

Open and endovascular combined procedures in lower limb arterial reconstructions

R. GABRIELLI, M.S. ROSATI*, L. IRACE, A. SIANI, S. VITALE, D. CRISTOFANI, G. MARCUCCI

SUMMARY: Open and endovascular combined procedures in lower limb arterial reconstructions.

R. GABRIELLI, M.S. ROSATI, L. IRACE, A. SIANI, S. VITALE, D. CRISTOFANI, G. MARCUCCI

Introduction. *The association of open and endovascular procedures in patients with obstructive disease of the lower limbs gives the opportunity to treat in a single step multi-segmental lesions which were currently treated in the past by more demanding open procedures.*

Patients and methods. *From January 2003 to May 2009, 52 patients with peripheral occlusive chronic arterial disease of the lower limbs were submitted to combined open and endovascular procedures. In 37 patients (71.2%) a femoro-popliteal/pedial bypass was carried out after Percutaneous Transluminal Arterio (PTA) stenting of the iliac/femoral arteries, while in the remaining 15 patients (28.8%) the endovascular procedures were performed following open approach, that consisted in a femoro-popliteal bypass. Iliac stenting interested the common iliac artery in 19 patients (51.3%), the common and external iliac artery in 11 patients (29.7%) and the external artery in 7 (19%). In this same group a fem-pop bypass below knee was carried out in 28 (75.6), a fem-pop above knee in 6 (16.2%), a fem-pop and jump on the posterior tibial in 2 (5.4%) and a superficial femoral-pedal in the last one (2.8%). In the other group the fem-pop bypass below knee was followed by a PTA of the tibial vessel in 12 cases (80%) and by a stenting in only 3 cases (20%).*

Results. *Three patient was lost to follow-up. Three (8.1%) iliac stents became occluded and the sudden onset of an acute ischemia of the limb required in all cases an aorto-femoral bypass. The occlusion of tibial stent in 2 patient (13.3%) was no clinical relevant, and the failure of the PTA procedure in other 4 patients with the reocclusion of the tibial arteries was followed by thigh amputation. Occlusion of the femoro-popliteal bypass occurred in 9 of 37 patients (24.3%) submitted to iliac stenting and in 4 of 15 (26.6%) patients with PTA of the tibial vessels. The overall patency rate was 69.2%. Limb salvage was 77.5%*

Conclusions. *Combination of the open and endovascular procedures to treat lesions of the lower limbs is effective and durable in terms of patency and complication rate. For validation this new approach needs the recruitment of much more patients and prospective protocol studies.*

RIASSUNTO: Trattamento ibrido vascolare ed endovascolare dell'arteriopatia ostruttiva cronica degli arti inferiori.

R. GABRIELLI, M.S. ROSATI, L. IRACE, A. SIANI, S. VITALE, D. CRISTOFANI, G. MARCUCCI

Introduzione. *L'associazione di procedure vascolari ed endovascolari in pazienti con arteriopatia ostruttiva cronica degli arti inferiori offre al chirurgo vascolare la possibilità di un singolo trattamento per lesioni multisegmentarie, che in passato erano trattate mediante procedure chirurgiche tradizionali invasive eseguite in tempi diversi. L'approccio endovascolare delle lesioni stenotiche prossimali e distali ad un bypass femoro-popliteo garantisce migliori risultati di pervietà a distanza e riduce il rischio operatorio della chirurgia classica.*

Pazienti e metodi. *Da gennaio 2003 a maggio 2009, 52 pazienti, affetti da arteriopatia cronica ostruttiva degli arti inferiori (3° - 4° stadio di Fontaine-Leriche), sono stati sottoposti a trattamento combinato vascolare ed endovascolare. In 37 pazienti (71.2% - gruppo 1) è stato eseguito un bypass femoro-popliteo dopo PTA / stenting delle arterie iliache; negli altri 15 pazienti (28,8% - gruppo 2) è stata eseguita una procedura endovascolare sui vasi tibiali dopo il confezionamento di un bypass femoro-popliteo sottogenicolato. Nel primo gruppo, in 19 pazienti (51.3%) la procedura endovascolare associata ha riguardato l'arteria iliaca comune (stenting primario in 11 casi e 2 PTA), in 11 casi (29,7%) l'intero asse iliaco (6 stenting e una PTA) e l'iliaca esterna in 7 pazienti (19%); di questi pazienti, 28 (75,6%) sono stati sottoposti ad un bypass femoro-popliteo sottogenicolato, in 6 pazienti (16,2%) è stato eseguito un bypass femoro-popliteo sovragenicolato, in 2 pazienti (5,4%) un bypass femoro popliteo con jump sulla tibiale posteriore ed infine in un caso (2,8%) un bypass femoro-pedidio. Nel secondo gruppo il bypass femoro-popliteo sottogenicolato è stato seguito da una PTA dei vasi tibiali in 12 casi (80%) e da uno stenting tibiale primario in 3 (20%). Durante il follow-up, compreso tra 6 e 65 mesi, i pazienti sono stati seguiti mediante ecocolor-Doppler e angio-RM; l'arteriografia è stata riservata ai soli casi con complicanze.*

Risultati. *Tre pazienti sono stati persi al follow up; non si è verificato alcun decesso. Tre stent iliaci (8.1%) sono andati incontro ad occlusione e la conseguente ischemia acuta è stata trattata in urgenza mediante confezionamento di un bypass aorto-femorale. L'occlusione di due stent tibiali (13,3%) non ha comportato sintomi rilevanti, mentre in 4 casi l'occlusione delle arterie tibiali dopo PTA ha richiesto un intervento demolitivo di amputazione. L'occlusione del bypass si è verificata in 9 pazienti del primo gruppo (24,3%) ed in 4 del secondo (26,6%); in 5 di questi 9 pazienti è stato necessario procedere ad una amputazione di coscia. In 2 pazienti del primo gruppo è stata necessaria la correzione di una stenosi anastomotica prossimale del bypass femoro-distale mediante stenting primario mentre in 2 casi si è resa necessaria una PTA dei vasi tibiali. La pervietà complessiva a distanza è stata pari al 69,2%. La percentuale di salvataggio d'arto è stata del 77,5%.*

"Sapienza" University of Rome, Italy
Policlinico "Umberto I"
Department of Vascular Surgery
* Department of Oncology

© Copyright 2011, CIC Edizioni Internazionali, Roma

Conclusioni. L'associazione della chirurgia vascolare ed endovascolare nel trattamento di lesioni a più livelli degli arti inferiori è certamente efficace, offrendo la possibilità di trattare in modo meno invasivo lesioni arteriose multisegmentarie e di correggere eventuali stenosi anastomotiche che possono verificarsi dopo tali interventi. Ulteriori valutazioni su casistiche più ampie sono necessarie per validare il miglioramento dei risultati immediati e a distanza.

KEY WORDS: Arterial peripheral disease - Combined procedures - Lower limbs. Arteriopatia ostruttiva cronica arti inferiori - Procedure ibride.

Introduction

Treating patients with multifocal obstructive lesions of the lower limbs requested in the past demanding open procedures. Furthermore, the final results of the treatment is burdened by longer and repeated hospitalizations and higher risk of infective complications. Obviously, costs were proportionally higher in those patients (pts) who needed surgery. Endovascular treatment offers the opportunity to treat multi-segmental lesions in a single step. This one step approach of the stenotic lesions, above and below the implanted graft, guarantees long-term patency rate compared with similar open procedures.

Few data are currently available on literature about the combination of open and endovascular procedures and no large prospective trials have been designed to compare combined treatment versus open surgery only.

Our report is a further contribution in this field.

Patients and methods

From January 2001 to May 2008, 52 patients (pts), 41 males and 11 females, with lower limb occlusive arterial disease (LLOAD) were enrolled ($n = 19$ pts in III – IV Fontaine stage $n = 33$ pts in critical ischemia according to European Working Group) (1). All pts received combined open and endovascular treatment. Arteriography and Ankle-Brachial Index (ABI) score have been performed in all patients, in 18 angio-MRI, in 27 angio-CT and in 14 duplex ultrasonography. Patients co-morbidity profile was: 46 pts with hypertension, 27 with diabetes, 9 with renal failure in dialysis.

In 37 patients (71.2%) a femoro-distal bypass was carried out after PTA/stenting of the iliac arteries (group 1), while in 15 (28.8%) pts endovascular procedures in tibial area followed the surgical femoro-popliteal bypass (group 2). Prosthetic material was autologous saphenous vein in 33 patients (63.4%), PTFE EXS in 13 (25%) and a biological graft (Omniflow II) in the remaining 6 (11.6%). In the first group endovascular approach has been reserved to the common

iliac artery in 19 patients (15 primary stenting and 4 PTA); to the common and external iliac in 11 patients (9 primary stenting and 2 PTA); to the external iliac artery in 7 pts (6 primary stenting and 1 PTA) (Table 1). Femoro-popliteal bypass below knee was carried out in 28 pts, a femoro-popliteal bypass above knee in 6 pts, a femoro-popliteal with jump on the posterior tibial in 2 and a superficial femoral-pedal in the last one (Table 2). In the second group the fem-pop bypass below knee has been followed by a PTA of the tibial vessel in 12 cases (80%) and by a tibial primary stenting in only 3 cases (20%) (Tables 3 and 4).

Routine Duplex scan at hospital discharge and during the follow-up at 1,3 and 6 months have been performed. The median follow-up was 34 months. MRI-angiography and CT or angiography were performed in complicated cases or in detected failing grafts.

The primary end-point of the study was to evaluate feasibility, safety and long term patency of the combined treatment. The secondary end-point was to compare these treatment with open surgery only (data from our experience). Difference between groups has been evaluated through *t*-Student test and $p < 0,05$ has been considered significative.

Results

Three patient was lost at follow-up and none died. Iliac stent obstruction has been recorded in 3 pts and sudden onset of acute ischemia of the limb required emergency aorto-femoral bypass in all cases. Two pts with tibial stent obstruction did not show relevant clinical symptoms, while the failure of the PTA procedure in other four with the obstruction of the tibial arteries was followed by thigh amputation. Femoro-popliteal bypass obstruction occurred in 24.3% pts of the first group (9/37) and in the 26.6% pts (4/15) of the second group. Overall patency rate was 69.2%. Limb salvage was 77.5%.

One patient from the second group had *S.aureus* infection and underwent the prosthesis removal, and no

TABLE 1 - FIRST GROUP: ENDOVASCULAR PROCEDURES.

| Anatomy | Pts | Stenting | PTA | Patency | Obstruction |
|----------------------------------|-----|----------|-----|---------|-------------|
| Common iliac artery | 19 | 15 | 4 | 19 | 1 stent |
| Common and external iliac artery | 11 | 9 | 2 | 9 | 2 stent |
| External iliac artery | 5 | 4 | 1 | 5 | |

TABLE 2 - FIRST GROUP: FEMORO-POPLITEAL BYPASS.

| Bypass anatomy | Pts | Patency | Obstruction |
|------------------------------------|-----|---------|-------------|
| Fem-pop below knee | 28 | 20 | 8 |
| Fem-pop above knee | 6 | 5 | 1 |
| Fem-pop + jump on posterior tibial | 2 | 2 | - |
| Superficial femoro-pedal | 1 | 1 | - |

tency for distal run-off improvement (5). According to Schneider et al. the role of the bypass in combined procedures is to protect tibial arteries treated by PTA thanks to increased inflow; moreover increasing distal run-off through tibial PTA femoro-popliteal bypass patency could be better (6-7).

Data from literature support the idea that primary stenting has been broadened to aorto-iliac lesions with

TABLE 3 - SECOND GROUP: ENDOVASCULAR PROCEDURES.

| Anatomy | Pts | Stenting | PTA | Patency | Obstruction |
|-------------------------|-----|----------|-----|---------|----------------|
| Posterior tibial artery | 7 | 2 | 7 | 5 | 2 stent, 2 PTA |
| Anterior tibial artery | 6 | 1 | 3 | 2 | 2 PTA |
| Peroneal artery | 2 | - | 1 | 1 | |

TABLE 4 - SECOND GROUP: FEMORO-POPLITEAL BYPASS.

| Bypass anatomy + endovascular | Pts | Patency | Obstruction bypass | Obstruction Tibial vessel |
|---------------------------------------|-----|---------|--------------------|---------------------------|
| Fem-pop below knee + posterior tibial | 7 | 5 | 2 | 2 stent, 2 PTA |
| Fem-pop below knee + anterior tibial | 6 | 4 | 2 | 2 PTA |
| Fem-pop below knee + peroneal | 2 | 1 | - | - |

amputation needed. Four pts showed homolateral deep venous thrombosis (DVT), in the first group and 1 in the second one. No major complications were recorded.

Discussion

Proximal reconstruction for multi-segmental aorto-iliac or distal femoro-popliteal lesions is not adequate to improve the clinical outcome. Nevelsteen et al. (2) and Brewster et al. (3) clearly demonstrated that increasing proximal inflow, by itself, doesn't improve distal hemodynamic. Since many years ago it has been clear the importance of simultaneous reconstruction of the different lesions to improve long term results; however, this procedure showed higher mortality rate and postoperative morbidity due to the progression of atherosclerosis (4).

Nevertheless, multi-step treatments are burdened by higher graft thrombosis and greater technical complexity in managing several times the same area.

Endovascular approach improved LLOAD treatment because it's possible to treat multi-level lesions simultaneously with the same mortality and morbidity rate.

Timaran clearly demonstrated that simultaneous treatment of the iliac lesions through the primary stenting and the femoro-popliteal one through bypass, guarantees optimal inflow to the bypass and improves stent pa-

cellent results; femoro-popliteal-tibial lesions take advantage from PTA approach even if a second treatment or open surgery is anyway possible (8). Notwithstanding the lack of codified protocols, especially for what concerns the best timing, our data suggest to treat with one step procedure proximal lesion first and then the distal one because of the hemodynamic mechanism we explained above. (9-10)

The overall patency rate of 74.3% is similar to the results obtained in the single treatments of the same lesions, while major complication rate is reduced ($p < 0,05$). Till now, no codified protocols on the combination are available, so the choice depends on the surgeon's experience only. In our personal opinion the good results obtained depends also on the patient's selection and on the arterial disease morphology (11).

Treating simultaneously multilevel lesions of the lower limbs with the combination of the vascular and endovascular surgery is effective and durable in terms of patency and complication rate. In fact no surgical related death were recorded. Major complications concern the prosthesis obstruction but these data do not differ from multi-step approach. This ensures the feasibility and safety of the procedures in terms of results. One-step approach is clearly not related with higher cardiac and pulmonary operative and post-operative events; none of our patients, in fact, showed these symptoms. Secondary complications as infection or DVT

were not as common as it would be expected and they were managing at all.

This new approach to the arterial disease of the lower

limb is an interesting and developing field for research but needs the recruitment of much more patients and the prospective protocol studies for validation.

References

1. TransAtlantic Inter-Society Consensus (TASC). *J Vasc Surg* 2000; 31: S1-S296.
2. Brewster DC, Perler BA, Robinson JG, Darling RC. Aorto-femoral graft for multilevel occlusive disease: predictors of success and need for distal bypass. *Arch Surg* 1982; 117:1593-1600.
3. Nevelsteen A, suy R, Daene W. Aortofemoral grafting: factors influencing late results. *Surgery* 1980; 88: 642-653.
4. Batt M, Declémy S. Synchronous reconstruction for combined aortoiliac and femoropopliteal occlusive disease. *J Cardiovasc Surg* 1990;31, 448-452.
5. Timaran CH, Ohki T. Iliac artery stenting in patients with poor distal run-off: influence of concomitant infrainguinal arterial reconstruction. *J Vasc Surg.* 2003; 38: 479-484.
6. Schneider PA, Abcarian PW. Should balloon angioplasty and stents have any role in operative intervention for lower extremity ischemia? *Ann Vasc Surg* 1997; 11: 574-580.
7. Schneider PA, Caps MT, Ogawa DY. Intraoperative superficial femoral artery balloon angioplasty and popliteal to distal bypass graft: An option for combined open and endovascular treatment of diabetic gangrene. *J Vasc Surg* 2001; 33: 955-962.
8. Harvard TR, D'Ingegno M, Carlton L. Threatening ischemia due to multilevel arterial occlusive disease. *Ann Surg* 1995; 221,5: 498-506.
9. Harris PL, Bigley DIC, McSweeney L. Aortofemoral bypass and the role of concomitant reconstruction. *Br J Surg* 1985; 72: 317-320.
10. Eidt G, Stowne JG. Iliac artery stenting and concomitant infrainguinal arterial reconstruction. *J Cardiovasc Surg* 1996; 31, 440-447.
11. Dougherty MJ, Young PL, Calligaro KD. One hundred twenty-five concomitant endovascular and open procedures for lower extremity arterial disease. *J Vasc Surg* 2003; 37: 316-322.