Journal of Experimental and Clinical Medicine
https://dergipark.org.tr/omujecm

Research Article

J Exp Clin Med
2025; 42(1): 5-9
doi: 10.52142/omujecm.42.1.2

Clinical characteristics and outcomes of chronic limb threatening ischemia patients after treated with endovascular treatment during COVID-19 outbreak in Vajira Hospital

Kittiyaphorn PANVILAI [1], Chananuch SARAWIT [2,*], Sudawan TIBPAYACHOL [2], Orathai KAEWJALADVILAI [2], Kanokpan NGAMMUK [2], Wuttichai SAENGPRAKAI [3], Wacharaphong PITAKSANTAYOTHIN [3]

[1]Kuakarun Faculty of Nursing, Navamindradhiraj University, Bangkok, Thailand
[2]Nursing Department, Faculty of Medicine, Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand
[3]Department of Surgery, Faculty of Medicine, Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand

Received: 17.01.2024 • **Accepted/Published Online:** 21.02.2025 • **Final Version:** 28.03.2025

Abstract

To study clinical characteristics and outcomes of chronic limb threatening ischemia patients after treated with endovascular treatment during COVID-19 Outbreak. This research is a retrospective descriptive study through electronic medical records. Samples are all patients that had been treated at Vajira Hospital during the COVID-19 outbreak in Thailand between January 2020 to December 2022. Results shown that out of 180 patients with chronic limb threatening ischemia, 106 are male (58.9%) while 74 are females (41.1%). The average age of the patients is 77.01 years old. Sixty-seven patients (37.2%) have history of smoking. Seventy-four patients (41.1%) were found with Wifi Classification state. One hundred and seventy-five patients (97.2%) have comorbidity including Hypertension 24.5%, Diabetes mellitus 23.1%, Dyslipidemia 19.2%. 38.7% of the patients receive Dual Antiplatelet 38.7%. It is found that low Serum Albumin (3.26 g/dL) and Wifi Classification are having significant correlation with occurrences of complications after surgeries ($p<.05$). Patients infected with COVID-19 who have chronic limb threatening ischemia have lower Serum Albumin than patients who do not have COVID-19 which becomes a variable that increases risks of complications after surgeries, losses of limbs, deaths and numbers of days admitted in hospital which leads to increased treatment expenditures.

Keywords: Chronic limb-threatening ischemia, COVID-19, Outcome, Serum Albumin

1. Introduction

In the present, health problems related to cardiovascular diseases can increasingly been found in urban society which was caused by daily lifestyles and changing environment that leans toward western lifestyles including inappropriate food consumptions, lacking of exercises, sleep deprivation, crowded housing and workplace. These factors have created more risks towards cardiovascular and other non-communicable diseases for people living in Bangkok more than people in other regions (1).

Chronic limb-threatening ischemia (CLTI) is cardiovascular disease in the end-stage of peripheral artery disease (PAD) which can cause effects to patients' health in which it creates risk of disabilities, high healthcare expenditures and increases rate of morbidity and mortality. It is found that ten percent of patients with peripheral artery disease will be worsen to the point of chronic limb-threatening ischemia within five years, and 80 percent of amputated patients were having chronic limb-threatening ischemia. Patients with chronic limb-threatening ischemia and were amputated are at risk of premature death (2). In addition, patients will have higher healthcare expenditures. It is found that the average treatment fees for these group of patients is 337,873.66 Thai baht with 21 days being admitted in the hospital. As a result, it is a complex disease with high healthcare expenditures (3).

Chronic limb-threatening ischemia happens with distal legs which causes ischemic pain in the foot while a person is at rest. Pain is caused to the foot, and severe pain will occur while a person is at rest or when raising the foot. The pain can last more than two weeks, and when there is a wound, tissues will start to be in shortage of blood and lead to gangrene. In chronic ischemic ulcer patients, they will be classified with Fontaine classification (stage IV) and Rutherford classification (stage 5-6). Moreover, the patients may be admitted with other complications such as foot infection which can commonly be found in diabetes patients with chronic limb-threatening ischemia due to decreased blood circulation. The number of white blood cells and oxygen circulating to the foot were decreased. Variables that can lead to chronic limb-threatening ischemia are Diabetes Mellitus. Patients with Diabetes Mellitus will be twice at-risk of chronic limb-threatening

*Correspondence: chananuch@nmu.ac.th

ischemia. Elderly people in each 10-year span is found 1.5 time more at-risk of having chronic limb-threatening ischemia while patients with hypertension is found 1.5 time more at-risk of having chronic limb-threatening ischemia. Patients with Dyslipidemia, especially having high cholesterol will be 1.25 times at-risk while patients with smoking habits are twice more at-risk. In addition, coronary artery disease which is an important factor that increases primary amputation rate to 30 percent and mortality rate at 25 percent within 1 year after diagnosis of COVID-19 will increase the mortality rate to 40 percent and amputation rate at 23.5 percent (4, 5). Treatment of chronic limb-threatening ischemia has the main target to reduce pain from the lack of blood circulation and prevent losses of legs. If the patient has ischemic wound, treatment should aim at removing severe inflamed tissues such as having extensive soft tissue infection or sepsis. This type of patient must go through surgeries. There are several types of treatment for chronic limb-threatening ischemia, but the treatment is more likely towards endovascular type because of the advanced equipment and methods of treatment. However, there is still limitations in terms of the treatment expenses. For patients with severe conditions which has several levels of clogged arteries, it is necessary to use mixed treatments between endovascular treatment and open bypass surgery, or what is called as Hybrid procedure (6).

Chronic limb-threatening ischemia affects patients in many aspects including that the infection around ischemic wounds can lead to longer length of stays and higher healthcare expenses. Moreover, after surgeries to increase blood flow to the legs or toes, patients will need continuous treatment on ischemic wounds which affects the rehabilitation after surgery. Patients are likely to be dependent on others when returning home (7). The COVID-19 outbreak has changed the way patients around the world are being treated which is similar to what happened at Vajira Hospital where it needs to control the infections and prevent patients from COVID-19. Chronic limb-threatening ischemia patients who are not emergency cases will not go through surgeries, while hospital referrals are ceased to operate. According to the Ministry of Public Health's policy, all incoming patients must be screened in each and every services post pf the outpatient clinic. Risk group will be referred to OPD ARI. Before chronic limb-threatening ischemia patients be treated as inpatient, they must go through COVID-19 or SARS-CoV-2 test with RT-PCR which will provide result within 4-10 hours depending on the time of receiving samples of test rounds. While waiting for the results, patients will be referred to the Buffer Ward which widen treatment time. Chronic limb-threatening ischemia patients that are infected with COVID-19 will be in worsening condition especially with the patients with cardiovascular diseases, diabetes or being elderly. This group of patients are in risk of being dead. Patients with COVID-19 will experience the release of Cytokine which can lead to organ failure and increase repeated blood clogged in peripheral blood vessels with higher risk of amputation. In the same time, lungs and respiratory system fail to operate leading to less oxygen risking more losses of blood circulation to legs (8). Factors supporting recovery of wounds, reducing of ischemic pains and prevent relapse of diseases of the chronic limb-threatening ischemia patients are knowledge towards the diseases and risk factors, knowledge and behaviors on how to take care of oneself and also knowledge of families or relatives of the patients (9, 10). Methods to preventing relapse of disease after treatment is to reduce risk factors including stop smoking, taking antiplatelet, exercise, control comorbid diseases including diabetes, hypertension and dyslipidemia while monitoring abnormalities of arteries. Literature reviews suggest that there are no studies towards the outcomes of chronic limb threatening ischemia patients' endovascular treatment during the COVID-19 outbreak in Thailand in which the situation has affected patients in every aspect, causing changes in livelihood and changes in hospital services to be more adaptive to new normal medical service which can cause impact to the time in accessing necessary and urgent healthcare services and the outcomes of treatment accordingly. Researchers would like to study clinical characteristics and outcomes of chronic limb threatening ischemia patients during the COVID-19 outbreak which have been treated with endovascular treatment in order to evaluate the outcomes of treatment resulted from the research which will become preliminary data to improve treatment of the hospital and the whole country, and to apply these knowledge in treatment plan in order to increase quality of treatment or adjust chronic limb threatening ischemia patient treatment system, reducing the likelihood of amputation, suffering from ischemia and mortality. Literature reviews suggest that important clinical characteristics of chronic limb threatening ischemia patient which have been treated with endovascular treatment are the general profile of the patients, genre, comorbidity diseases and its control, smoking habit, COVID-19 infection, outcomes of important treatments including complication after surgeries such as Myocardial infarction or Ischemic stroke (major adverse cardiovascular; MACE) Major Amputation (major adverse limb events; MALE) and Limb salvage shown in fig. 1 (11).

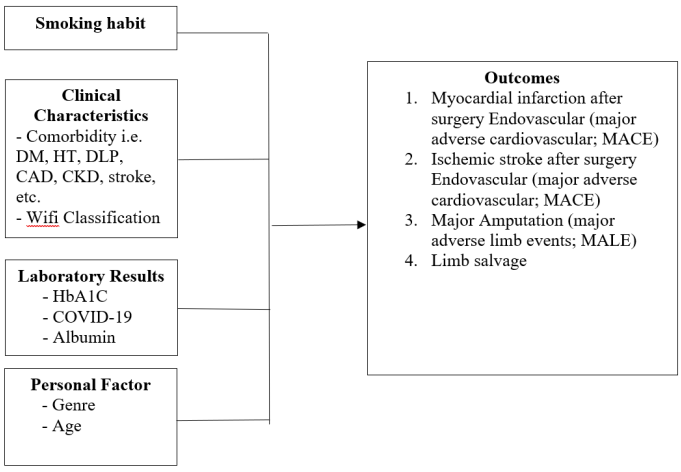

Fig. 1. Conceptual Framework

2. Materials and Methods

This research is a Retrospective descriptive study to study clinical characteristics and outcomes of chronic limb threatening ischemia patients during the COVID-19 outbreak which have been treated with endovascular treatment at Vajira Hospital. Samples are medical records of all chronic limb threatening ischemia patients by searching from disease code ICD 10 (I7020-29) which has gone through medical procedures ICD 9 (0045, 0041, 0047, 0023, 3990, 0055, 3950) and have received treatment at Vajira Hospital during COVID-19 outbreak in Thailand from January 2020 to December 2022.

2.1. Research Tools

There are five sets of research tools to collect data and implement the study including patients' basic information and clinical symptoms record form, medical procedures record form, complication after surgery record form and number of hospital admission days, laboratory testing results record form and medication record form. These tools must be examined of its content validity by three vascular surgery physician and nursing instructors. The tools got CVI=0.84. For other issues that receive additional recommendations, researchers have modified the tools according to the recommendations of experts.

2.2. Patients' confidentiality

Researchers are tasked to access the data, copy and record from medical records. The research presents the results in general. Moreover, the researchers keep patients' data in confidential. Names of the patients will not be mentioned but rather use codes instead.

2.3. Data Collection

Researchers review electronic medical records and record them into the developed tools. Researchers collect data from the medical records since January 2020 to December 2022 in which researchers are the one who collect and record the data themselves. Researchers are careful of how the data is kept to protect patients' confidentiality by using codes. In analyzing the data, researchers use SPSS version 28 to process and analyze the data, then present it in two parts following the type of data and with frequency, percentage and identify $p< 0.05$ of having statistically significant difference.

3. Results

3.1. General information and clinical symptoms of patients

From 180 electronic medical records of chronic limb threatening ischemia patients, 106 patients are male (58.9%) while 74 patients are female (41.1%). The average age of the patients is 67.01 years old. Sixty-seven patients (37.2%) have history of smoking. Seventy-four patients (41.1%) are at Wifi Classification clinical state 4. In terms of comorbid diseases, 175 patients (97.2%) have comorbid diseases with 157 patients (87.2%) have Hypertension, 148 patients (82.2%) have Diabetes mellitus, 123 patients (68.3%) have Dyslipidemia, 62 patients (34.4%) have Coronary artery disease, CAD), 84 patients (46.7%) have Chronic kidney disease, CKD) and 18 patients (10%) have Ischemic stroke). In terms of medication that the patients receive, 14 patients (7.8%) got single Antiplatelet, 143 patients (97.4%) got dual Antiplatelet and 146 patients (81.1%) got Statin. It is also found that Wifi Classification are having significant correlation with occurrences of complications after surgeries ($p<.05$) as shown in table 1.

Table 1. General Information and Clinical Symptoms of patients

Characteristic		Total N=180 (%)	CLTI + COVID-19	CLTI non COVID-19	*p*
Genre	Male	106 (58.9)	2	104	.282
	Female	74 (41.1)	1	73	
Age (years) mean ± SD		67.01 ± 11.46	67.33	67	
	Less than 40 years old	1 (0.6)	-	1	.926
	41-60 years old	49 (27.1)	1	48	
	61-70 years old	68 (37.8)	-	68	
	71-80 years old	41 (22.8)	2	39	
	More than 80 years old	21 (11.7)	-	21	
History of smoking	Yes	67 (37.2)	-	67	.821
	No	113 (62.8)	3	110	
Comorbid diseases	Diabetes Mellitus	148 (23.1)	2	146	.893
	Hypertension	157 (24.5)	3	154	.111
	Dyslipidemia	123 (19.2)	3	120	.567
	CAD	62 (9.7)	-	62	.964
	CKD	84 (13.1)	1	83	.109
	Ischemic stroke	18 (2.8)	-	18	.251
	other	49 (7.6)	2	47	.094
Clinical symptoms Wifi classification	State 1	9 (5.0)	-	9	.003*
	State 2	32 (17.8)	1	31	
	State 3	65 (36.1)	1	64	
	State 4	74 (41.1)	1	73	
Medication	Single antiplatelet therapy/Aspirin or Clopidogrel	14 (3.7)	1	13	-
	Dual antiplatelet therapy/Aspirin and Clopidogrel	143 (38.0)	2	141	
	Aspirin and Statin	22 (5.8)	-	22	
	Statin	146 (38.7)	3	143	
	Other	52 (13.8)	1	51	

3.2. Medical Procedures

Medical procedures that the patients received are PTA constituting for 90 cases (50%), PTA together with stent constituting for 84 cases (46.7%), Endarterectomy constituting for 4 cases (2.2%), Hybrid procedure (By Pass together with Stent, PTA together with Stent and Endarterectomy) constituting for 7 cases (3.9%). After medical procedures taken, complications found include 9 cases (5%) of acute kidney Injury, 2 cases (1.1%) of acute limb ischemia, 1 case (0.6%) of Myocardial Infarction, 1 case (0.6%) of Ischemic stroke, 1 case (0.6%) of major amputation and 5 cases (2.8%) of Peri-operative death. The average length of stay is 18.77 days with the shortest of 2 days and longest of 127 days. The median is at 18.23 days. For patients infected with COVID-19, the average length of stay is 50.33 days, as shown in table 2.

Table 2. Medical Procedures, Complications and Treatment Results

Medical Procedures/ Complications/ Treatment Results		Total N=180 (%)	CLTI + COVID-19	CLTI non COVID-19	*p*
Medical Procedures	PTA	90 (48.6)	1	89	-
	PTA with stent	84 (45.4)	2	82	
	Endarterectomy	4 (2.2)	-	4	
	Hybrid procedure	7 (3.8)	-	7	
Complications	Myocardial Infarction	1 (2.3)	-	1	-
	Acute Kidney Injury	9 (21.0)	-	9	
	Ischemic stroke	1 (2.3)	-	1	
	Acute limb ischemia	2 (4.7)	-	2	
	Major Amputation	1 (2.3)	1	-	
	Peri-operative death	5 (11.6)	-	5	
	Other	24 (55.8)	-	24	
Length of stay (Days) mean ± SD		18.77 ± 21.69	50.33	18.23	-

3.3. Laboratory Test Results

Laboratory testing results show HbA1C at average of 6.93% and Serum Albumin at 3.26 g/dL. COVID-19 test results found 3 patients (1.70%) detected with COVID-19 in which the level of Serum Albumin has a statistically significant correlation with complications after surgery at p<.001 as shown in Table 3.

Table 3. Laboratory Testing Results

Laboratory Testing Results	Total N = 180 (%)	CLTI + COVID-19	CLTI non COVID-19	*p*
HbA1C mean ± SD	6.93 ± 1.49	7.40	6.93	.761
Albumin mean ± SD	3.26 ± 0.68	2.70	3.27	<.001*
COVID-19 (Detected)	3 (1.7)	-	-	.542

4. Discussion

The outbreak of COVID-19 has affected the time to access treatment due to increasing procedures taken to screen for COVID-19 before being accepted as inpatient. In the early stage of COVID-19 infection, technologies to detect and report COVID-19 infections were taking much time while infected patients would experience the release of Cytokine which can lead to organ failures and increasing blood clogged in the same peripheral artery risking of higher chance of amputation (8). As this research aims to study clinical characteristics and outcomes of chronic limb-threatening ischemia patients which were treated with Endovascular treatment during COVID-19 outbreak, it is found that the majority of patients are male and have history of smoking which is in accordance to several researches being studied (12). Most of the patients are elderly and since Thai society is moving towards Aging-society, there are higher chances to find more chronic limb-threatening ischemia patients (13). Older patients treated with Endovascular Treatment can experience higher risk of complications and high mortality rate of 20 percent especially in patients whose age is more than 75 years old (14). Wifi Classification state IV which can lead to higher risk of amputation can refer to the level of advanced tertiary care hospital that can treat patients with chronic and complex conditions and that it can receive referral patients from sub-urban hospitals and adjacent regions. Most patients have comorbid diseases especially hypertension and diabetes at 87.2 percent and 82.2 percent in consequence. These diseases are risk factors that can cause chronic limb-threatening ischemia and complications after surgeries more than patients with no comorbid disease (3). Medication that most of the patients received is Dual Antiplatelet at 38 percent which explains that after the revascularization to reduce blood clogged, relapse of arterial disease and reduce risk of amputation, patients should continue receiving Dual Antiplatelet for 1-6 months after going through medical procedures. However, the efficacy of medication might be reduced depending on types of medical procedures taken, anatomy and other personal factors such as the complexity of disease or record of failed revascularization (2). One male chronic limb-threatening ischemia patients infected with COVID-19 were found experiencing complication after surgery due to the pathology of the patients with five clogged spots and Wifi Classification state 3. It is also found that the average length of stay is 2.68 times longer than

the patients who are not infected, which might be caused by the procedures taken during COVID-19 outbreak where infected patients must be separated to Isolation Ward for 2 weeks. After that, they will receive treatment of the main disease. Patients infected with COVID-19 has lower level of Serum Albumin than the patients who were not infected. The Wifi Classification at state 2-4 explains that chronic limb-threatening ischemia patients that were infected with COVID-19 has more risk to have complications and amputation because Serum Albumin was low (2.70 g/dL) and the level of Serum Albumin has statically significant correlation with complications after surgery ($p<.001$). Rates of losing legs are also associated with many factors both internal and external which related to the management of each hospital during COVID-19 outbreak (15).

Chronic limb-threatening ischemia is a complex and chronic disease which can be found commonly in elderly, smokers and patients with comorbid diseases. This group of patients is in risk of being disabled from losing legs, and the disease could be more severe and lead to death. Patients with COVID-19 infection and lower Serum Albumin are in risk of losing legs, deaths and wider length of stay in hospitals which eventually lead to higher treatment expenses. Thus, medical personnel and nurses should give more attention to the management of Nutrition status to solve low level of Serum Albumin because the patients will have higher state of Wifi classification which lead to higher risk of amputation.

Ethical Statement

This research has been certified by the ethical committee of the Faculty of Medicine, Vajira Hospital (COA 038/2566) on February 20, 2023, by collecting data based on the respect for persons.

Conflict of interest

None of the authors has any potential financial conflict of interest related to this manuscript.

Funding

No to declare.

Acknowledgments

Researchers are highly appreciated of the Faculty of Medicine of Vajira Hospital, Kuakarun Faculty of Nursing, Navamindradhiraj University and Assist.Prof. Sathit Panvilai of correcting English Grammar.

Authors' contributions

Concept: P.K., S.W., Design: S.C., P.W., Data collection or Processing: P.K., S.C., Analysis or Interpretation: S.C., Literature Search: T.S., K.O., N.K., Writing: P.K., S.C.

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