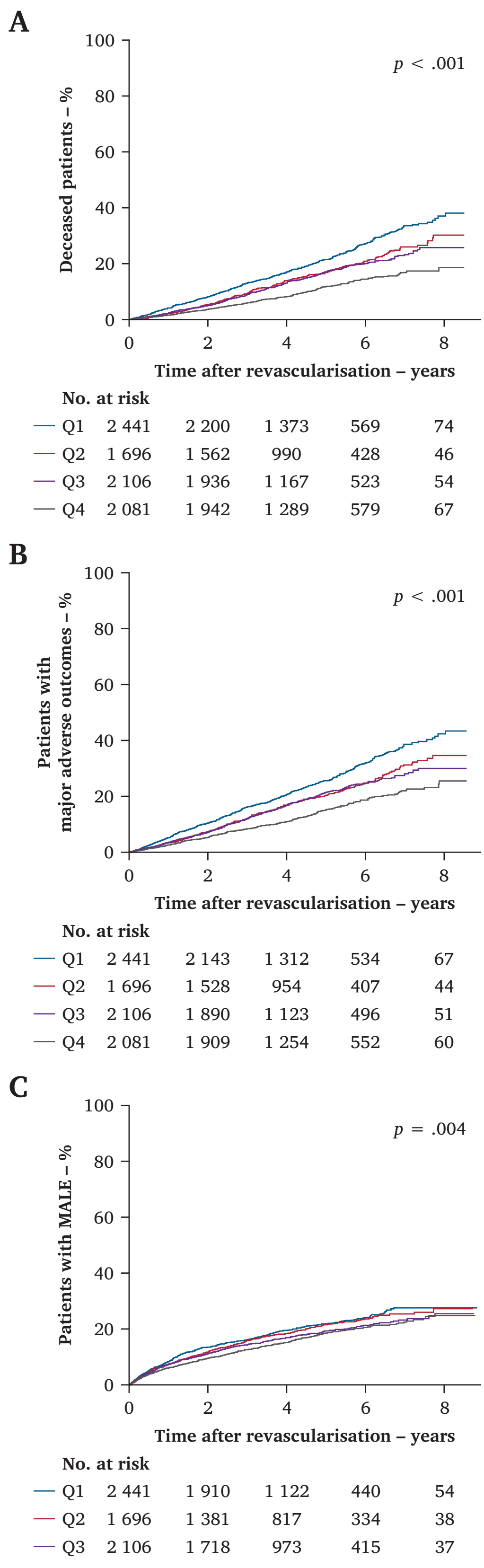
**Table 2.** Hazard ratios for death, major adverse outcomes, and major adverse limb events (MALE) according to physical activity and tobacco use in a cohort of 8 324 patients revascularised for peripheral arterial disease between 2010 and 2015 in Korea

| Group | Patients – *n* | Event – *n* | Follow up – person years | Incidence rate* | Crude (95% CI) | *p* | Model 1 (95% CI)† | *p* | Model 2 (95% CI)‡ | *p* |
|---|---|---|---|---|---|---|---|---|---|---|
| *Death* | | | | | | | | | | |
| *Physical activity* | | | | | | | | | | |
| Active | 5 603 | 773 | 25 349.6 | 30.494 | 0.643 (0.577–0.716) | <.001 | 0.700 (0.627–0.780) | <.001 | 0.766 (0.685–0.855) | <.001 |
| Inactive | 2 721 | 565 | 11 940.6 | 47.318 | Ref. | | Ref. | | Ref. | |
| *Tobacco use* | | | | | | | | | | |
| Current user | 2 193 | 365 | 9 892.3 | 36.898 | 1.037 (0.919–1.169) | .56 | 1.126 (0.994–1.276) | .062 | 1.279 (1.124–1.456) | <.001 |
| Non-user | 6 131 | 973 | 27 397.9 | 35.514 | Ref. | | Ref. | | Ref. | |
| *Major adverse outcome* | | | | | | | | | | |
| *Physical activity* | | | | | | | | | | |
| Active | 5 603 | 991 | 24 724.1 | 40.082 | 0.684 (0.62–0.754) | <.001 | 0.740 (0.670–0.816) | <.001 | 0.795 (0.719–0.878) | <.001 |
| Inactive | 2 721 | 677 | 11 582.2 | 58.452 | Ref. | | Ref. | | Ref. | |
| *Tobacco use* | | | | | | | | | | |
| Current user | 2 193 | 456 | 9 615.7 | 47.422 | 1.043 (0.936–1.161) | .44 | 1.138 (1.017–1.273) | .024 | 1.263 (1.124–1.418) | <.001 |
| Non-user | 6 131 | 1 212 | 26 690.5 | 45.409 | Ref. | | Ref. | | Ref. | |
| *MALE* | | | | | | | | | | |
| *Physical activity* | | | | | | | | | | |
| Active | 5 603 | 1 010 | 22 382.7 | 45.124 | 0.835 (0.753–0.926) | <.001 | 0.831 (0.749–0.921) | <.001 | 0.858 (0.773–0.953) | .004 |
| Inactive | 2 721 | 563 | 10 311.2 | 54.601 | Ref. | | Ref. | | Ref. | |
| *Tobacco use* | | | | | | | | | | |
| Current user | 2 193 | 431 | 8 654.8 | 49.799 | 1.048 (0.938–1.171) | .41 | 1.052 (0.937–1.182) | .39 | 1.291 (1.143–1.458) | <.001 |
| Non–user | 6 131 | 1 142 | 24 039.1 | 47.506 | Ref. | | Ref. | | Ref. | |

CI = confidence interval; Ref. = reference.
* The number of outcomes per 1 000 person years.
† Adjusted for age and sex.
‡ Adjusted for age, sex, procedure type, income quartiles, rural residence, past medical history, Charlson Comorbidity Index, medication use, length of hospital stay, days from revascularisation to health check up, categorised waist circumference, fasting plasma glucose, and low density lipoprotein.

29% higher adverse clinical outcomes than non-users after adjusting for multiple confounders. While these findings are concordant with those of a previous study,[10] this has now been established in a large number of patients with PAD who received revascularisation therapy, using nationwide, representative data, and in a broad range of clinical outcomes, such as mortality, recurrent revascularisation, and amputation, important to patients, clinician-scientists, and payers alike. After revascularisation, active patients with PAD showed better clinical outcomes with some degree of dose response relationship, although limited data on frequency, intensity, and type of PA were obtained. This supports the finding that patients with PAD need to increase PA after revascularisation in Korea. Low PA is a known risk factor for cardiovascular diseases and mortality;[28] however, few studies on the mechanisms underlying the benefit of PA in PAD have been conducted. PA decreases cytokines such as tumour necrosis factor α, interleukin 6, and interferon γ and inflammatory markers such as C reactive protein.[29] In addition, PA in PAD increases circulating endothelial progenitor cells, thus improving endothelial function[30] while decreasing adhesion molecules such as E selectin and intercellular adhesion molecule 1.[31] Consequently, muscle blood flow, capillary density, maximum heart rate, and peak oxygen consumption increases, while total and low density lipoprotein cholesterol decreases in response to PA in patients with PAD.[32]

However, there are barriers that limit PA in patients with PAD. Common barriers included walking induced pain, comorbid health concerns, lack of knowledge, and poor mobility.[3] Lack of physical energy and green space are reported barriers to PA in PAD.[33] Hence, it would be beneficial for patients to be prescribed individually tailored exercise programmes after taking into consideration a patient's PA history, current ability, preferences, and pain. Assessing other domains of PA such as leisure time activity could be effective considering that it is closely related to the ankle brachial index.[34] In addition, it is important to support and monitor patients to improve adherence and progress in activity. The benefits of exercise programmes were even greater when supervised by trained personnel.[35] Comprehensive approaches including supervised exercises and tobacco cessation similar to that delivered in cardiac rehabilitation could be an option in the management of PAD as shown in a recent randomised controlled study.[36] Given the prevalence of PAD in Korea




A — No. at risk

| | 0 | 2 | 4 | 6 | 8 |
|---|---|---|---|---|---|
| Q1 | 2 441 | 2 200 | 1 373 | 569 | 74 |
| Q2 | 1 696 | 1 562 | 990 | 428 | 46 |
| Q3 | 2 106 | 1 936 | 1 167 | 523 | 54 |
| Q4 | 2 081 | 1 942 | 1 289 | 579 | 67 |

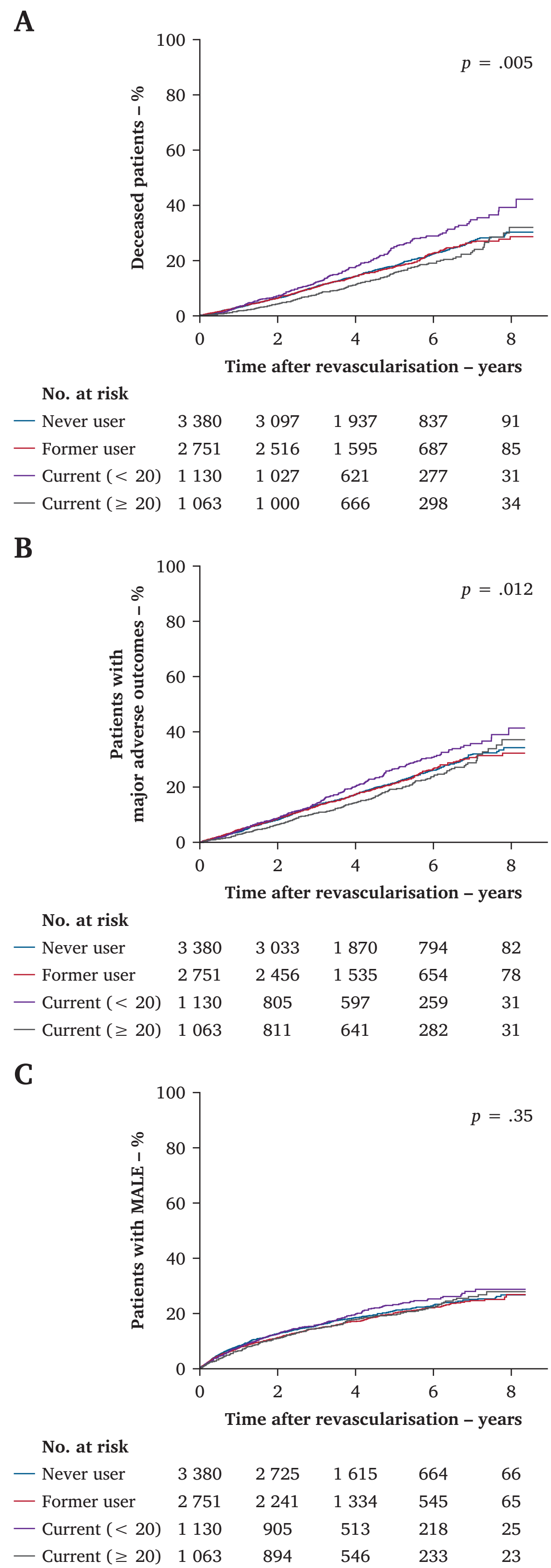
B — No. at risk

| | 0 | 2 | 4 | 6 | 8 |
|---|---|---|---|---|---|
| Q1 | 2 441 | 2 143 | 1 312 | 534 | 67 |
| Q2 | 1 696 | 1 528 | 954 | 407 | 44 |
| Q3 | 2 106 | 1 890 | 1 123 | 496 | 51 |
| Q4 | 2 081 | 1 909 | 1 254 | 552 | 60 |

C — No. at risk

| | 0 | 2 | 4 | 6 | 8 |
|---|---|---|---|---|---|
| Q1 | 2 441 | 1 910 | 1 122 | 440 | 54 |
| Q2 | 1 696 | 1 381 | 817 | 334 | 38 |
| Q3 | 2 106 | 1 718 | 973 | 415 | 37 |
| Q4 | 2 081 | 1 756 | 1 096 | 471 | 50 |

**Figure 1.** Cumulative Kaplan–Meier estimates for (A) mortality, (B) major adverse outcome, and (C) major adverse limb events (MALE) in 8 324 patients revascularised for peripheral arterial disease stratified by physical activity (PA) related energy expenditure in quartiles (Q1 being the lowest and Q4 the highest).




A — No. at risk

| | 0 | 2 | 4 | 6 | 8 |
|---|---|---|---|---|---|
| Never user | 3 380 | 3 097 | 1 937 | 837 | 91 |
| Former user | 2 751 | 2 516 | 1 595 | 687 | 85 |
| Current (< 20) | 1 130 | 1 027 | 621 | 277 | 31 |
| Current (≥ 20) | 1 063 | 1 000 | 666 | 298 | 34 |

B — No. at risk

| | 0 | 2 | 4 | 6 | 8 |
|---|---|---|---|---|---|
| Never user | 3 380 | 3 033 | 1 870 | 794 | 82 |
| Former user | 2 751 | 2 456 | 1 535 | 654 | 78 |
| Current (< 20) | 1 130 | 805 | 597 | 259 | 31 |
| Current (≥ 20) | 1 063 | 811 | 641 | 282 | 31 |

C — No. at risk

| | 0 | 2 | 4 | 6 | 8 |
|---|---|---|---|---|---|
| Never user | 3 380 | 2 725 | 1 615 | 664 | 66 |
| Former user | 2 751 | 2 241 | 1 334 | 545 | 65 |
| Current (< 20) | 1 130 | 905 | 513 | 218 | 25 |
| Current (≥ 20) | 1 063 | 894 | 546 | 233 | 23 |

**Figure 2.** Cumulative Kaplan–Meier estimates for (A) mortality, (B) major adverse outcome, and (C) major adverse limb events (MALE) in 8 324 patients revascularised for peripheral arterial disease stratified by tobacco use, and < 20 or ≥ 20 cigarettes per day.

**Table 3.** Hazard ratios for death, major adverse outcomes, and major adverse limb events (MALE) based on the combination of physical activity and tobacco use in a cohort of 8 324 patients revascularised for peripheral arterial disease between 2010 and 2015 in Korea

| Group | Patients – *n* | Event – *n* | Follow up – person years | Incidence rate* | Crude (95% CI) | *p* | Model 1 (95% CI)† | *p* | Model 2 (95% CI)‡ | *p* |
|---|---|---|---|---|---|---|---|---|---|---|
| *Death* | | | | | | | | | | |
| Inactive tobacco user | 777 | 161 | 3 461.4 | 46.512 | Ref. | <.001 | Ref. | <.001 | Ref. | <.001 |
| Inactive tobacco non-user | 1 944 | 404 | 8 479.1 | 47.647 | 1.028 (0.857–1.235) | | 0.972 (0.806–1.172) | | 0.833 (0.688–1.009) | |
| Active tobacco user | 1 416 | 204 | 6 430.8 | 31.722 | 0.681 (0.554–0.838) | | 0.759 (0.617–0.933) | | 0.816 (0.662–1.006) | |
| Active tobacco non-user | 4 187 | 569 | 18 918.8 | 30.076 | 0.647 (0.543–0.771) | | 0.664 (0.557–0.793) | | 0.636 (0.531–0.761) | |
| *Major adverse outcome* | | | | | | | | | | |
| Inactive tobacco user | 777 | 192 | 3 359.7 | 57.148 | Ref. | <.001 | Ref. | <.001 | Ref. | <.001 |
| Inactive tobacco non-user | 1 944 | 485 | 8 222.5 | 58.985 | 1.035 (0.876–1.224) | | 0.968 (0.815–1.149) | | 0.851 (0.715–1.014) | |
| Active tobacco user | 1 416 | 264 | 6 256.0 | 42.199 | 0.737 (0.612–0.888) | | 0.812 (0.674–0.978) | | 0.859 (0.712–1.037) | |
| Active tobacco non-user | 4 187 | 727 | 18 468.0 | 39.365 | 0.689 (0.587–0.807) | | 0.697 (0.594–0.819) | | 0.670 (0.569–0.789) | |
| *Male* | | | | | | | | | | |
| Inactive tobacco user | 777 | 154 | 2 997.3 | 51.380 | Ref. | .002 | Ref. | .002 | Ref. | <.001 |
| Inactive tobacco non-user | 1 944 | 409 | 7 314.0 | 55.920 | 1.085 (0.901–1.305) | | 1.091 (0.902–1.319) | | 0.834 (0.686–1.014) | |
| Active tobacco user | 1 416 | 277 | 5 657.6 | 48.961 | 0.959 (0.787–1.167) | | 0.955 (0.785–1.164) | | 0.934 (0.766–1.138) | |
| Active tobacco non-user | 4 187 | 733 | 16 725.2 | 43.826 | 0.860 (0.723–1.023) | | 0.860 (0.721–1.026) | | 0.707 (0.590–0.846) | |

CI = confidence interval.
* The number of outcomes per one 000 person years.
† Adjusted for age and sex.
‡ Adjusted for age, sex, procedure type, income quartiles, rural residence, past medical history, Charlson Comorbidity Index, medication use, length of hospital stay, days from revascularisation to health check up, categorised waist circumference, fasting plasma glucose, and low density lipoprotein.

and high degree of unhealthy behaviours, modifying these behaviours has the potential to substantially reduce morbidity and associated healthcare cost.

In the present study, tobacco users had approximately 30% higher rates of death, major adverse outcome, and MALE than non-users, while the amount of tobacco use did not substantially affect the clinical outcomes. In addition, active tobacco users showed approximately 20% higher mortality and morbidity than active non-users. The harmful consequences of tobacco are because of its effects on the endothelium, platelets, and coagulation.[37] Tobacco use induces vascular inflammation and oxidative stress.[38] Accordingly, tobacco users have more severe claudication, reduced exercise capacity, and poorer peripheral circulation.[39] However, tobacco users can achieve improvements in physical function after exercise, although users often have greater impairment than non-users at baseline.[40] Complete cessation is far more beneficial than only decreasing the amount of tobacco use as seen in a previous study.[41] Repeated counselling on cessation, nicotine replacement therapy, and medication such as bupropion should be offered.[42]

It is worth pointing out that the present study cohort included patients with less severe PAD than those in the real world setting. Because revascularisation is not practically possible in some patients with advanced diffuse disease, anatomically limited lesions, or severe comorbidities (so called no option patients),[43,44] these non-revascularisable patients with severe CLI were not included. In addition, patients with severe physical or cognitive disabilities were not able to participate in regular health check ups,[45] therefore, they were not analysed. Those with history of MI, stroke, and amputation were excluded from the analysis to increase the reliability of using medical claim code data, because the same diagnostic code can be claimed again without a new event (e.g., admission to receive follow up exams after MI). Last, patients who died or suffered from MI, stroke, and amputation during the washout period (the days from revascularisation to health check up was approximately one year) could not be investigated. The risk of amputation for CLI compared with intermittent claudication was especially high during the first six months, but it levelled out thereafter.[46] Therefore, the present study cohort consists of relatively healthier patients who underwent revascularisation for PAD. However, this population contains excellent candidates for supervised exercise programmes, considering their potential for compliance and expected benefits.

The strength of the present study was that a relatively large, nationwide study of the PAD population treated by revascularisation was evaluated. In addition, the study population stems from the Western Pacific region where cases of PAD are highest and tobacco habits differ from that of other regions from where much of the research in this area stems. Information on health behaviours such as PA, tobacco use, and alcohol, medication, past medical history, and socioeconomic status were obtained and adjusted for in the analysis. Long term adverse clinical outcomes were followed up for a median of 4.4 years.

This study has several limitations. First, the diagnosis of PAD was based on claim code data. However, intervention codes were used instead of diagnostic codes to increase the reliability as used in the previous study that reported national trends for treatment of PAD in Korea.[23] Given the relatively high cost for revascularisation procedures and the fact that input of claim codes for these procedures is mandatory for re-imbursement in Korean NHIS, missing data should be minimal. This approach has been used successfully in a previous study.[23] Second, selection bias may be present, considering that patients who did not attend a health check up were excluded; non-attendance may have been due to death, physical, or cognitive disabilities. In addition, patients who experienced MI, stroke, recurrent revascularisation, or amputation before the health check up (i.e., a washout period) were excluded. This explains why the present study cohort had a relatively lower annual mortality rate of about 3.7% compared with previous studies.[4,47] However, the results were consistent even when the analyses were conducted without the washout period (Supplementary Table S4). Third, other confounding factors were not included such as the extent of the lesion and severity or classification of PAD; attempts were made to include as many confounders for mortality and morbidity as possible in the analysis such as comorbidities, compliance with medication, and the length of hospital stay. Even though the length of stay is not an indicator for PAD severity, Giannopoulos *et al.* recently showed in the LIBERTY 360 study that the mean length of hospital stay after endovascular procedures was higher in CLI than intermittent claudication (Rutherford category [RC] 2 − 3: 14.2 days, RC 4 − 5: 32 days, and RC 6: 106.3 days).[48] Fourth, PA and tobacco use were assessed via a self administered questionnaire. Hence, the degree of PA may have been overstated; however, previous studies have established the psychometric properties and usefulness of self administered questionnaires in identifying inactivity.[24,49] In addition, although assessment by self report may underestimate the prevalence of tobacco use, it has been shown to be as sensitive in assessing tobacco use as urinary cotinine concentration.[50] Finally, the effects of supervised exercise programmes could not be evaluated because re-imbursement for comprehensive rehabilitation programmes including supervised exercise for cardiovascular diseases started after the study enrolment period in Korea.

### Conclusion

After receiving revascularisation therapy for PAD, 32.7% patients were inactive and 26.4% used tobacco in Korea. Inactive patients and tobacco users showed higher adjusted hazard ratios for death, cardiovascular morbidity, and amputation. Therefore, patients with PAD should be encouraged to attend supervised exercise and tobacco cessation programmes after revascularisation.

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## AVAILABILITY OF DATA AND MATERIALS

The data are available through the Korean National Health Insurance Sharing Service. Researchers who wish to access the data should apply on the website (https://nhiss.nhis.or.kr/bd/ay/bdaya001iv.do) and request access to NHIS-2020-1-339.

## CONFLICT OF INTEREST

None.

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## APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2022.05.047.

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**COUP D'OEIL**

# No Symptoms for Over 70 Years! Incidentally Discovered Congenital Dysplasia of Infrarenal Aorta

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A 75 year old female with a past history of pulmonary embolism was admitted with dyspnoea. Computed tomography angiography unexpectedly revealed a significantly narrowed and completely occluded abdominal aorta at the infrarenal level. She did not have any intestinal or lower limb problems, but she had had resistant hypertension for 40 years. Bilateral femoral, popliteal, and pedal pulses were palpable. The superior mesenteric artery (violet arrow), the arc of Riolan (white arrows), and the inferior mesenteric artery (red arrow) were dilated, providing adequate blood flow to the abdomen, pelvis, and lower limbs.

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