# Long-term Outcome of Femoropopliteal Chronic Total Occlusion Percutaneous Treatment

Evolución alejada del tratamiento percutáneo de las oclusiones totales crónicas femoropoplíteas

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## ABSTRACT

**Background:** The endovascular approach of peripheral vascular disease is currently the treatment of choice in patients with severely limited functional status. Chronic total occlusions (CTO) are lesions that pose a great challenge both for the clinician and the interventionist.

**Objective:** The aim of this study was to analyze the feasibility and long-term outcome of CTO patients undergoing percutaneous intervention.

Methods: From January 2008 to July 2013, consecutive patients with at least one chronic total occlusion of the femoropopliteal segment, undergoing elective or urgent percutaneous intervention, were included in the study. Demographic, angiographic and technical aspects were analyzed and clinical long-term follow-up was performed by telephone or medical contact.

**Results:** From a total of 431 treated patients, 129 presented with femoropopliteal CTO. TASC A-B lesions accounted for 62.8% of cases and TASC C-D lesions for 37.2%. Stents were implanted in 62.7% of patients and complementary techniques were used in 22% (change of access, re-entry catheters, microdissection). Angiographic success of the procedure was 85.2%.

Clinical improvement of 782.2 meters in the walking distance (25-75% interquartile range: 391-1,173) was obtained in the successfully treated patients. In the multivariate analysis, run-off (OR 3.71, 95% CI 1.01-9.65; p=0.048) was the only independent success variable. During the 623-day follow-up period (25-75% interquartile range: 430.7-1,292.2) 20 reinterventions (15.5%) and 3 intervention-unrelated amputations were performed.

**Conclusions:** Percutaneous CTO treatment in the femoropopliteal territory is feasible in a high proportion of patients, with significant improvement in walking distance. The long-term outcome is associated with a significant rate of reinterventions.

Key words: Arterial Occlusive Diseases - Femoral Artery - Popliteal Artery - Angioplasty

#### RESUMEN

**Introducción:** El abordaje endovascular de la enfermedad vascular periférica es en la actualidad la opción terapéutica de preferencia en pacientes seriamente limitados funcionalmente. Las oclusiones totales crónicas (OTC) son lesiones que suponen un gran desafío tanto para el médico clínico como para el intervencionista.

Objetivo: Analizar la factibilidad y la evolución alejada de los pacientes con OTC intervenidos en forma percutánea.

Material y métodos: Desde enero de 2008 hasta julio de 2013 se incluyeron pacientes consecutivos portadores de al menos una oclusión total crónica del segmento femoropoplíteo intervenidos percutáneamente tanto en forma electiva como urgente. Se analizaron aspectos demográficos, angiográficos y técnicos y se efectuó un seguimiento clínico alejado mediante consulta clínica o vía telefónica. **Resultados:** De un total de 431 pacientes intervenidos, 129 presentaban OTC femoropoplítea. Las lesiones TASC A-B representaban el 62,8% y las lesiones TASC C-D, el 37,2%. Se implantaron stents en el 62,7% y se utilizaron técnicas complementarias en el 22% (cambio de acceso, catéteres de reentrada, microdisección). El éxito angiográfico del procedimiento fue del 85,2%.

Se obtuvo una mejoría clínica de 782,2 metros en la caminata (rango intercuartil 25-75% 391-1.173) en la población intervenida en forma exitosa. En el análisis multivariado, el run-off (OR 3,71, IC95% 1,01-9,65; p = 0,048) fue la única variable independiente de éxito. En el seguimiento de 623 días (rango intercuartil 25-75% 430,7-1.292,2) se objetivaron 20 reintervenciones (15,5%) y 3 amputaciones no relacionadas con la intervención.

**Conclusiones:** El tratamiento percutáneo en OTC en el territorio femoropoplíteo es factible en una elevada proporción de pacientes, con mejora significativa en la caminata. La evolución a largo plazo está asociada con una tasa significativa de reintervenciones.

Palabras clave: Arteriopatías oclusivas - Arteria femoral - Arteria poplítea - Angioplastia

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### Abbreviations

CTO Chronic total occlusion

# INTRODUCTION

Chronic total occlusions (CTO) represent a significant proportion of peripheral vascular lesions with great treatment variability. The management of these patients both with intermittent claudication as with critical ischemia involves from risk factor corrections to specific percutaneous surgical or hybrid interventions in order to reduce pain or save the limb. The introduction of different techniques and innovative materials has allowed achieving a growing success rate in highly complex lesions. The optimal treatment strategy between endovascular and surgical intervention is often debated due to the absence of randomized studies, to the difficult assessment of new endovascular treatment options in clinical studies and to the lack of consistent definitions. (1,2)

This study analyzes the characteristics and/or results obtained in patients with femoropopliteal chronic occlusions treated with percutaneous interventions and their long-term outcome.

#### METHODS

From January 2008 to July 2013 all consecutive patients with at least one symptomatic chronic total occlusion of the femoropopliteal segment, due to intermittent claudication or severe ischemia under went percutaneous intervention.

All patients were premedicated with acetyl salicylic acid 100 mg/day. Patients with stent implantation and no contraindications received 300-mg loading dose of clopidogrel prior to the procedure and a maintenance dose of 75 mg for at least 3 months. Stent implantation was performed according to the interventionist criteria and strongly recommended for cases where there was residual lesion>30%, dissection with impaired blood flow and wall thrombus image or CTO greater than 4 cm in length. Technical success was defined as residual stenosis <30% after the intervention without angiographic or clinical complications. Chronic kidney disease was defined as glomerular filtration rate under 60 ml min/1.73 m2.

Active follow-up was done by telephone contact and outpatient clinical control. Clinical success was analyzed as distance walked prior to the intervention and within 6 months after the intervention.

### Ethical considerations

The protocol was reviewed and approved by the Institutional Review Board.

# RESULTS

The study included 431 patients with 524 lower limb injuries treated percutaneously. Chronic total occlusions accounted for 34.9% (n=183) of limb injuries. Femoropopliteal involvement was present in 70.4% of cases (129 patients). Mean age was  $64\pm9.6$  years, most patients were male (67.4%), and there was an elevated incidence of diabetes (39.5%) coexisting with

multiple risk factors.

The prevalent presentation form was clinical claudication (73.7%), however, advanced rest pain and trophic lesion conditions were present in 26.3% of the population.

Regarding the angiographic complexity of injuries, more than half of the injuries were TASC (Trans Atlantic Inter Society Consensus) A-B, whereas 37.2% of patients presented TASC C-D injuries.

Mean occlusion length was  $80.3 \pm 55$  mm. Clinical presentations did not vary significantly in relation with angiographic complexity (Table 1).

The number of distal patent or run-off beds was 0 in 7.7% (n=10), 1 in 13.2% (n=17),2 in 28.3%(n=36) and 3 in 51% of vessels (n=66). In 91% of cases retrograde femoral artery access with cross-over was chosen as initial strategy and in the remaining cases femoral antegrade access was selected. After a first unsuccessful attempt, popliteal access was used as a second approach in 17% of patients. Subintimal angioplasty was performed in most patients (96.9%) or intraluminal angioplasty was done with a Glide catheter, hydrophilic guidewire, straight guidewire or complemented

 Table 1. Contribution of risk factors in the Women's Health

 Study

	TASC A-B	TASC C-D	Р	
Age (mean ± SD), years	65.7 ± 9.5	66.1 ± 7.3	0.3	
Diabetes, n (%)	28 (40.5)	14 (30.4)	0.16	
CRF, n (%)	6 (8.6)	5 (10.8)	0.6	
Run-off 0-1, n (%)	6 (8.6)	5 (10.8)	0.5	
Rutherford 1-4, n (%)	62 (89.8)	38 (82.6)	0.9	
Rutherford 5-6, n (%)	7 (10.1)	4 (8.6)	0.6	

SD: standard deviation. CRF: Chronic renal failure.





with devices for microdissection (Front Runner® XP). Subintimal angioplasty with re-entry catheter (Outback® LTD) was performed in 5% of cases.

Self-expandable stents were implanted in 62.7% of lesions (n=81). Only in 10% of patients (13/129) the infrapatellar territory was treated in the same procedure.

Mean overall angiographic success was 85.2%, with a descending gradient according to the complexity of the treated lesion (TASC classification) (Figure 1). It is worth mentioning that the change of popliteal access has increased 5% the angiographic success. The distance walked before surgery was 126.5±108.5 meters. A clinical improvement of 782.2 meters (interquartile range 25-75% 391-1,173) was obtained after angioplasty. Only 6 patients with angiographic success had no clinical improvement after the procedure. Failure of technical recanalization (19 patients) resulted in surgical bypass in 36.8% of cases (7 patients). The remaining patients without angiographic success continued under medical treatment with a mean clinical improvement of 130 meters (interguartile range 25-75%; 81.5-243.7).

Univariate analysis showed that age reduced angiographic success (OR 2.0, p=0.01). On the other hand, increased infrapatelar blood flow (infrapatelar run-off 3-2 vs. 0-1 OR 3.65, p=0.05) and lower complexity (TASC A-B vs. C-D, OR 0.34, p=0.049) were independent variables of increased angiographic success. A suitable infrapatellar angiographic outflow (run-off 3-2) (OR 3.71 95% CI 1.01 to 9.65, p=0.048) was the only independent success variable in the multivariate analysis.

After the procedure, no major complications such as death or myocardial infarction occurred. Three hematomas in the puncture site without hemodynamic involvement and three distal embolizations requiring glyco protein IIb/IIIa inhibitors, thrombo aspiration or distal mechanical recanalization were registered. In addition, one of the patients presented superficial femoral artery perforation without clinical manifestation, requiring reversal of anticoagulation and external compression. No amputation complications related to the procedure were observed.

In the 623-day follow-up (interquartile range 25-75%; 430.7-1,292.2) 20 reinterventions (15.5%) due to new limiting symptomatology and 3 interventionunrelated amputations were observed. The latter occurred in elderly patients treated for trophic lesions and after one year (395 days, 1,070 days and 484 days) of CTO treatment (Figure 2).

#### DISCUSSION

Chronic total occlusions of the femoropopliteal territory represent an important proportion of percutaneous procedures posing a major challenge both for the clinician and the interventionist.

In cohorts with a large number of patients, success is evaluated by the permeability of the angioplasty



Fig. 2. Kaplan-Meier curve. Reoperation of successful angioplasties.

performed or by the rescue of the involved limb in cases of critical ischemia. (3, 4) Both in our study as in the cited studies, most of the treated patients present with intermittent claudication, and therefore treatment benefit focuses on quality of life. That is why we evaluated the clinical variable which mainly focuses on improved walking distance, as a simple variable committed with the patient.

We can not rule out that the success of the intervention deteriorates as we progress in the degree of the pathology to be treated; however, thanks to both technical and material development, the decision is not so specific and its use should be evaluated in each case in an interdisciplinary manner emphasizing the safety of the procedure.

Infrapopliteal involvement is related to poor prognosis risk factors such as diabetes, diffuse disease or end-stage chronic conditions. In our study a good infrapatelar outflow proved to be an independent variable of successful procedure. This is an interesting finding, since in addition to the revascularization strategy it incorporates another factor to the TASC classification on the safe and efficient management of our patients in the context of a complex pathology in the femoropopliteal territory.

Complementary strategies, such as changes to an antegrade femoral access to increase support, a popliteal approach, and re-entry or recanalization devices, enhance these results. (5-7) In our study, the use of these devices is low, since their introduction has begun in recent years. In addition, the implementation of these techniques is limited in proportion to the selection of these patients. However, an increase in angioplasty success is evident when different techniques are combined.

Given our high rate of stent implantation we consider the use of self-expanding stents of great value for the success of the procedure and safe for their proven low percentage of fractures. (8) The development of new stents and the introduction of drug-eluting balloons are becoming more accepted in this field and we must allow for new results in major works to attain definitive conclusions. (9)

# CONCLUSIONS

Percutaneous treatment of CTO in the femoropopliteal territory is possible in a high number of patients, significantly improving walking distance. The technique is safe and effective, and currently growing for patients with severe functional limitations, in whom quality of life improvement is planned. Long-term outcome is associated with a significant rate of re-interventions.

### **Conflicts of interest**

None declared

(See author's conflicts of interest forms in the web / Supplementary Material)  $% \left( {{\left[ {{{\rm{Supple}}} \right]}_{\rm{Supple}}} \right)$ 

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