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EDITORIAL

Considerations about TASC II: Is it a Suitable Document for Specialists?

The Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC)[1–3] was a milestone for angiology and vascular surgery impacting on the indications and treatment of vascular diseases. I think that many surgeons, angiologists and interventional radiologists were waiting for its revision, as stated in the last sentence of the first chapter ''*the participating societies therefore commit themselves to continuing the update process*''.

It's true that in the following years many national Vascular Societies wrote their guidelines, based on the new experiences, expanded to all fields of vascular pathology and applicable to the local availability. Nevertheless, the update of so detailed document was an expected event.

The Authors declare the new goals of TASC II,[4,5] that is addressed also to physicians in primary health care, saying that they wont ''*to focus on key aspects of diagnosis and management, and to update the information based on new publications and the newer guidelines, but not to add an extensive list of references*''.

The second edition of the Consensus is intentionally abbreviated and with less references based on the concept that: ''*Unreferenced statements are, therefore, to be found, provided they are recognized as common practice by the authors, with existing evidence*''.

So I could conclude that TASC II is a disappointing document for specialist like me that imagined the consensus as a document produced to analyze in particular the argument with low evidence, and to state in few sentences the evidence based knowledge.

Moreover the document is disappointing for the many mistakes and inaccuracies.

Analyzing the chapter on revascularization, the reported citations are mainly review and meta-analysis of old publication in which surgeons used graft deeply modified. For example, the Table F7a, that summarizes the 5-year patency following femoral popliteal bypass, is taken from a paper of 1994,[6] moreover the reported citation is wrong, being referred to a meta-analysis of aortic surgery.[7]

The figures of this table, as in other papers reported in literature, show better results of vein bypass, in particular in chronic critical limb ischemia (CLI), and the equivalence of vein and expanded polytetrafluoroethylene (PTFE) in above the knee position in patients with claudication. In the section ''*F3.3.2 Conduit*'' the authors declare that ''*Vein has better long-term patency than prosthetic in the infra inguinal region* (Table F7). *Over the short term, PTFE has delivered near equivalent results in the above-knee position* (Fig. F6)''. This sentence is clearly in contrast with the figures reported in the Table F7b.

Moreover, in this table the authors cited 2 paper: the first is a prospective randomized multicentric trial of Green *et al*.[8] that compares PTFE with Dacron Hemashield (and not with the vein) implanted between 1991 and 1996 in the above the knee position. This paper reports unexpected results of polyester graft (5 year secondary patency of 68% for both conduits), that indeed now is rarely used in femoro-distal revascularization.

The other paper cited in Table F7b is a report of Klinkert,[9] that deal with femorotibial bypass grafting and not with A-K femoropopliteal graft. Very probably the authors would refer to another paper published by Klinkert[10] in the same year but in another journal. This paper reports a 5 year primary patency of 75.6% in the vein group and of 51.9% for PTFE ($p = 0.035$); secondary patency are 79.7% and 57.2% respectively ($p = 0.036$), without difference of limb salvage. This is one of the randomized paper with the worse results of PTFE conduit in the above the knee position.

Analyzing these data one can conclude that the numbers reported in the Table F7b does not correspond to the cited articles.

Other studies support the equivalences of vein and PTFE for above the knee revascularisations, in particular for the secondary patency, either for claudication and for CLI, but a significantly difference for primary patency; one of these is a meta-analysis[11] that

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Table F7a. 5-year patency following femoral popliteal bypass[191]

	Claudication	CLI
Vein	80	66
Above-knee PTFE	75	47
Below-knee PTFE	65	65

CLI - critical limb ischemia; PTFE - polytetrafluoroethylene graft.

evaluated 73 papers published between 1986 and 2004 regarding more than 6000 procedures. Even this meta-analysis (not reported very probably because published contemporarily with TASC II), show the lower early patency of PTFE in AK position and the greater need of redo treatment to reach an secondary patency equivalent to those reached with the vein.

Very probably the most interesting prospective randomized study has been reported by Ballotta *et al*.[12] whose 51 patients (102 limbs) underwent between 1994 and 1997 to a vein bypass in one limb and to a PTFE bypass in the other. This study avoid some important bias: the biologic differences between patients, all patients had bilateral disabling claudication and all were operated by the same group. The primary assisted patency at 1, 3 and 5 year follow-up were: 100%, 98%, and 94% for vein grafts, and 96%, 84%, and 84% for PTFE grafts respectively; the differences were not statistically significant ($p = .09$). Even this paper was not reported in TASC II.

Many other prospective randomized controlled trial[13] such as retrospective review of series[14] showed no statistical difference between secondary or assisted patency between vein and PTFE in AK revascularization, even if the primary patency is significantly better for vein graft.

The paper of Allen[15] did not show any differences even in BK position (5 year primary patency of 55% with PTFE and 60.3% with vein bypass ($p = 0.88$), and secondary patency of 79.2, 73.3 and 74.4% respectively ($p = 0.84$).

Analyzing these and many others data, the equivalence between vein and PTFE could be acceptable; but, at the same time, I think the justification of many surgeons (me included) to spare the saphenous vein for BK or coronary bypass should be discussed by the consensus' authors.

Pereira *et al*.[11] did not analyze limb salvage, they remarked the lower use of saphenous vein in the AK position (580 vs 1713 in claudication and 703 vs 2431 in CLI), and concluded that vein sparing is not justified because of an amputation rate double using PTFE (citing a paper of 1988[16]), because the need for redo treatment is higher, and moreover because the rate of use of saved vein in a late bypass has been consistently low. Similarly Berglund[17] analyzing retrospectively the results of Swedvasc, concluded that PTFE cannot be recommended in claudicants, since occlusion occurs often and frequently leads to CLI.

Table F7b. Randomized trials of types of conduits[206–209]

Above-knee femoral popliteal bypass	5-year patency
Vein	74–76%
PTFE	39–52%

PTFE - polytetrafluoroethylene graft.

If a surgeon looks at these 2 papers (one of which is a Class I publication), should say that in AK position the 2 graft are non equivalent.

The authors of TASC II do not give recommendations on this controversial point but, citing a retrospective not randomized trial with some bias,[18] they remind that the occlusion of PTFE graft need a higher number of redo operation (that it is true), with significantly worse limb salvage (81% with the vein and 56% with PTFE; $p = 0.019$); these results contrast with other paper reported above.

Other two important points were not analyzed by TASC II authors: the alternative conduits to PTFE and the results of new generations of PTFE (thin wall, ringed grafts, stretched grafts, carbon-impregnated grafts, pre-cuffed grafts, heparin bonded grafts).

The authors of a Cochrane review[19] in 1999, concluded "*there is no clear evidence which type of graft is best for femoro-popliteal grafting. In terms of autologous graft patency, in-situ and reversed vein grafts are equally successful, while HUV performs better than PTFE. A distal vein cuff may improve primary patency for below-knee PTFE femoro-popliteal grafts*".

More recently alternative grafts have been analyzed by Albers[20] with a meta-analysis of studies published from 1982 through 2003. This study shows that the best limb salvage was achieved with cryopreserved arteries, followed by cryopreserved veins, umbilical-cord veins, and cold-storaged veins. Surprisingly a paper of Devine[21] reports the results of the only prospective randomized trial on 209 femoropopliteal reconstruction (179 AK and 30 BK), that show a significant better patency of heparin-bonded Dacron (HBD) compared with untreated PTFE. After 5 years the differences were no more significant, but limb salvage was better in HBD group ($p = 0.025$).

As RCT on the new grafts are missing, the analysis of series and registries should be useful to produce the first observations, to define the limits of the existing publications, and to find a consensus for surgeons.

Similar considerations can be done about the new endovascular devices as drug-eluting stents, nitinol

stents, carbofilm-coated stents, reabsorbable stents, and stent-grafts.

TASC II cite the meta-analysis of Muradin[22] that concludes ''*balloon dilation and stent implantation for claudication and stenosis yield similar long-term patency rates. For more severe femoropopliteal disease, the results of stent implantation seem more favourable*'', and 3 studies of Cejna,[23] Grimm e Vroegindeweij that reports results of Palmaz stent, almost no more utilized for femoro-popliteal lesions.

The cited randomized study[24] tested a drug-eluting stents against bare stents in femoro-popliteal artery obstructive disease in claudicants. TASC II emphasize the significantly larger in-stent mean lumen diameter in the sirolimus-eluting stent group (4.95 mm versus 4.31 mm in the uncoated stent group; $p = 0.047$); the authors of the study conclude more prudently: ''*Although there is a trend for greater efficacy in the sirolimus-eluting stent group, there were no statistically significant differences in any of the variables*''.

Another argument I would emphasize is the endovascular treatment of claudication. The authors conclude, without grading their statement or writing a recommendation: ''*Endovascular treatment of infrainguinal disease in patients with intermittent claudication is an established treatment modality. The low morbidity and mortality of endovascular techniques such as PTA makes it to the preferred choice of treatment in limited disease such as stenoses/occlusions up to 10 cm in length.*'' This statement seems in contrast with the results published by cited authors[25] that reports at 6 months, a restenosis rate of 24% in the stent group and 43% in the angioplasty group ($P = 0.05$); and a 12 months restenosis rates of 37 percent and 63 percent, respectively ($P = 0.01$), that conclude that in the intermediate term, treatment of superficial-femoral-artery disease by primary implantation of a self-expanding nitinol stent yielded results that were superior to those with the currently recommended approach of balloon angioplasty with optional secondary stenting.

Moreover this statement seems in contrast even with the flow-chart (Fig. C3) reported in the chapter of claudication treatment, that take in consideration the angiographic or radiological evaluation only in patients with suspected proximal (aorto-iliac) lesions.

More prudent were the writer of the ACC/AHA guidelines, version 2005,[26] that in the chapter ''2.6.2.4. Endovascular Treatment for Claudication'' recommend: *Endovascular procedures are indicated for individuals with a vocational or lifestyle-limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and (a) there has been an inadequate response to exercise or pharmacological therapy and/or (b) there is a very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease). (Class I - Level of Evidence: A).*

In the last 3 years, searching on Pubmed for ''endovascular treatment for claudications'' with the limits of ''meta-analysis − RCT, Controlled Clinical Trial and Multicenter Study'' we can find only 9 paper, very probably 6 of these were available before the publication of TASC II, including the cited paper.[25] None of these paper gives results useful to change the ACC/AHA recommendation.

In the remaining 3 paper, the first[27] concludes: ''*…results are inferior to those of conventional femoro-popliteal synthetic bypass grafts. In order to become competitive to conventional bypass surgery, further technical refinements will be necessary…*''.

The aSpire Registry, including the treatment of SFA stenosis in 55/166 enrolled patients, reports a13% procedural complications and a 1 year 74.2% secondary patency obtained with 32 (19.3%) reinterventions, at a mean follow-up of 13 months.[28] The last paper deals with benefits of a supervised exercise program after lower limb bypass surgery.

These data do not support the endovascular treatment of any type of claudication.

The last topic that should have been treated more accurately by TASC II is the management of patients at risk of ischemia, those with a claudication <100 m, the so-called ''chronic subclinical ischemia. In the chapter *D6-Prevention of Critical Limb Ischemia* the authors refer only to aggressive management of cardiovascular risk factors, but evidently they did not find any useful data to suggest the revascularization of patients in this phase, that seem more dangerous than the mild or moderate claudication stage. In other terms, in TASC II it is not clear which patients should be scheduled for an invasive treatment.

It is evident that authors did not have enough multiple randomized clinical trials, meta-analyses, single randomized trial or nonrandomized studies to give strong recommendations, however they should reach sufficient agreement on many items using the published paper or state their limits. Moreover, the Scientific Societies that endorsed the guidelines, well knowing the lack of information that obliged to grade C recommendations in the first edition of TASC should have promoted or sponsored the necessary studies to give an answer to many of the unresolved questions.

The mistakes, the inaccuracies and the lack of information I report is only a part of which can be found reading this document, that we hoped more accurate after a so long period needed for its revision.

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