Conservative Regimen for Chronic Critical Limb Ischemia

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Abstract

Objective : The objective of this study was to determine the effectiveness of the treatment of chronic critical limb ischemia by conservative regimen.

Method : Data for all patients who underwent a conservative regimen at a single institution from January 1997 to December 2001 were entered into the registry. Conservative regimen consisted of cilostazol (Pletaal) 200 mg/day, a vegetarian diet, had completely stopped smoking and had progressive walking training.

Results : A total of 53 patients (59 limbs) with chronic critical limb ischemia were treated with a conservative regimen. The conservative regimen failed in 19 limbs (32.2%). In the failed limbs, infrainguinal bypass was performed on 8 limbs, aortoiliac endarterectomy was performed on 1 limb and 6 had primary amputation. The other four limbs were treated conservatively until death because of very poor cardiac function. Post-operatively, 2 grafts had thrombosis and led to amputation.

Conclusion : These early results appear to be promising with 67.8 per cent limb saving. This conservative regimen may be appropriately performed in selected chronic critical limb ischemia, especially those who presented with clinical severe claudication, rest pain or nonhealed ulcer. Cilostazol administration may play a positive role in gangrenous limbs.

Key word : Conservative Regimen, Critical Limb Ischemia, Cilostazol

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As the number of persons surviving to old age increases, chronic critical limb ischemia (CLI) is a progressively growing problem[1]. The main goal of CLI management is to avoid major amputation. Evidence is now accumulating that appropriately performed vascular bypass can reduce the amputation rates[2-4]. Reports have identified deficiencies in the delivery of care to patients with CLI[5,6]. The varies published results of arterial reconstructive surgery are usually ascribed to differences in patient selection rather than surgical technique[7]. Late reinterventions are common after infrainguinal bypass, and contribute to morbidity and discomfort[8].

CLI occurs when resting blood flow is insufficient to meet the maintenance metabolic requirements for nonexercising tissue. Progressive gangrene with an ultimate need for amputation is believed by most vascular surgeons to be the inevitable outcome in patients with unrelieved CLI. Although it is conceded that CLI may resolve spontaneously in the occasional patient, in association with the development of collaterals, this is thought to be a rare event[9].

Atherosclerosis is initially a slow process that involves endothelial dysfunction and the accumulation of intimal lipids, monocytes, and T lymphocytes, which leads to the migration and proliferation of smooth muscle cells and the elaboration of collagen and matrix in the subintimal layer. The magnitude of endothelial dysfunction correlates with the number of risk factors[10]. The role of rheologic factors in the progression of CLI has been investigated[11-13]. Patients with intermittent claudication also have impaired fibrinolysis associated with elevated plasminogen activator inhibitor[11]. Experimentally, the phosphodiesterase inhibitor HL 725 has been observed to decrease plasminogen activator inhibitor messenger RNA levels[12]. Researchers have found significant associations between fibrinogen and whole blood and plasma viscosity and the risk of moderate progression of peripheral arterial disease[13].

Multiple pharmacological agents have been investigated for efficacy in elimination of symptoms of limb ischemia. Pentoxifylline improves red cell deformability; lowers fibrinogen levels, decreases platelet aggregation, and has been shown to increase walking distance in patients with claudication. Cilostazol was approved by the USFDA. Mean maximal walking distance of cilostazol treated patients was significantly greater at every postbaseline visit compared with patients who received pentoxifylline or placebo[14]. Cilostazol has antiaggregation effects on platelets, beneficial effects, but how these might relate to improvements in walking is unknown. Cilostazol is not known to have direct effects on skeletal muscle and CLI.

Adenosine 3′,5′-cyclic monophosphate (cAMP) promotes vasodilatation. cAMP phosphodiesterases degrade cAMP to 5′-AMP. Cilostazol is a type III phosphodiesterase inhibitor which produces mild vasodilation by direct action on vascular smooth muscle by increasing intracellular cyclic adenosine monophosphate. This effect blocks the release of calcium ions from intracellular storage granules, inhibiting contractile protein function[15]. cGMP phosphodiesterases play an essential role by limiting increases in cellular cGMP, and inhibition of these enzymes was found to potentiate the effects of nitric oxide and nitric oxide donors on platelets and other cells. The increase of cAMP is attributable to the inhibition of phosphodiesterase III by cGMP that mediated the synergistic inhibition of platelet aggregation by activators of adenylyl and guanylyl cyclases[16]. Nitric oxide is a very potent vasodilator. Therefore, cilostazol may play an important role in CLI.

The purposes of the following analysis were to assess the effectiveness of cilostazol in-patients with CLI and to define the role of cilostazol in CLI.

PATIENTS AND METHOD

Patient evaluation

Patients were recruited from the diabetic foot and vascular clinic. Each patient underwent a full clinical assessment. Patients were considered to have CLI if they had gangrenous tissue, a nonhealed ulcer, rest pain and claudication class III (claudication distance less than 200 m). Nonhealed ulcers were considered if skin epithelization and wound contraction was not seen after appropriate treatment for one month. Rest pain without other clinical vascular ischemia was excluded because there might be similar painful neuropathy. Angiography was performed in almost all of the patients, except for those who refused the procedure due to possible angiographic complications. Angiographic Assessment Score was published by Faglia et al (Table 1)[17]. Angiographic Assessment Score was the summation of individual scores from 1) common iliac-external iliac-common femoral artery 2) superficial femoral artery 3) profunda femoris artery 4) popliteal artery 5) anterior tibial artery 6) posterior tibial artery 7) peroneal artery. Angiographic score was calculated and those with a score < 6 were excluded. The angiogram must show complete occlusion of one

Table 1. Angiographic assessment score(17).

Level of Stenosis	Score
Stenosis < 50%	0
Stenosis 50-75%	1
Stenosis 75-99%	2
Complete occlusion	3

artery at least. Patients without angiography underwent a measurement of ankle-brachial pressure index (ABI) and patients with an ABI of more than 0.7 were excluded.

Conservative regimen

Patients with CLI who didn't undergo urgent revascularization and/or amputation, gave their informed written consent. Patients were told about cilostazol and the conservative regimen. Conservative regimen consisted of cilostazol (Pletaal) 200 mg/day, a vegetarian diet, had completely stopped smoking and had progressive walking training. All patients were treated with cilostazol. Patients who completely and incompletely performed the conservative regimen were classified as the "full regimen group" and "partial regimen group", respectively.

Follow-up

Patients who had the conservative regimen with weekly visits were checked regularly for clinical limb ischemia. Gangrene was recorded in the ischemic area and classified to four levels (Table 2). Clinical wounds were classified as 'failure' status, when the grade decreased. A clinical wound was classified as 'stable' status, when the grade did not change. A clinical wound was classified as 'success', when the grade increased.

Clinical rest pain was based on the American Heart Association Committee on Exercise and Rehabilitation classification(18) (Table 3). Clinical pain was classified as 'failure' status, when the grade increased. Clinical pain was classified as 'stable', when the grade did not change. Clinical pain was classified as 'success', when the grade decreased. Clinical claudication was classified as severe and non-severe. Severe claudication had a claudication distance of less than 200 meters and non-severe had a value of more than 200 meters. Claudication treatment was classified as 'failure', when claudication distance had decreased. Claudication treatment was classified as 'stable', when claudication distance had not changed. Claudication treatment was classified as 'success', when claudication distance had increased.

End result was classified as 'failure', when amputation or vascular bypass was performed. End result was classified as 'success', when clinical symptoms had complete resolution, and the patients were physically fit or had improved in patients who had poor physical fitness status.

Data analysis

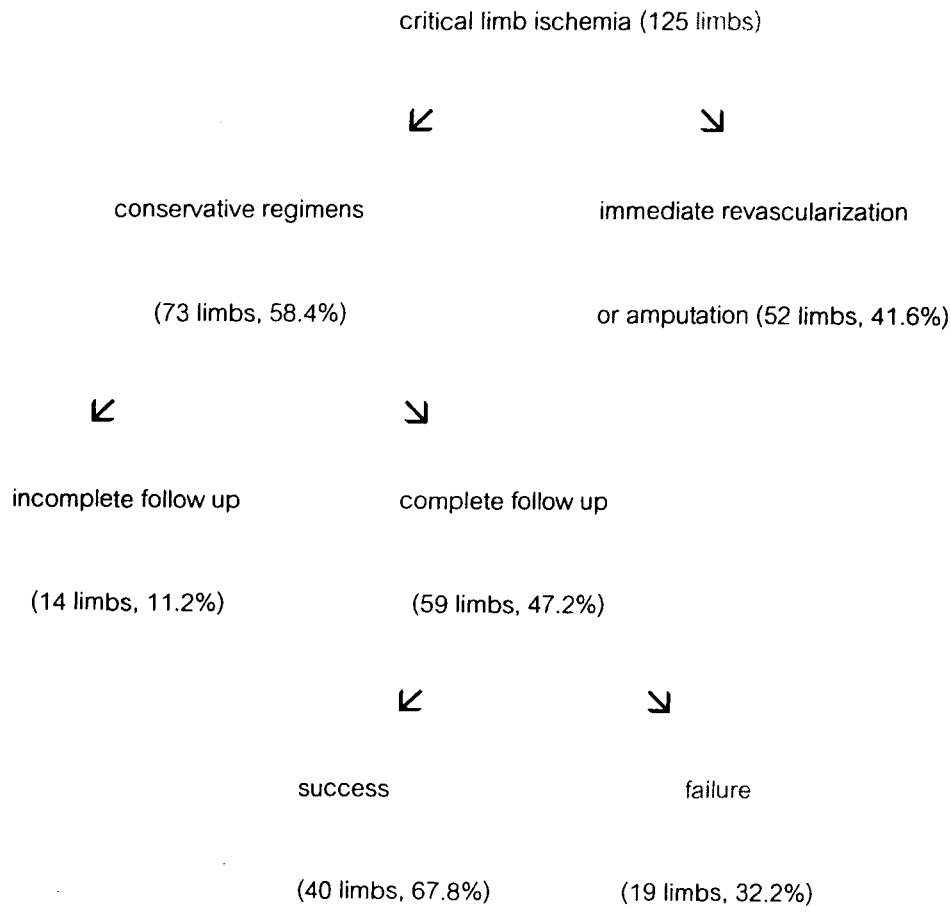
Patients with full regimen or partial regimen were compared with the Chi-square test. Data in the

Table 2. Clinical gangrene-nonhealing ulcer classification.

Grade	Clinical Description
0	Worsening of gangrene area (depth or size).
I	Absent granulation tissue, stable gangrene area.
II	Positive blood stain after the dressing was changed, skin epithelization can be seen.
III	Some blood oozing after the dressing was changed, skin epithelization can be seen.

Table 3. Rest pain grading(18).

Grade I	Definite discomfort or pain, but only of initial or modest level.
Grade II	Moderate discomfort or pain from which the patient can have his or her attention diverted by a number of other stimuli.
Grade III	Pain from which the patient's attention cannot be diverted, but which is short of grade IV.
Grade IV	Excruciating and unbearable pain.



second week after starting the regimen was compared with the end result by the Contingency Coefficient. Failure was defined by major amputation or vascular bypass. Result in pain, nonhealed ulcer and tissue loss were compared with the Chi-square test.

RESULTS

Patient population

Between January 1, 1997, and December 31, 2001, the authors performed vascular service on 125 limbs in 110 patients for CLI. Five patients with Buerger's disease were excluded. Patients with CLI who needed serial debridement were also excluded. Forty-seven patients who underwent urgent debridement, revascularization and/or amputation were also excluded. These exclusions yielded a primary study of 63 patients who underwent a conservative regimen. Ten patients in the conservative group had incomplete follow-up and were excluded. Six patients were bilateral. A total of 15.09 per cent (8/53) of patients had a positive history of cigarette smoking, and two were current smokers. Patients with diabetes accounted for 83.02 per cent (44/53) of the population. Seventeen patients (32.07%) had secondary infection. Twenty-four of these patients were male and twenty-nine were female. Angiogram was performed on 41 limbs and 18 patients refused angiogram.

Treatment

Fifty-three patients received cilostazol 200 mg/dl. Twenty-seven limbs were treated by full regimens. Thirty-two limbs were treated by partial regimens.

Outcome

The conservative regimen succeeded in 40 limbs (67.8%) and failed in 19 limbs (32.2%). The partial regimen succeeded in 16 limbs (50%). The full

regimen succeeded in 24 limbs (88.88%) (Table 4). In the failed limbs, infrainguinal bypass was performed on 8 limbs, aortoiliac endarterectomy was performed on one limb and six limbs had primary amputation. The other five limbs had conservative treatment until death because of very poor cardiac function. In situ autogenous vein grafts were used for six bypasses (75%) and two reversed bypasses (25%). Post-operatively, two grafts had thrombosis and led to amputation.

When the data was analyzed depending on the clinical presentation the result was excellent in the pain and nonhealed tissue group. Treatment in those with pain presentation succeeded in all cases. In those with nonhealed tissue presentation treatment succeeded in 16 limbs (94.11%). In tissue loss presentation it succeeded in 14 limbs (43.75%) (Table 4).

When the data was analyzed on timing the results were dramatic. After 2 weeks, thirty-four limbs had been treated successfully. In this group, thirty limbs were treated successfully and four limbs had a failed end result. After 2 weeks, twelve limbs were stable. In this group, ten limbs were treated successfully and two limbs had a failed end result. After 2 weeks, thirteen limbs had failed. In this group, all cases were cross limbs.

Data analysis

Ten patients were in the pain group. All of the pain patients were treated successfully with conservative regimen. Seventeen patients were in the nonhealed tissue group. In the nonhealed tissue group, sixteen were successful. Thirty-two patients were in the tissue loss group. In the tissue loss group, fourteen were successful. The pain and nonhealed tissue group were compared with the tissue loss group. The differences achieved statistical significance ($p < 0.005$). The full regimen and partial regimen were compared with Chi-square test. The full regimen showed a significantly better success rate than the partial regimen group ($p < 0.005$). At the second week, clinical results were successful or stable in 46 limbs. In these patients, forty limbs had a successful end result (86.96%).

Table 4. Full conservative regimen and partial conservative regimen.

Clinical presentation	Full regimen		Partial regimen		Total
	Success	Fail	Success	Fail	
Gangrene	8	3	6	15	32
Nonhealed ulcer	7	-	9	1	17
Rest pain (alone)	2	-	1	-	3
Disabling claudication	7	-	-	-	7
Total	24	3	16	16	59

Table 5. Results after conservative regimen in CLI.

Clinical presentation	Total limbs	2 weeks success	End result success
Pain	10	8	10
Rest pain alone	3	2	3
Severe claudication (< 200 m)	7	6	7
Tissue loss	32	14	14
Toe gangrene alone	7	4	4
Foot gangrene alone	7	2	3
Toe gangrene with pain	11	5	5
Foot gangrene with pain	7	3	2
Nonhealed tissue	17	12	16
Nonhealed ulcer alone	12	8	12
Nonhealed ulcer with pain	5	4	4
Total result	59	34	40

DISCUSSION

Vascular bypass showed a significant reduction in peri-operative mortality from the double-digit levels of the 1960s to a current rate of 1.5 per cent [19]. Morbidity remains high. Wound complication after infrainguinal bypass was common[20]. Diabetic patients with end-stage renal disease (ESRD) who have CLI are at significant risk for limb loss despite aggressive and successful revascularization[21]. Furthermore, twenty per cent of patients subsequently needed intervention in the contralateral leg (infrainguinal bypass 83%, primary major amputation 17%)[22]. Vascular bypass may be temporary in limb ischemia, especially in a critical ischemia attack. Seeking medical treatment is necessary for quality of life.

Atherosclerosis is the most common pathology in critical limb ischemia, cardiac ischemia and cerebrovascular occlusive disease. At present, it is known that the pathogenesis of atherosclerotic formation includes smoking, diet, diabetes, and hypertension. When patients reduce these atherosclerotic factors, clinical ischemia improves.

Dietary intake plays a pivotal role in atherosclerosis formation. In controlled animal studies, dietary plants significantly reduced the atherosclerotic area[23]. *In vitro* study showed that garlic has a direct effect on the inhibition of smooth muscle cell proliferation and reduces fatty streak development [24]. In an epidemiological study, animal fat and saturated fat were positively related to atherosclerosis, while vegetable fat and polyunsaturated fat were inversely related to athrosclerosis[25]. In a long-term cohort study, daily consumption of vegetables was associated with significantly reduced mortality from ischemic heart disease and cerebrovascular disease [26]. Therefore, a vegetarian diet is necessary for atherosclerotic prevention in the long-term.

The effects of lower limb exercise training in patients with intermittent claudication is well known. Yang et al concluded that walking training directly improved the lower limb structure[27]. However, patients with lower limb ischemia who perform upper limb exercises, improve their walking distances[28]. This result is in concordance with cardiac pumping improvement. The patients in the present study performed both upper limb and lower limb exercises. In upper limb exercise, the author recommends handgrip exercise for patients.

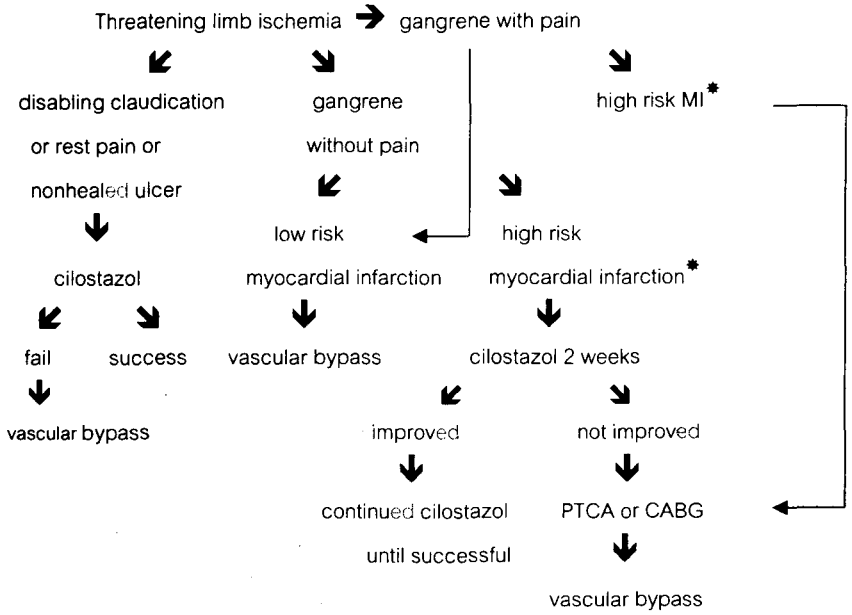
Cilostazol (6-[4-(1-cyclohexyl-1H-tetrazol-5-yl) butoxyl]-3,4-dihydro-2(1H)-quinolinone, OPC-13013, CAS 73963-72-1) is a type III phosphodiesterase inhibitor. Although its mechanism of action is not fully understood, cilostazol is thought to inhibit cyclic adenosine monophosphate phosphodiesterase, which leads to an increase in cyclic adenosine monophosphate in platelets and blood vessels, and to promote the effect of prostaglandin I_2, an endothelial cell-derived substance that inhibits platelet aggregation and relaxes vascular smooth muscle. Cilostazol is an antithrombotic agent that inhibits platelet aggregation and increases vasodilatation. Its antiplatelet activity is 10 to 30 times more potent than aspirin[29].

Cilostazol inhibits platelet aggregation in a dose-dependent manner in the presence or absence of endothelial cells, although their presence potentiates this inhibitory effect[30,31]. It also inhibits replication and growth of rat vascular smooth muscle cells in tissue culture[32]. The inhibition of primary or secondary platelet aggregation by cilostazol may have relevance to claudication through reduction in inflammatory cytokines stimulated by the ischemia reperfusion cycle of exercising muscles with a restricted blood supply[33].

Cilostazol has other significant effects. Significant positive changes were observed in high-density lipoprotein cholesterol and triglyceride levels in patients receiving placebo. A dose-dependent increase in heart rate was observed in patients who received cilostazol[34].

Table 6. Comparison between second week and end result.

End result	2nd week			
	Success	Stable	Failure	Total
Success	30	10	0	40
Failure	4	2	13	19
Total	34	12	13	59



Guideline management limb ischemia with cilostazol.

This study indicates that conservative regimen will palliate critical limb ischemia. Based on research experience with full regimen and partial regimen, there appears to be a higher success rate in full regimen. The value of a conservative regimen for patients with pain or a nonhealed ulcer is dramatic healing. The value of a conservative regimen for patients with tissue loss remains unresolved. In patients with tissue loss, fourteen limbs were successful (43.75%). This result may consider a fair result; however, clinical success in tissue loss usually occurs after six months.

In general, however, the compliance of the regimen of patients in the partial regimen group are low. Some patients have severe foot pain or a large gangrenous wound and the majority of patients cannot perform walking exercise. Therefore, this paper has some bias in patient selection. Therefore, selection before inclusion in these studies may also play a role in the outcome. Many patients with severe critical limb ischemia, who needed serial debridement, were also excluded.

Based on research experience with a conservative regimen, cilostazol should be considered in patients with pain or a nonhealed ulcer. Patients with tissue loss and low risk of developing myocardial infarction should be considered for vascular bypass. Patients with tissue loss with a high risk of developing myocardial infarction may be treated by a full conservative regimen. The clinical results in the second week after treatment can predict the end result. Absence of clinical deterioration is associated with a successful end result. However, gangrenous limbs with pain should be considered for vascular bypass.

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การรักษาภาวะขาขาดเลือดวิกฤติแบบไม่ผ่าตัด

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วัตถุประสงค์ : เพื่อศึกษาถึงประสิทธิภาพของการรักษาภาวะขาขาดเลือดวิกฤติแบบไม่ผ่าตัด

วิธีการศึกษา : ศึกษาจากผู้ป่วยขาขาดเลือดวิกฤติที่เข้ารับการรักษาในวิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาลตั้งแต่เดือนมกราคม พ.ศ. 2540 ถึงเดือนธันวาคม พ.ศ. 2544 โดยใช้วิธีการรักษาแบบไม่ผ่าตัด ซึ่งประกอบไปด้วย การใช้ยา cilostazol (Pletaal) 200 มก.ต่อวัน, การรับประทานอาหารมังสวิรัติ, การหยุดสูบบุหรี่เด็ดขาดและการฝึกฝนการเดินอย่างค่อยเป็นค่อยไป

ผลการศึกษา : มีจำนวนผู้ป่วยขาขาดเลือดวิกฤติในการศึกษาทั้งสิ้น 53 ราย (59 ขา) ที่ได้รับการรักษาแบบไม่ผ่าตัด การรักษาให้ผลล้มเหลว 19 ขา (ร้อยละ 32.2) ผู้ป่วยที่การรักษาล้มเหลวได้รักษาด้วยการผ่าตัดชนิด infrainguinal bypass 8 ขา, aortoiliac endarterectomy 1 ขาและตัดขาทิ้ง 6 ขา ส่วนผู้ป่วยที่ล้มเหลวอีก 4 ขา ไม่ทำการรักษาใด ๆ เพิ่มเติม เพราะปัญหาการทำงานของหัวใจที่ไม่ดีมาก และภายหลังการผ่าตัดแบบ infrainguinal bypass มีหลอดเลือดอุดตันสองราย ได้ทำการตัดขาในท้ายสุด

สรุป : ผลของการรักษาแบบไม่ผ่าตัดในระยะแรกนี้ได้ผลดีร้อยละ 67.8 การรักษาแบบไม่ผ่าตัดอาจจะเหมาะสมสำหรับการรักษาผู้ป่วยขาขาดเลือดวิกฤติที่ได้รับการคัดเลือกอย่างเหมาะสม โดยเฉพาะอย่างยิ่งผู้ป่วยที่มาพบด้วยอาการเดินระยะสั้นแล้วปวดน่อง, การปวดเท้าเมื่ออยู่เฉยและแผลไม่หายภายใน 4 สัปดาห์ สำหรับขาขาดเลือดที่มีเนื้อตาย การรักษาแบบไม่ผ่าตัดอาจได้รับผลดีบ้าง

คำสำคัญ : การรักษาแบบไม่ผ่าตัด, ภาวะขาขาดเลือดวิกฤติ, cilostazol

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