

Outcomes and Risk Factors Associated with Major Amputation in Patients with Acute Lower Limb Ischemia Undergoing Revascularization

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Abstract

Objective: To identify outcomes and risk factors associated with major amputation in patients with acute limb ischemia (ALI) undergoing revascularization.

Materials and Methods: This retrospective cohort risk-factor study (PROGRESS II) included patients treated in the Vascular Surgery Unit at Khon Kaen Hospital between 2017 and 2024. Baseline and operative characteristics were extracted from medical records. Eligible participants were adults (≥ 18 years) diagnosed with acute limb ischemia (ALI) who underwent revascularization. The primary outcome was major amputation. Operative techniques included thrombo-embolectomy and surgical bypass. Risk factors for major amputation were evaluated using risk ratio regression. Statistical uncertainty was summarized using two-sided 95% confidence intervals (95% CIs), and a p-value < 0.05 was considered statistically significant.

Results: A total of 152 patients underwent surgical revascularization for ALI, and 63.5% were male. The major amputation rate was 17.1%. The mean age was 61.8 ± 16.0 years. Factors significantly associated with major amputation included longer symptom onset-to-treatment time, sepsis, and acute kidney injury (AKI). In multivariable analysis, hypertension (HT, mRR 3.27, p-value 0.047), chronic kidney disease (CKD, mRR 2.23, p-value 0.006), reperfusion injury (mRR 6.35, p-value 0.016), chronic heart failure (CHF, mRR 4.68, p-value 0.009), sepsis (mRR 4.68, p-value 0.009), and late onset > 24 h (mRR 2.11, p-value 0.009) were significant risk factors for major amputation among patients with ALI who underwent revascularization.

Conclusion: This high-volume retrospective cohort study demonstrated a substantial rate of major limb loss and identified several potentially modifiable prognostic factors. Fasciotomy may help improve limb salvage in selected patients. In addition, improving public awareness and health literacy may encourage earlier hospital presentation among patients with ALI.

Keywords: Acute limb ischemia, Revascularization, Thrombo-embolectomy, Bypass, Risk factors

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INTRODUCTION

Acute limb ischemia (ALI) is defined as a sudden decrease in blood flow to a limb,¹ with onset ranging from a few hours to up to 14 days.² It is associated with substantial morbidity, including limb loss, acute kidney injury (AKI), and a mortality rate of 15 – 20%.³ Common etiologies include atrial fibrillation (AF) with emboli formation, atherosclerotic plaque rupture, hypercoagulable states, trauma, and aortic dissection (AD).⁴ The management strategies are guided by the Rutherford classification severity – I, IIA, IIB, and III.⁵ Conservative treatment is generally used for class I, while primary amputation is often required for class III. For class II disease, revascularization, either catheter-based or open surgical, is the treatment of choice.⁶ The selection between approaches depends on the duration and severity of ischemia, as well as the surgeon's preferences.⁷

Despite the increasing use of endovascular techniques in ALI management,⁸ open surgical revascularization remains the standard treatment in many settings.⁹ Surgical options include thrombo-embolectomy, surgical bypass, endovascular, and hybrid approaches. However, even with timely and appropriate treatment, complications from revascularization can be fatal, for example, ischemic-reperfusion injury. In severe cases, surgeons may resort to limb amputation as a life-saving measure. The reported rate of major amputation within 30 days after revascularization ranges from 10% to 30%.^{10,11} Various prognostic factors were identified: age, emergent revascularization,¹² chronic kidney disease (CKD),¹³ diabetes, and preexisting cerebrovascular disease.

The majority of the studies are in a chronic limb ischemia setting. There are very few findings on ALI. Furthermore, most prior Thai studies^{10,14,15} have had small sample sizes ($n < 100$), and few have evaluated risk factors for major amputation. This study aims to identify outcomes and risk factors for major limb amputation in patients with ALI who underwent surgical revascularization in a tertiary care referral hospital in northeastern Thailand.

MATERIALS AND METHODS

Study design

This retrospective cohort prognostic (PROGRESS II) study was conducted at a tertiary care referral hospital in northeastern Thailand. The data were obtained from the electronic medical records (EMRs) of the vascular surgery unit in the Department of Surgery between 1st January 2017 and 31st December 2024. Eligible participants were patients aged 18 years or older who were diagnosed with ALI of

the lower extremities and underwent primary surgical revascularization. ALI patients with Rutherford classification of I or III were automatically excluded, in accordance with the disease characteristics and international management guidelines⁵. Patient data were collected from disease onset until hospital discharge or in-hospital death. Multiple occlusion sites would be recorded as the most proximal occluded one. All patients received surgical revascularization and standard perioperative care. Baseline characteristics included sex, age, body mass index (BMI), comorbidities, clinical characteristics, and laboratory findings. Additional variables included disease severity and classification, time of onset, operative techniques, outcomes, and complications. The study was ethically approved by the Institutional Review Board (IRB) of the hospital (approval number: KEXP68018). The primary outcome was major amputation. Study size estimation was based on a prior institutional study, which reported a major amputation rate of 16.9%. Using onset proportions of 0.36 and 0.64, with 80% power, a significance level (alpha) of 0.05, and a 5:1 ratio, the required study size is estimated at 174 patients.

Surgical revascularization techniques

Two revascularization techniques were employed at the authors' institution: thrombo-embolectomy and surgical bypass.

Patients were diagnosed by preoperative computed tomography angiography of the lower extremities with distal run-off (CTA). Standard preparation included intravenous heparinization, hydration, oxygen supplementation, and analgesia. All procedures were performed under general anesthesia (GA). The lower abdomen, groin, and both legs were prepared and draped in a sterile fashion. The standard approach was exposure of the common femoral artery (CFA) at the bifurcation; exposure of the popliteal artery below the knee was occasionally required.

After induction of GA, the CFA was exposed at the groin under ultrasound guidance. The CFA, superficial femoral artery (SFA), and profunda femoris were identified and encircled with vascular loops, and proximal and distal control was ensured. A transverse arteriotomy was performed 1-2 centimeters above the bifurcation. Thrombus extraction was performed using appropriately sized Fogarty balloon catheters until balloon retrieval showed no residual thrombus and satisfactory antegrade and retrograde flow were achieved. A completion angiogram was performed to confirm clearance. The arteriotomy was closed. When concomitant atherosclerotic lesions or focal dissections impeded distal flow, trans-arterial bal-

loon angioplasty and stenting were performed following thrombus removal.

Surgical bypass was selected based on preoperative CTA findings or intraoperative failure of thrombo-embolectomy and/or angioplasty. Proximal and distal target vessels were exposed and controlled, and a polytetrafluoroethylene (PTFE) conduit or an autologous vein was used. Patency was confirmed with a completion angiogram. Fasciotomy was considered for patients with compartment syndrome or when clinical findings were equivocal. Technical success was defined as restoration of lower-limb blood flow confirmed by intraoperative angiography, Doppler ultrasonography, and palpable pedal pulses. Postoperatively, patients were admitted to either the intensive care unit (ICU) or the vascular surgery ward for routine monitoring. Continuous intravenous heparin infusion was maintained until the underlying etiology of ALI was identified and definitively managed.

When patients progressed to irreversible limb damage, amputation was performed. In this study, major amputation was defined as an amputation at or above the ankle. Minor amputation was defined as an amputation below the ankle.

Statistical analysis

Categorical variables were summarized as frequencies and percentages and compared using the exact probability test. Normally distributed continuous variables were summarized as means and standard deviations (mean $\pm$ SD) and compared using independent t-tests. Non-normally distributed continuous variables were summarized

as medians and interquartile ranges (IQRs). Statistical uncertainty was expressed as 95% two-sided confidence intervals (95% CI). A p -value < 0.05 was considered statistically significant.

Risk factors for major amputation among patients with ALI who underwent surgical revascularization were evaluated using risk ratio regression. Variables for univariable analysis were selected based on clinical rationale and prior evidence. All potential variables were then entered into a multivariable model. All statistical analyses were performed using STATA version 18 (StataCorp. 2023. Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC)

RESULTS

Patient characteristics

Among 152 patients who underwent surgical revascularization for ALI, 63.5% were male. The mean age was 61.8 ± 16.0 years. The most common comorbidities were hypertension (53.9%), dyslipidemia (50.0%), and AF (40.8%). Dyslipidemia was not significantly more prevalent in the major amputation group, whereas AF was significantly more prevalent in the limb salvage group. Alcohol use (32.9%) and intracardiac thrombus (11.2%) were also significantly more common in the limb salvage group. CKD was more frequent among patients who underwent major amputation. There were no significant between-group differences in BMI, smoking status, DM, cerebrovascular diseases, ischemic heart disease, or AAA, as shown in **Table 1**.

Table 1 Baseline characteristics of the patients who underwent surgical revascularization for ALI

Baseline characteristics, n (%)	All, n = 152 (%)	Limb salvage n = 126, (82.9%)	Major amputation n = 26, (17.1%)	<i>p</i> -value
Male sex	96 (63.2)	80 (63.5)	16 (61.5)	0.828
Age, years (mean $\pm$ SD)	61.8 $\pm$ 16.0	61.1 $\pm$ 16.1	65.6 $\pm$ 15.5	0.192
BMI, kg/m² (mean $\pm$ SD)	23.2 $\pm$ 5.0	23.5 $\pm$ 5.2	21.5 $\pm$ 3.6	0.061
Smoking	42 (27.6)	35 (27.8)	7 (26.9)	1.000
Alcohol use	50 (32.9)	47 (37.3)	3 (11.5)	0.011
Underlying diseases				
Hypertension	82 (53.9)	63 (50.0)	19 (73.1)	0.050
DM	37 (24.3)	31 (24.6)	6 (23.1)	1.000
Dyslipidemia	76 (50.0)	59 (46.8)	17 (65.4)	0.131
Presence of intracardiac thrombus	17 (11.2)	17 (13.5)	0 (0.0)	0.045
CKD stage $\geq$ 3	11 (7.2)	6 (4.8)	5 (19.2)	0.022
AF	62 (40.8)	56 (44.4)	6 (23.1)	0.050
Cerebrovascular disease	24 (15.8)	21 (16.7)	3 (11.5)	0.768
IHD	16 (10.5)	15 (11.9)	1 (3.8)	0.309
AAA	4 (2.6)	4 (3.2)	0 (0.0)	1.000

ALI = acute limb ischemia; SD = standard deviation; BMI = body mass index; kg = kilograms; m = meters; DM = diabetic mellitus; CKD = chronic kidney disease; AF = atrial fibrillation; IHD = ischemic heart disease; AAA = abdominal aortic aneurysm

Clinical characteristics

All patients had lower-extremity ALI. Overall, 26 of 152 (17.1%) underwent major amputation. Rutherford class 2B predominated (87.5%), followed by class 2A (12.5%), with no significant between-group difference. Patients in the major amputation group presented after a significantly longer symptom duration; 50% presented more than 72 hours from onset. The anatomic level of occlusion varied across the aorta, iliac, femoral, popliteal, and tibioperoneal segments, with no significant differences between groups. Surgical revascularization consisted primarily of thromboembolectomy (141 of 152 patients); the remaining 11 patients underwent bypass surgery. The median length of stay was 6 [4, 10] days. The data were shown in **Table 2**.

Risk factors associated with major amputation

In univariable analysis, alcohol use was associated with a lower risk of major amputation (uRR 0.27, 95% CI 0.08 – 0.84, p -value = 0.025). Factors associated with a higher risk included hypertension (uRR 2.32, 95% CI 1.04 – 5.19, p -value = 0.041), CKD (uRR 3.05, 95% CI 1.43 – 6.51, p -value = 0.004), AKI (uRR 2.74, 95% CI 1.31 – 5.75, p -value = 0.008), sepsis (uRR 4.65, 95% CI 2.52 – 8.63, p -value < 0.001), and symptom onset more than 24 hours (uRR 2.39, 95% CI 1.16 – 4.19, p -value = 0.018). The multivariable risk ratio regression, protective factors were male sex (mRR 0.85, 95% CI 0.85 – 0.85, p -value < 0.001), alcohol use (mRR 0.14, 95% CI 0.03 – 0.73, p -value = 0.020), DM (mRR 0.48, 95% CI 0.27 – 0.85, p -value = 0.011), AF (mRR 0.14, 95% CI 0.04 –

Table 2 Clinical characteristics of the patients diagnosed with ALI who underwent surgical revascularization

Clinical characteristics	all, n = 152 (%)	Limb salvage n = 126 (82.9%)	Major amputation n = 26 (17.1%)	p -value
Rutherford classification				
2A	19 (12.5)	17 (13.5)	2 (7.7)	0.532
2B	133 (87.5)	109 (86.5)	24 (92.3)	
Onset (hours)				
< 6	38 (25.0)	38 (30.2)	0 (0.0)	< 0.001
6 – 24	53 (34.9)	43 (34.1)	10 (38.5)	
24 – 72	29 (19.1)	26 (20.6)	3 (11.5)	
> 72	32 (21.1)	19 (15.1)	13 (50.0)	
Occlusion site				
Aortoiliac	13 (8.6)	13 (10.3)	0 (0.0)	0.303
Iliofemoral	34 (22.4)	30 (23.8)	4 (15.4)	
Femoropopliteal	59 (38.8)	47 (37.3)	12 (46.2)	
Popliteal bifurcation	40 (26.3)	31 (24.6)	9 (34.6)	
Tibioperoneal	6 (3.9)	5 (4.0)	1 (3.8)	
Revascularization technique				
Thrombo-embolectomy	141 (92.8)	116 (92.1)	25 (96.2)	0.691
Surgical bypass	11 (7.2)	10 (7.9)	1 (3.8)	
LOS, days [median, IQR]	6 [4, 10]	6 [4, 9]	7 [4, 13]	0.132

ALI = acute limb ischemia; IQR = interquartile range, LOS = length of stay

Outcomes and complications

No patient who underwent a major amputation also underwent a minor amputation. Fasciotomy was performed more frequently in the limb salvage group, but the difference was not statistically significant. AKI and sepsis occurred significantly more often in the major amputation group. In-hospital mortality was 11.2% overall and higher in the major amputation group (19.2%), although this difference did not reach statistical significance. The details were presented in **Table 3**.

0.54, p -value = 0.005), and fasciotomy performed (mRR 0.09, 95% CI 0.02 – 0.50, p -value = 0.005). Risk factors included hypertension (mRR 3.27, 95% CI 1.02 – 10.52, p -value = 0.047), CKD (mRR 2.23, 95% CI 1.26 – 3.91, p -value = 0.006), reperfusion injury (mRR 6.35, 95% CI 1.42 – 28.45, p -value = 0.016), CHF (mRR 4.68, 95% CI 1.48 – 14.80, p -value = 0.009), sepsis (mRR 2.11, 95% CI 1.21 – 3.70, p -value = 0.009), and symptom onset more than 24 hours (mRR 2.11, 95% CI 1.21 – 3.0, p -value = 0.009). The details were also shown in **Table 4**.

Table 3 Outcomes and complications of the patients diagnosed with ALI who underwent surgical revascularization

Complications, n (%)	all, n = 152 (%)	Limb salvage n = 126 (82.9%)	Major amputation n = 26 (17.1%)	p-value
Minor amputation	9 (5.9%)	9 (7.1%)	0 (0.0%)	0.359
Fasciotomy	14 (9.2%)	13 (10.3%)	1 (3.8%)	0.466
Reperfusion injury	19 (12.5%)	13 (10.3%)	6 (23.1%)	0.099
Postoperative MI	13 (8.6%)	11 (8.7%)	2 (7.7%)	1.000
AKI	15 (9.9%)	9 (7.1%)	6 (23.1%)	0.024
Postoperative stroke	10 (6.6%)	8 (6.3%)	2 (7.7%)	0.681
CHF	22 (14.5%)	16 (12.7%)	6 (23.1%)	0.217
Sepsis	18 (11.8%)	8 (6.3%)	10 (38.5%)	< 0.001
in-hospital dead	17 (11.2%)	12 (9.5%)	5 (19.2%)	0.173

ALI = acute limb ischemia; MI = myocardial infarction; AKI = acute kidney injury; CHF = congestive heart failure

Table 4 Risk factors associated with major amputation

Risk factors	uRR	Lower 95% CI	Upper 95% CI	p-value	mRR	Lower 95% CI	Upper 95% CI	p-value
Male sex	0.93	0.46	1.91	0.851	0.85	0.85	0.85	< 0.001
Age > 75 years	1.54	0.74	3.23	0.251	1.05	0.73	1.51	0.775
BMI < 18.5 kg/m ²	1.25	0.48	3.24	0.641	1.38	0.41	4.59	0.603
Smoking	0.96	0.44	2.13	0.929	2.02	0.56	7.24	0.282
Alcohol	0.27	0.08	0.84	0.025	0.14	0.03	0.73	0.020
DM	0.93	0.41	2.15	0.869	0.48	0.27	0.85	0.011
Hypertension	2.32	1.04	5.19	0.041	3.27	1.02	10.52	0.047
Dyslipidemia	1.89	0.90	3.97	0.093	1.91	0.53	6.96	0.325
AF	0.44	0.19	1.02	0.056	0.14	0.04	0.54	0.005
CKD	3.05	1.43	6.51	0.004	2.23	1.26	3.91	0.006
IHD	0.34	0.05	2.34	0.273	0.26	0.03	1.90	0.182
Aortoiliac occlusion	0.41	0.15	1.11	0.080	0.37	0.11	1.27	0.115
Fasciotomies perform	0.39	0.06	2.69	0.343	0.09	0.02	0.50	0.005
Reperfusion injury	2.10	0.97	4.56	0.061	6.35	1.42	28.45	0.016
MI	0.89	0.24	3.35	0.865	0.30	0.05	1.94	0.207
Acute kidney injury	2.74	1.31	5.75	0.008	0.63	0.21	1.85	0.396
Stroke	1.18	0.33	4.31	0.798	13.33	0.42	418.86	0.141
CHF	1.77	0.80	3.92	0.157	4.68	1.48	14.80	0.009
Sepsis	4.65	2.51	8.63	< 0.001	2.11	1.21	3.70	0.009
Embolectomy	1.95	0.29	13.07	0.491	1.60	0.18	14.30	0.673
Rutherford 2B	1.71	0.44	6.68	0.437	3.99	0.15	105.96	0.408
Onset > 24 h	2.39	1.16	4.91	0.018	2.11	1.21	3.70	0.009

uRR = univariable risk ratio; CI = confident interval; mRR = multivariable risk ratio; BMI = body mass index; kg = kilograms; m = meters; DM = diabetic mellitus; AF = atrial fibrillation; CKD = chronic kidney disease; IHD = ischemic heart disease; CHF = congestive heart failure; h = hours

DISCUSSION

ALI is a common vascular emergency. In the United States, the incidence is estimated at 4.16 – 7.16 per 100,000 persons per year.¹⁶ Management strategies of ALI vary by occlusion type, etiology, Rutherford classification, ischemic duration, and available resources.^{17,18} Endovascular therapies can be adopted in high-volume centers with sufficient capacity¹⁹ and are associated with fewer in-hospital cardiopulmonary complications,²⁰ albeit with a moderate increase in hospital costs.²¹ Nevertheless, open surgical revascularization remains crucial in patients with threatened limbs and prolonged ischemia.¹⁷

Major adverse cardiac and limb events (MACE and MALE, respectively) may occur after emergent or urgent revascularization for ALI. Hospitalization for MALE occurs in approximately 1 in 10 patients within one year after peripheral revascularization.²² Previously reported risk factors for limb loss included patient sex, etiology, including aneurysmal diseases and trauma, and hemodynamic instability.²³ Thai studies have also identified predictors such as clinical severity, symptom onset, and anatomic location; SFA occlusion has been associated with major limb loss.¹¹ Poor tibial runoff on completion angiography also gave a worse prognosis.²³

In our cohort, hypertension, CKD, reperfusion injury, CHF, sepsis, and delayed presentation (more than 24 hours from onset) were associated with a higher major amputation rate. Hypertension, via arterial stiffness²⁴ Atherosclerosis likely increases the technical difficulty of revascularization due to pre-existing occlusions, calcification, and stenosis. These lesions can impede Fogarty catheter passage and often necessitate adjunct angioplasty to prevent re-occlusion. CKD, frequently coexisting with hypertension, confers both systemic and local vulnerabilities.²⁵ Patients with CKD have a higher prevalence of PAD, and revascularization in the setting of pre-existing PAD and CKD is associated with poorer outcomes.^{22,26} Reperfusion injury after revascularization carries substantial morbidity, including AKI and hyperkalemia, and can be fatal.²⁷ These complications may precipitate the need for life-saving amputation. The associations observed with CHF and sepsis likely reflect systemic compromise that further jeopardizes limb viability. The effect of delayed presentation is intuitive; longer ischemic time intensifies ischemia-reperfusion injury and worsens tissue viability after revascularization.

Conversely, male sex, alcohol use, DM, AF, and performance of fasciotomy were identified as protective factors in multivariable analysis. The direction of association were lower probability of outcome occurring. Sex-related differences in arterial stiffness and vascular biology have been proposed,²⁷ but the direction of effect in our study contrasts with much of the literature and may be influenced by study size and residual confounding. The apparent protective association of diabetes and alcohol use also contradict most reports that identify diabetes and alcohol use as the risk factors for limb loss after ALI revascularization.^{28,29} The limited power of the study size may explain this finding. In our institute, we did not select ALI management strategies based on underlying diseases. So, the confounding by indication was methodologically eliminated. AF is a common cause of ALI.³⁰ It often produces embolic occlusions in otherwise healthy arteries. Such patients tend to present earlier because of severe pain, the thrombus is typically fresh, and thrombo-embolectomy is often sufficient without the need for adjunct angioplasty or bypass, all of which may favor limb salvage. In our study, adjunctive angioplasty was occasionally required after thromboembolectomy in patients with thrombotic occlusion associated with pre-existing chronic stenotic lesions. Angioplasty was also performed to treat residual dissection following thromboembolectomy or to correct residual tibial vessel disease in order to improve distal runoff after either thromboembolectomy or bypass procedures. If angioplasty failed, patients subsequently underwent surgical bypass when adequate distal runoff was present. Finally, early or prophylactic fasciotomy can mitigate reperfusion-related edema and prevent compartment syndrome³¹, thereby reducing the risk of limb loss, although prior evidence on outcome differences is mixed³². Delayed fasciotomy was also discussed in previous evidence. It is associated with a higher major amputation risk in patients with ALI³³. Furthermore, because of the retrospective design, the indication and timing of fasciotomy were not consistently documented; therefore, we could not distinguish between prophylactic and therapeutic fasciotomy. This limitation may affect the interpretation of the observed association between fasciotomy and major amputation. Notably, recent studies have reported similar amputation-free survival between prophylactic and therapeutic fasciotomy in selected patients with acute limb ischemia, although these findings should be interpreted in the context of patient selection and ischemia severity³⁴.

This study has limitations inherent to its retrospective design. Including potential unmeasured confounding, especially on surgeon preferences and intraoperative decision-making. Recall bias is possible, particularly in symptom-onset time. The definition and diagnostic classification of reperfusion injury, sepsis, and acute kidney injury were not always clearly defined and depended on the treating surgeon's clinical judgment at the time of care. The achieved sample size was smaller than the prespecified estimate, reducing the statistical power to detect clinically meaningful associations. As a result, effect estimates, particularly in multivariable models and potential subgroup analyses, may be unstable with wide confidence intervals, and some true associations may have been missed (type II error). Future studies with larger study sizes are warranted. Furthermore, due to data-collection limitations, the etiology of ALI was not clearly documented, resulting in missing data for this variable. However, a preliminary review of the available records suggested that the etiologies were mixed. Despite these constraints, this work is among the first reports from Thailand to examine risk factors for major amputation after surgical revascularization for ALI, using a relatively large single-center cohort.

Our findings underscore the importance of timely presentation and aggressive management of systemic comorbidities (hypertension, CKD, CHF, sepsis) to optimize limb outcomes after ALI. The protective associations observed for AF and fasciotomy highlight potentially modifiable aspects of care (rapid diagnosis in suspected embolic ALI and selective early fasciotomy) that warrant further prospective evaluation.

CONCLUSION

ALI remains a common and clinically significant emergency. In this high-volume, single-center retrospective cohort, we observed a substantial rate of major limb loss. Several prognostic factors, such as Hypertension, CKD, reperfusion injury, CHF, sepsis, alcohol use, diabetes, and AF, some of which are potentially modifiable, were identified. Early or prophylactic fasciotomy may aid limb salvage in selected patients. Enhancing public and provider health literacy to promote earlier recognition and hospital presentation for ALI could reduce ischemic time and improve outcomes. Prospective studies are warranted to validate these findings and guide targeted interventions.

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