

# Surgical Treatment for Intermittent Claudication in Patients Who do Not Improve with Clinical Treatment

Nelson Wolosker, Marco Antonio S. Munia, Ruben Rosoky, Ronald J. Fidelis, Livio Nakano, Paulo Kauffman, Pedro Puech-Leão.  
São Paulo, SP - Brazil

## Objective

To study the results obtained with surgical treatment of patients with intermittent claudication (IC) who did not clinically improve with conservative treatment, accompanied by a long follow-up (average 6 years).

## Methods

From January 1992 to January 2002, 26 patients treated surgically in a group of 1380 IC patient, representing 1.88% of the total.

## Results

Sixteen patients did not experience walking limitations after the surgery. Nine patients improved, however, with some degree of limitation. No intraoperative mortalities occurred. Three patients experienced thrombosis of the treated artery 6, 48, and 60 months after the procedure and started to suffer IC with onset at the same distances as before the surgery. During the long-term follow-up, we observed a mortality rate of 23.0% due to myocardial infarctions (4 patients), renal insufficiency (1 patient), and cerebral infarction (1 patient). Two patients underwent coronary bypasses 2 and 4 years after the vascular surgery, and one underwent coronary angioplasty after 3 years of follow-up. The mean follow-up was 73 months.

## Conclusion

In our study, the results from surgical treatment of IC brought about a lasting regression of the ischemic conditions in a significant number of patients, with excellent patency rates (88.4%). We conclude that this is a good alternative for select patients, with low rates of complications and positive long-term results.

## Key words

surgical treatment, claudication, clinical treatment

For patients with ischemic limb loss, the treatment of choice is revascularization with the aim of saving the limb. Arterial grafting and endovascular procedures are the methods utilized<sup>1,2</sup>. On the other hand, in patients with intermittent claudication (IC), the goal of treatment is to improve quality of life through increasing walking distances.

The relative benign natural evolution of IC<sup>3</sup> and the dubious surgical results obtained in the 1960s and 1970s<sup>4</sup> have justified conservative treatment for the majority of cases. Thus, in our service, a clinical approach is used in the initial stage of treatment. After a period of physical training, the therapeutic response is evaluated. When a good response is not achieved and the patient is in good physical condition, revascularization is proposed, which allows immediate benefits to be obtained<sup>5-7</sup>.

The use of revascularization in cases of IC has been progressively increasing. However, few prospective studies analyze its results among individuals who have not obtained improvement through clinical treatment, and even fewer in our environment, especially among patients with long-term follow-up.

The goal of this work was to prospectively study the results obtained through surgical treatment of patients with IC who did not improve clinically with conservative treatment, and with long-term follow-up (average of 6 years).

## Methods

From January 1992 to January 2002, 26 patients who were surgically treated for IC were followed up. These formed part of a group of 1380 patients with this condition, who were admitted during this period to an outpatient service for peripheral obstructive arterial disease and IC. The patients operated on represented 1.88% of the total.

All the patients treated in our service followed the sequence of therapeutic options presented in figure 1.

The clinical approach (unsupervised physical training and treatment of the risk factors for peripheral obstructive arterial disease) was utilized in the initial phase of treatment. After a period of clinical treatment lasting at least 6 months, the therapeutic response was analyzed. When it was unsatisfactory and the patient's clinical condition so allowed, the surgical approach came into play<sup>6</sup>.

In following this therapeutic sequence, we observed that, of the 1380 patients treated for IC in our institution, only 380 (27.5%) progressed without increasing their walking distance capability

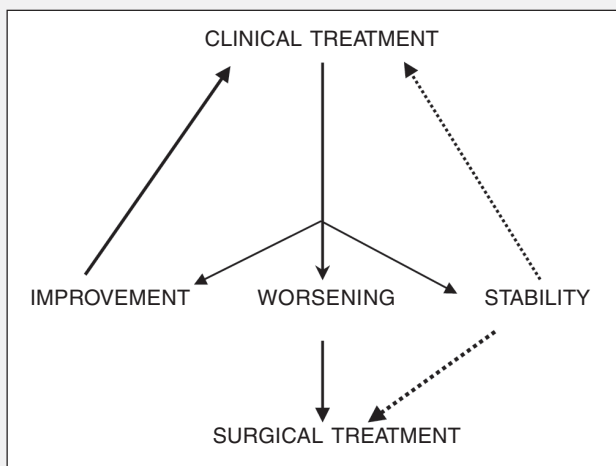


Figure 1 - Treatment schema for IC at Hospital das Clínicas, Faculty of Medicine of the University of São Paulo. The full lines represent the natural (accepted) sequence of treatment. The dashed lines represent alternative sequences that may or may not be utilized.

after a minimum period of 6 months of unsupervised clinical treatment. Of these 380 with poor results, 55 patients (4%) evolved to limb loss ischemia, and for these, revascularization was indicated as a form of therapy for saving the limb. For the remaining 325 (23.5%), revascularization was suggested for improving the walking distances. The majority of these patients (237 or 17.2%) preferred to continue with the clinical treatment because they did not want to run the risks inherent in the revascularization procedures, while the other 88 (6.2%) decided to avail themselves of this alternative. Thus, 62 endovascular procedures (4.4%) and 26 surgical procedures (1.8%) were performed. The latter is presented in this work.

Of these 26 patients who underwent surgical procedures, the average age was 56.4 years (43 to 68 years), with 88.4% of them smokers, 38.4% hypertensive and 26.9% diabetic. Nineteen were male.

The average duration of the claudication, from its appearance until the time of the surgery was 25 months, with a range of 7 to 72 months.

No patient included in this study experienced ischemic rest pain, tissue loss, or gangrene of ischemic cause. The average ankle-arm index was 0.55. No patient had arterial pressure lower than 40 mmHg in the tibial arteries.

All the patients underwent preoperative digital arteriography to determine the type of arterial revascularization to be used in each case. Surgery was performed on the patients who had obstructive disease in arterial segments of lengths greater than 5 cm. Cases that had lesions of lengths less than 5 cm were treated via endovascular methods. Aortoiliac disease was observed in 21 cases and femoropopliteal disease in the other 5.

To objectively assess the severity of IC, we measured the maximum walking distance (MWD) by using a progressive treadmill test. This was done at a constant velocity of 3.2 km, initially on the level (0 degrees) with a progressive increase of 2% in the inclination every 2 minutes. The test was performed until pain prevented the patient from continuing to walk, and this formed a comparison standard during the follow-up <sup>7</sup>.

The vascular evolution was determined by means of the

walking distance values obtained in progressive treadmill tests performed at all return visits. The evolution was considered favorable when an increase of more than 50 meters occurred in the distance walked. The remaining cases were considered to have unfavorable evolution.

The surgical techniques used are shown in Table I.

Patients were reevaluated after 3 months, 6 months, and every 6 months thereafter. Follow-up duration ranged from 6 to 123 months, with an average of 73 months. At each visit, the treadmill test was performed and MWD determined. The functioning of the grafts was confirmed by physical examination and color duplex scan.

The variables analyzed were the functioning of the graft and the evolution in the maximum walking distance.

## Results

Only 1 primary failure occurred, which was in a patient who received an aortobifemoral graft. This patient immediately underwent thrombectomy of the graft, associated with femoropopliteal grafting above the knee, to improve the runoff.

No worsening of the degree of ischemia or necessity of amputation occurred in this group.

Sixteen patients did not mention any remaining limitation to walking distances after the surgery. Eight patients experienced a significant improvement, although with some degree of limitation, and 2 had a little improvement in their maximum walking distance (less than 50 meters). Thus, 24 patients had a favorable evolution and only 2 had an unfavorable evolution.

During the follow-up, 3 patients experienced thrombosis of the treated artery, which occurred 6, 48, and 60 months after the procedure. After this occlusion, these patients started to suffer IC with onset at the distances that applied before the surgery. These were walking distances that did not inhibit their basic activities. We observed relapse to previous claudication levels in another 3 patients, due to disease progression in the femoropopliteal segment. These were patients who had previously undergone aortobifemoral grafting.

Four patients suffered acute myocardial infarctions 21, 48, 52, and 72 months after surgery, and died. One patient died because of renal insufficiency 48 months after the surgery, and 1 died 32 months after the surgery due to cerebral infarction. Two patients underwent coronary bypasses 2 and 4 years after the vascular surgery, and 1 patient required coronary angioplasty after 3 years of follow-up.

Results of the long-term patency are shown in table II and figure 2.

	número
Aorto-bifemoral graft	12
Aorto-bi-iliac graf	5
Iliac-femoral graft	3
Femoropopliteal	4
Crossed femoral	1
Distal femoral	1

Table II - Follow-up results									
Interval (Months)	No. at risk at start of interval	No. failing during interval	Withdrawn during interval			Interval patency rate patency rate (%)	Cumulative	Standard error	
			Death	Time	Lost to follow-up				
0-3	26	0	0	0	0	100	100	0	
3-6	26	1	0	1	0	96.07843	96.07843	0.037678	
6-12	24	0	0	1	0	100	96.07843	0.039248	
12-18	23	0	1	0	0	100	96.07843	0.040111	
18-24	22	0	0	0	0	100	96.07843	0.040564	
24-30	22	0	1	1	0	100	96.07843	0.041519	
30-36	20	0	0	1	0	100	96.07843	0.043086	
36-42	19	0	0	2	0	100	96.07843	0.044846	
42-48	17	1	2	1	0	93.54839	89.87982	0.072626	
48-54	13	0	0	1	0	100	89.87982	0.080873	
54-60	12	0	0	0	0	100	89.87982	0.08254	
60-66	12	0	0	1	0	100	89.87982	0.084315	
66-72	11	1	0	1	0	90.47619	81.31984	0.108466	
72-78	9	0	0	1	0	100	81.31984	0.120553	
78-84	8	0	1	1	0	100	81.31984	0.132843	
84-90	6	0	0	0	0	100	81.31984	0.143487	
90-96	6	0	0	1	0	100	81.31984	0.149867	
96-102	5	0	0	1	0	100	81.31984	0.165684	
102-108	4	0	0	1	0	100	81.31984	0.187868	
108-114	3	0	0	2	0	100	81.31984	0.248526	
114-120	1	0	0	1	0	100	81.31984	0.497052	

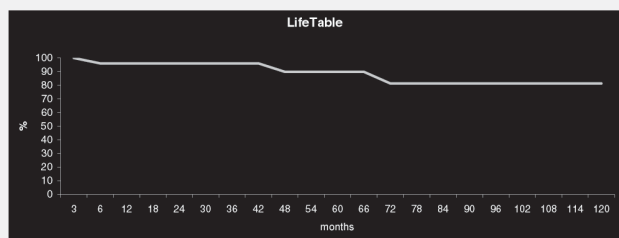


Figure 2 - Long term follow-up and graft patency.

## Discussion

At the beginning of the revascularization era, in the 1960s and 1970s, it was thought that the natural evolution of IC would be an inexorable progression of the ischemia until consequent loss of the limb, which appeared to justify early surgical treatment. However, the surgical techniques and equipment available at that time were less developed than those of today, and the results were debatable<sup>4</sup>. Although the risk of losing the limb with conservative treatment does exist, studies using large samples have demonstrated that this progression is unusual. Boyd<sup>10</sup> studied 1440 patients with IC and saw that, after 10 years, 12.2 % had required amputation. In the Framingham study, only 1.6 % of claudication patients required amputation within a period of 8.3 years<sup>8</sup>.

Because patients treated clinically had low amputation rates, the clinical approach came to be utilized more reassuredly, safely, and frequently from the 1970s onwards<sup>3</sup>, thus relegating surgical treatment to a secondary position.

Reduction in the risk of limb loss has ceased to be the main objective of treatment. Instead, the objective has become improvement in the quality of life of IC sufferers, by reducing their physical limitations while always respecting the risks and benefits of each procedure<sup>9</sup>.

Based on such premises, we have begun in our service to utilize the sequence of therapeutic options presented in figure 1.

In our sample, we observed that 80.7% of the patients had aortoiliac disease, and only 19.3% had disease in the infra-inguinal segment. This is because revascularization in more proximal (aortofemoral) segments favors good evolution<sup>10</sup>, which is why the indication of such procedures is marked by better prognoses and is done more frequently.

Bypass with an arterial prosthesis is the surgical procedure most frequently used in patients with extensive obstructive arterial lesions in the aortoiliac segment. The synthetic substitute is generally placed in an aortobifemoral, aortoiliac, or iliac-femoral position, which was observed in 76.9% of our cases.

In femoropopliteal obstructive arterial disease, it has been demonstrated that femoropopliteal grafts above the knee performed using the inverted or noninverted saphenous vein, a Dacron or polytetrafluoroethylene prosthesis, and endarterectomy of the superficial femoral artery have similar results. On the other hand, femoropopliteal grafting up to just below the knee has had results that are evidently better by using an autogenous arterial substitute, in comparison with synthetic substitutes<sup>11</sup>. We observed that, of the 4 femoropopliteal grafts, 2 were performed using a prosthesis and the other 2 used an inverted saphenous vein, as well as femorotibial grafting.

Surgical techniques and materials have provided great improvements over the years. This has allowed improvements in the immediate surgical results, and this is seen both in the literature in general<sup>12,13</sup> and in our sample, in which we had primary patency of 96% and secondary of 100%, and 88.4% of the grafts showed patency after an average of 73 months of follow-up.

In relation to the evolution, attention must be paid to obstructive and nonobstructive late complications (infection and pseudoaneurysm). Nonobstructive complications have not yet been seen in our sample. The fact that the patients operated on did not have serious ischemia suggests that these were patients with artery margins less affected by peripheral obstructive arterial disease and possibly with a better prognosis than for those that are more



compromised and have more severe clinical manifestations. On the other hand, since all the operations in this study were performed on an elective basis, all our patients experienced their best possible clinical conditions.

Atherosclerotic disease progression is a significant reason for recurrence of ischemic symptoms in the lower limbs<sup>14</sup>. In our series, even with the control of risk factors and close follow-up, 3 patients (11.5%) had thrombosis in the treated artery, and 3 other patients (11.5%) had distal occlusions, probably because of the longer follow-up period, which had allowed evolution of the atherosclerotic disease.

Despite the fact that these patients were considered at moderate surgical risk, we did not observe intraoperative mortality among this sample, probably because it was a small sample. On the other hand, during the long-term follow-up, we observed, as in other samples<sup>15</sup>, a mortality rate of 23.0% over our average follow-up time of 73 months. The main cause of death was acute myocardial infarct (15.3%). In addition to this, 3 patients underwent cardiac revascularization during this period. These data confirm data found in the literature and confirm the consensus that occlusive disease of lower limbs is an important marker for associated coronary disease.

The treatment of IC has been evolving and is being refined with knowledge of the natural history of the condition, and with the utilization of physical training techniques and surgical techniques that are steadily becoming more developed.

The clinical approach has in its favor its noninvasive nature, with a low incidence of complications<sup>16</sup>, as well as its systemic action. It tends to improve walking distance capability in a slow and gradual manner, bringing benefits to the whole cardiovascular system and interrupting or at least diminishing the progression of the atherosclerotic disease<sup>17-24</sup>. Nonetheless, to obtain the desired effect, great effort is required on the part of the patient, and the treatment takes a long time.

The surgical approach is defended because of the rapidity with which its benefits emerge and can be made use of<sup>18-27</sup>. In our sample, 92% of the patients experienced immediate improve-

ment in their symptomatology after the surgical procedure. From a socioeconomic point of view, the rapid reintegration of patients into their habitual activities, including work and especially among younger patients, justifies the adoption of this type of therapy more frequently<sup>19</sup>.

The data obtained from the literature and our personal experience over the last 10 years allows us to give patients with IC up-to-date information regarding their prognosis with a large safety margin. On the other hand, the results from the present study and those from other work regarding the surgical treatment of IC lead to the conclusion that this is a therapeutic approach that is now very mature, as a result of the sophistication and refinement of techniques and technologies. Although the indication of surgery for IC is still the exception, the results contrast greatly with those that obliged the relegation of surgical treatment to a secondary position.

In making a detailed analysis of our sample, it can be noted that only the patients with an unsatisfactory response to clinical treatment underwent surgery. Thus, these patients possibly had a more reserved prognosis in relation to those who had better evolution when approached in the same way. It is possible that the patients studied here had arterial margins that were more compromised, disease of a more aggressive character or muscle conditions that were less favorable than those in the patients who improved with clinical treatment. In this way, considering the good results obtained with this sample, we may infer that the surgical treatment of patients who do not necessarily experience improvement with clinical treatment will possibly bring results that are equal to or even more promising than clinical treatment. We believe that the role of surgery in the treatment of IC must be reconsidered in the sense of expanding its coverage.

In our study, the results from surgical treatment of IC brought about a lasting regression of the ischemic conditions in a significant number of patients, with excellent patency rates. We conclude that this is a good alternative for select patients, with low rates of complications and positive long-term results.

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