# Predictive Factors to Determine Post-Operative Mortality in Patients with Peripheral Arterial Disease

Rungrujee Kaweewan MD*, Saritphat Orrapin MD*,
Antika Wongthanee MSc**, Kittipan Rerkasem MD, PhD*.**

** NCD Center, Department of Surgery, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand*
*** NCD Research Center, Research Institute for Health Science, Chiang Mai University, Thailand*

***Objective:*** *Major vascular surgery of peripheral arterial disease (PAD) is a high post-operative mortality procedure. There are few studies in predictive factors for post-operative mortality in Asian populations. Assessing the predictive factors preoperatively can prolong survival in this population.*

***Material and Method:*** *The prospective study included patients with PAD who had major vascular surgery between December 2002 and December 2005 at the Maharaj Nakorn Chiang Mai Hospital. Survival status and predictive factors of mortality were analyzed.*

***Results:*** *One hundred one patients were included in the present study. Fifty-three patients died (62.3%) with 4.19 years of median survival time; 5-year survival was 47.28%. The predictive factors effecting mortality were hyponatremia (hazard ratio (HR) 17.69, 95% confidence interval (CI) 2.02 to 154.91), respiratory distress sign (shortness of breath at rest) (HR 12.36, 95% CI 2.12 to 71.75), atrial fibrillation (HR 3.18, 95% CI 1.39 to 7.29), abnormal plasma potassium (HR 2.80, 95% CI 1.28 to 6.15), and preoperative hypertension (HR 0.54, 95% CI 0.30 to 0.98).*

***Conclusion:*** *Serum hyponatremia, shortness of breath, atrial fibrillation, abnormal plasma potassium level, and hypertension were the predictive factors for high mortality in patients with PAD.*

***Keywords:*** *Post-operative mortality, Peripheral arterial disease, Risk factor*

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Vascular surgical operations are high-risk surgery because the rate of post-operative morbidity and mortality are very high[1]. This is the case for most patients with vascular disease who have multiple co-morbidities including cardiovascular disease, cerebrovascular disease, diabetes mellitus (DM), advanced age, renal insufficiency, and chronic lung disease due to heavy smoking, especially in patients with peripheral arterial disease (PAD) who need major vascular surgery, including vascular bypass and leg amputation[2]. Therefore, a study in the predictive factors associated with high mortality is needed. In fact, most studies in this aspect were already conducted in Western countries. Although the risk factors of PAD in Asian populations are due to hypertension, hypercholesterolemia, DM, and smoking as shown in the Western studies, the natural history and prognosis of metabolic disease in the Asian subjects appeared to be different from the Caucasians[3]. Tan et al showed that Asian patients with DM have higher rate of mortality and lower rate of limb salvage than Caucasians[4]. The study aimed to assess the predictive factors associated with long-term mortality in patients with PAD in order to improve the survival of patients, but there have been little data about predictive factors in Asian populations. Therefore, the authors piloted a study in such factors at Maharaj Nakorn Chiang Mai Hospital, Chiang Mai, Thailand.

***Correspondence to:***
*Rerkasem K, Division of Vascular and Endovascular Surgery, Department of Surgery, Faculty of Medicine, Chiang Mai University, Chiang Mai 50200, Thailand.*
*Phone: +66-53-935532, Fax: +66-53-936139*
*E-mail: rerkase@gmail.com*

## Material and Method

The data from patients with PAD with major vascular disease whom were operated between December 2002 and December 2005 at the Maharaj Nakorn Chiang Mai Hospital were collected. Major vascular surgery included arterial bypass and major lower extremities amputation (above and below the knee). Demographic data and baseline characteristics included age, gender, heart disease, chronic kidney disease, hypertension, DM, and history of smoking were collected. Heart diseases included these conditions: coronary artery disease, valvular heart disease, arrhythmia, and congestive heart failure. Other potential risk factors, such as respiratory rate, pulse rate, blood pressure, Glasgow coma score, complete blood count, serum electrolyte, and electrocardiogram were

recorded following procedures from previous studies including the Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) study[5]. Survival status data were collected through medical records and various hospital databases. These survival data were collected in October 2012. The study was approved by the Ethical Committee of Faculty of Medicine, Chiang Mai University.

The univariate analysis was performed by log rank test, and the multivariate analysis was carried out by Cox regression analysis. Statistical significant parameters on univariate analysis were included in multivariate analysis. The significance was considered to be $p<0.05$. All the statistical analyses were performed with STATA/IC Version 12.0 for Windows (StataCorp LP, Texas, USA). The survival curve was presented by Kaplan-Meier Survival curve.

## Results

One hundred one PAD patients were included in the present study. There were 57 males and 44 females. Fifty-three patients died (62.3%). Median survival time was 4.19 years. For 5 years-survival was 47.28%. The bypass operation and major amputation were carried out in 76 and 25 patients respectively (Table 1).

The result of univariate analysis showed that a previous history of heart disease was a statistically significant risk factor affecting the mortality of patients with PAD. Of the 16 patients who had heart disease, 14 died (87.5%). Patients who had cardiac distress severity sign and respiratory distress severity were associated with high mortality. In preoperative laboratory tests, the abnormalities in serum sodium, serum potassium, serum urea, white blood cell count, and electrocardiogram (EKG) were statistically and significantly associated with high mortality (Table 2).

In the results of multivariate analyzes (Table 3), factors affecting high mortality were hypertension (hazard ratio (HR) 0.54%, 95% confidence interval (CI) 0.30 to 0.98), respiratory distress sign (shortness of breath at rest) (HR 12.36, 95% CI 2.12 to 71.75), serum sodium less than 126 millimole per liter (mmol/L) (HR 17.69; 95% CI 2.02 to 154.91), abnormal serum potassium levels (HR 2.80, 95% CI 1.28 to 6.15), and abnormal EKG, especially atrial fibrillation (AF) (HR 3.18, 95% CI 1.39 to 7.29). Previous history of heart disease and abnormal white blood cell count were not a statistically significant association with high mortality in multivariate analyses. Kaplan-Meier survival curves of post-operative mortality were presented in Fig. 1 and 2. Patients with severe hyponatremia (serum sodium <126 mmol/L) were not survived in first year follow-up (Fig. 1). In EKG findings, the 6-year survival in patients with AF was lower than those with other EKG findings (Fig. 2).

**Table 1.** The types of operation

| Type of operation | Number of patients |
|---|---|
| Extra anatomical bypass | |
| Femoro-femoral bypass | 11 |
| Axillobifemoral bypass | 9 |
| In situ bypass | |
| Femoral-tibial bypass | 50 |
| Aorto bifemoral bypass | 6 |
| Major amputation | |
| Above knee amputation | 11 |
| Below knee amputation | 14 |

## Discussion

Patients with PAD showed a high post-operative mortality rate with a median survival time of 4.19 years, and a long-term mortality rate of 62.3% as in a previous UK trial[6]. The overall survival of PAD patients was 4.48 and 4.25 years after bypass surgery and balloon angioplasty, respectively. The high mortality rate of PAD was caused by multiple underlying patient diseases combined with high physiologic disturbances of vascular surgery procedures[2]. The authors also found that hyponatremia, respiratory sign of shortness of breath, AF, abnormal plasma potassium levels, and hypertension were predictive factors for high mortality in patients with PAD. The results indicated that cardiovascular disease included AF and hypertension, and both were significant risk factors as shown in the previous study by Criqui et al, which concluded that patients with PAD were high-risk candidates for death due to cardiovascular disease[7].

Hypertension directly affects either the cardiac system (hypertensive heart disease) by left ventricular hypertrophy and heart failure, or the systemic vascular system (hypertensive vasculopathy) by coronary heart disease, renal artery stenosis, and cerebrovascular disease, which is associated with myocardial infarction, chronic renal insufficiency, and stroke[8]. All of these are life-threatening diseases and cause high mortality as mention above. The West Birmingham atrial fibrillation project study suggested that the symptomatic PAD with AF should be regarded as the high mortality condition, and these high-risk patients should have surgery[9]. Goto et al[10] showed

**Table 2.** Patient characteristics

| Characteristics | Person-years | Died | Incidence rate (per person-year) | Rate ratios | 95% CI | *p*-value |
|---|---|---|---|---|---|---|
| Gender | | | | | | |
| Male | 238.18 | 32 | 13.44 | Ref. | | |
| Female | 154.21 | 31 | 20.10 | 1.47 | 0.88 to 2.43 | 0.136 |
| Age group (years) | | | | | | |
| <60 | 110.87 | 16 | 14.43 | Ref. | | |
| 60-70 | 141.68 | 21 | 14.82 | 1.03 | 0.53 to 1.99 | 0.925 |
| >70 | 139.84 | 26 | 18.59 | 1.12 | 0.83 to 1.52 | 0.461 |
| Diabetic mellitus | | | | | | |
| No | 245.64 | 41 | 16.69 | Ref. | | |
| Yes | 146.76 | 22 | 14.99 | 0.91 | 0.54 to 1.53 | 0.729 |
| Hypertension | | | | | | |
| No | 185.55 | 37 | 19.94 | Ref. | | |
| Yes | 206.84 | 26 | 12.57 | 0.66 | 0.40 to 1.08 | 0.096 |
| History of cerebrovascular disease | | | | | | |
| No | 386.19 | 63 | 16.31 | Ref. | | |
| Yes | 6.21 | 0 | | 0 | | 0.339 |
| Heart disease | | | | | | |
| No | 348.25 | 49 | 14.07 | Ref. | | |
| Yes | 44.14 | 14 | 31.72 | 2.17 | 1.19 to 3.96 | 0.010 |
| Chronic kidney disease | | | | | | |
| No | 378.28 | 59 | 15.60 | Ref. | | |
| Yes | 14.12 | 4 | 28.33 | 1.87 | 0.67 to 5.22 | 0.223 |
| Smoking | | | | | | |
| No | 200.94 | 27 | 13.44 | Ref. | | |
| Yes | 191.46 | 36 | 18.80 | 1.40 | 0.85 to 2.32 | 0.188 |
| Cardiac sign | | | | | | |
| Normal | 348.91 | 52 | 14.90 | Ref. | | |
| Use cardiac drug | 6.21 | 0 | 0.00 | 0.36 | 0.04 to 3.15 | 0.356 |
| Warfarin use, borderline cardiomegaly | 24.05 | 4 | 16.63 | 1.10 | 0.63 to 1.90 | 0.744 |
| Cardiomegaly | 13.23 | 7 | 52.89 | 1.98 | 1.28 to 3.05 | 0.002 |
| Respiratory sign | | | | | | |
| Normal | 377.20 | 55 | 14.58 | Ref. | | |
| Mild COPD | 7.63 | 2 | 26.20 | 2.15 | 0.34 to 13.74 | 0.419 |
| Moderate COPD | 6.03 | 4 | 66.29 | 3.97 | 1.53 to 10.30 | 0.005 |
| Short of breath at rest | 1.53 | 2 | 130.45 | 4.16 | 1.44 to 12.03 | 0.009 |
| Systolic blood pressure (mmHg) | | | | | | |
| 110-129 | 227.87 | 33 | 14.48 | Ref. | | |
| 130-170 or 100-109 | 154.38 | 28 | 18.14 | 1.21 | 0.72 to 2.01 | 0.470 |
| >170 or 90-99 | 10.14 | 2 | 19.72 | 1.11 | 0.51 to 2.41 | 0.798 |
| Pulse rate (beats per minute) | | | | | | |
| 50-80 | 195.02 | 32 | 16.41 | Ref. | | |
| 81-100 or 40-49 | 179.46 | 28 | 15.60 | 0.94 | 0.56 to 1.58 | 0.818 |
| 101-120 | 17.92 | 3 | 16.74 | 1.03 | 0.56 to 1.89 | 0.922 |
| Serum sodium (mmol/L) | | | | | | |
| >136 | 253.48 | 41 | 16.17 | Ref. | | |
| 131-135 | 106.07 | 19 | 17.91 | 1.09 | 0.63 to 1.91 | 0.750 |
| 126-130 | 32.65 | 2 | 6.12 | 0.73 | 0.45 to 1.19 | 0.206 |
| <126 | 0.19 | 1 | 521.79 | 58.00 | 5.40 to 622.56 | 0.001 |
| Serum potassium (mmol/L) | | | | | | |
| 3.5-5.0 | 351.43 | 47 | 13.37 | Ref. | | |
| 3.1-3.4 or 5.1-5.3 | 26.75 | 9 | 33.65 | 3.31 | 1.23 to 8.90 | 0.018 |
| 2.9-3.1 or 5.4-5.9 | 7.15 | 5 | 69.97 | 4.84 | 1.97 to 11.86 | 0.001 |
| <2.9 or >5.9 | 7.07 | 2 | 28.27 | 1.38 | 0.72 to 2.64 | 0.336 |
| Electrocardiogram | | | | | | |
| Normal | 356.74 | 48 | 13.46 | Ref. | | |
| Atrial fibrillation rate 60-90/minute | 19.98 | 11 | 55.07 | 8.27 | 2.88 to 23.81 | 0.000 |
| Any other | 15.68 | 4 | 25.51 | 1.55 | 0.78 to 3.05 | 0.208 |

CI = confidence interval; Ref. = reference; COPD = chronic obstructive pulmonary disease; mmHg = millimeter of mercury; mg/dl = milligram per deciliter; mmol/L = millimole per liter; g/dl = grams per deciliter

**Table 3.** Characteristics of patient that effecting mortality on multivariate analysis

| Risk factors | Adjusted hazard ratio | 95% CI | *p*-value |
|---|---|---|---|
| Hypertension | | | |
| No | Ref. | | |
| Yes | 0.54 | 0.30 to 0.98 | 0.042 |
| Respiratory sign | | | |
| Normal | Ref. | | |
| Mild COPD | 1.98 | 0.45 to 8.65 | 0.362 |
| Moderate COPD | 1.98 | 0.62 to 6.32 | 0.250 |
| Short of breath at rest | 12.36 | 2.12 to 71.75 | 0.005 |
| Serum sodium (mmol/L) | | | |
| >136 | Ref. | | |
| 131-135 | 1.57 | 0.85 to 2.91 | 0.149 |
| 126-130 | 0.49 | 0.11 to 2.16 | 0.349 |
| <126 | 17.69 | 2.02 to 154.91 | 0.009 |
| Serum potassium (mmol/L) | | | |
| 3.5-5.0 | Ref. | | |
| 3.1-3.4 or 5.1-5.3 | 2.80 | 1.28 to 6.15 | 0.010 |
| 2.9-3.1 or 5.4-5.9 | 3.40 | 1.05 to 10.99 | 0.041 |
| <2.9 or >5.9 | 3.26 | 0.73 to 14.52 | 0.121 |
| Electrocardiogram | | | |
| Normal | Ref. | | |
| Atrial fibrillation rate 60-90/minute | 3.18 | 1.39 to 7.29 | 0.006 |
| Any other | 3.00 | 1.00 to 9.02 | 0.050 |

CI = confidence interval; Ref = reference; mg/dl = milligram per deciliter; mmol/L = millimole per liter

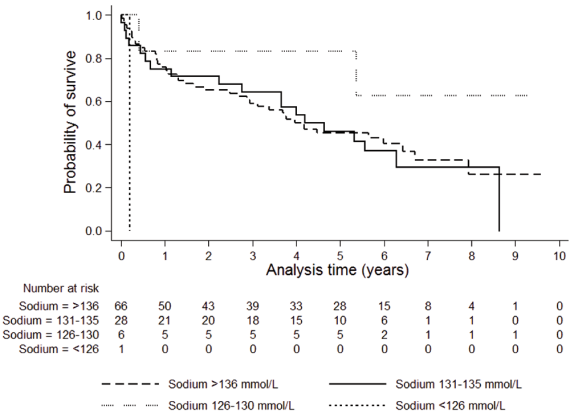


**Fig. 1** The Kaplan-Meier curve of the survival rates of peripheral arterial disease patients related with serum sodium level, mmol/L: millimole per liter.

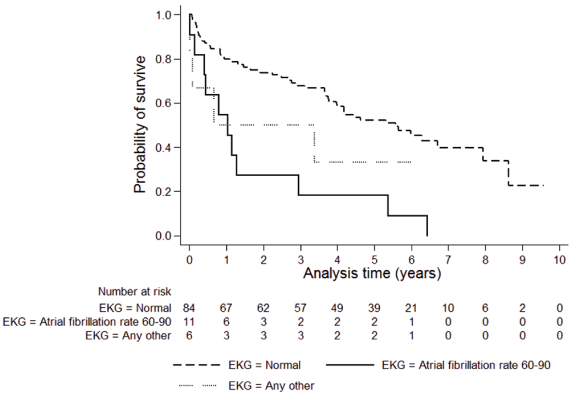


**Fig. 2** The Kaplan–Meier curve of the survival rates of peripheral arterial disease patients related with electrocardiogram result, mmol/L: millimole per liter.

that the high prevalence of AF in PAD patients to be 11.5%. In addition, the incidence of stroke and unstable angina of AF patients are higher than non-AF patients, which can double the cardiovascular death rate[10]. Therefore, AF patients should be treated with adequate anticoagulants, anti-arrhythmic drugs, and regular follow-ups in order to decrease mortality from complication of AF.

Another predictive factor is shortness of breath. This is a severe respiratory failure sign, which indicates severe respiratory disease and other fatal systemic disturbances including cardiac disease, metabolic disease, and other systems. Previous studies about the correlation between PAD and respiratory signs showed that dyspnea is a predictive factor for remission after lower extremity bypass[11]. The results of Davenport et al showed that dyspnea was an important preoperative risk factor for increasing mortality rate by 5 years[12]. Thus, patients with PAD who had shortness of breath should have their symptoms investigated to show possible respiratory causes, such as chronic obstructive pulmonary disease (COPD), or other system failures, such as congestive heart failure, septicemia with severe acidosis as well as other life-threatening diseases.

The preoperative serum electrolytes of potassium, sodium were significant risk factors to determine mortality. These are crucial to heart beating by nerve conduction and muscle contraction[13]. Hyponatremia implies a relative excess of total body water to sodium and is seen in a variety of medical conditions including congestive heart failure, liver disease, and chronic renal insufficiency. On the other hand, pathophysiology of hyponatremia of critical or chronically ill patients preoperatively, may have poor intake, absorption of extravascular sodium defect, and/or excessive loss of sodium. As previously described, hyponatremia represents the poor condition of patients associated with high mortality. Waikar et al showed that hyponatremia (serum sodium <135 mill equivalents per liter (mEq/L)) is associated with increased 1-year and 5-year mortality[14]. Consequently, hyponatremia

should be corrected not only preoperatively, but also in long-term follow-up. Umesawa et al[15] described the correlation between dietary sodium and potassium intakes, and mortality from cardiovascular disease. They found that low potassium intake increased cardiovascular disease[15], and that abnormal potassium led to arrhythmia and worsening heart disease. For that reason, serum potassium should be closely monitored and corrected to a normal range peri-operatively.

Our study defines the predictive factors for PAD patients and specify to symptomatic patients who perform the major vascular operation related to long-term post-operative mortality. Differ from previous studies which described about peripheral arterial occlusive disease related to long-term cardiovascular mortality which included both symptomatic and asymptomatic PAD patients regardless of the performed operation[2,7,12,16-18]. The serum hyponatremia and abnormal plasma potassium levels were the novel predictive factors associated to post-operative mortality. These data are particularly useful for physicians, vascular surgeons, and anesthesiologist to benefit patients by correcting these factors before performing major vascular surgery.

**Limitation**

Although the cause of death is very important, the present paper did not specify it as the authors could not identify the reliable causes of death in most patients. In Thailand, 65% of Thais died at home and the cause of death indicated by the village heads with limited knowledge in cause of death provided little information. The remaining 35% Thais die in hospital, and the cause of hospital death was also problematic[19]. One study in Thailand found death certificate matched the medical panel in only 48% for in hospital death[19]. In addition, because of the small sample size, the relationship between predictive factors and post-operative mortality, as well as survival rate had some degree of confounded outcome. Based on the sample size calculation[20], the power of this study was 77%. Larger sample studies are needed for a more reliable outcome.

**Conclusion**

Hyponatremia, respiratory failure, AF, abnormal plasma potassium levels, and hypertension were the predictive factors for high post-operative mortality in patients with symptomatic PAD undergone major vascular surgery. Therefore, not only the meticulous technique of the vascular surgeon during surgery, but also the peri-operative optimization of patients to get rid of the predictive factors associated with the mortality were crucial for the PAD patient's best outcome.

**What is already known on this topic?**

In patients with PAD carry high mortality.

**What this study adds?**

Predictive factors to determine post-operative mortality in Thai patients with PAD were identified in this study.

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**Potential conflicts of interest**

None.

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*การศึกษาปัจจัยเสี่ยงที่มีผลต่อการเพิ่มอัตราการเสียชีวิตในผู้ป่วยโรคหลอดเลือดแดงที่ขาตีบตัน*

*รุ่งรุจี กาวีแว่น, อันธิกา วงศ์ธานี, สฤษฏ์พัฒน์ ออรพินท์, กิตติพันธุ์ ฤกษ์เกษม*

***วัตถุประสงค์:*** *การผ่าตัดรักษาโรคหลอดเลือดแดงที่ขาตีบตันเป็นการผ่าตัดที่มีอัตราการเสียชีวิตสูง ในเอเชียมีการศึกษาเกี่ยวข้องกับการสืบค้นปัจจัยเสี่ยงต่อการเพิ่มอัตราการเสียชีวิตหลังการผ่าตัดดังกล่าวน้อย การสืบค้นปัจจัยเสี่ยงดังกล่าวตั้งแต่ก่อนผ่าตัดสามารถลดโอกาสการเสียชีวิตหลังผ่าตัดในผู้ป่วยโรคหลอดเลือดแดงที่ขาตีบตันได้*

***วัสดุและวิธีการ:*** *รวบรวมข้อมูลผู้ป่วยที่เข้ารับการผ่าตัดรักษาโรคหลอดเลือดแดงที่ขาตีบตัน ในโรงพยาบาลมหาราชนครเชียงใหม่ตั้งแต่เดือนธันวาคม พ.ศ. 2545 ถึง ธันวาคม พ.ศ. 2548 และทำการวิเคราะห์เพื่อสืบหาปัจจัยเสี่ยงต่อการเพิ่มอัตราการเสียชีวิตรวมทั้งอัตราการรอดชีวิตของผู้ป่วยโรคหลอดเลือดแดงที่ขาตีบตัน*

***ผลการศึกษา:*** *จากผู้ป่วยทั้งหมด 101 ราย มีผู้ป่วยเสียชีวิต 53 ราย (62.3%) อัตราการรอดชีวิตที่ 5 ปี คิดเป็น 47.28% ปัจจัยที่มีผลต่อการเสียชีวิต ได้แก่ ภาวะโซเดียมในเลือดต่ำ ภาวะระบบหายใจล้มเหลว ภาวะหัวใจเต้นผิดจังหวะแบบ atrial fibrillation ภาวะโพแทสเซียมในเลือดต่ำ และความดันโลหิตสูงก่อนผ่าตัด*

***สรุป:*** *ภาวะโซเดียมในเลือดต่ำ ภาวะระบบหายใจล้มเหลว ภาวะหัวใจเต้นผิดจังหวะแบบ atrial fibrillation ภาวะโพแทสเซียมในเลือดต่ำ และความดันโลหิตสูงก่อนผ่าตัด เป็นปัจจัยเสี่ยงต่อการเพิ่มอัตราการเสียชีวิตหลังการผ่าตัดของผู้ป่วยโรคหลอดเลือดแดงที่ขาตีบตัน*