TASC II SUPPLEMENT PROVIDES LITERATURE UPDATE AND EXPANDS TASC LESION CLASSIFICATION

Since the 2007 update to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) guidelines, new innovations in endovascular revascularization strategies have emerged for patients with peripheral arterial disease (PAD). The TASC Steering Committee provided an updated literature review of these new endovascular techniques and practice patterns as well as a complete anatomic lower-limb TASC lesion classification, which includes the infrapopliteal segment.

Due to the lack of well-controlled randomized clinical trials evaluating surgical intervention vs endovascular approaches, this update does not include formal treatment recommendations. Key trials addressing this deficit in evidence are currently under way in the United States and Europe.


STUDY REPORTS 3-YEAR FOLLOW-UP RESULTS OF OLIVE REGISTRY PATIENTS

Led by Osamu Iida, MD, a prospective multicenter study investigated the 3-year follow-up results of OLIVE registry patients. Researchers looked at consecutively enrolled patients who received infrarenal endovascular therapy (EVT) for critical limb ischemia (CLI). Their primary outcome was 3-year amputation-free survival (AFS), with secondary outcome measures of 3-year freedom from major adverse limb event (MALE), wound-free survival, and wound recurrence rate.

The completion rate of 3-year follow-up was 95%, and 3-year AFS, freedom from MALE, and wound-free survival rates were 55.2%, 84.0%, and 49.6%, respectively. The study concluded that the 3-year clinical results of EVT in CLI patients with infrarenal lesions were reasonable despite high reintervention rate and a moderate ulcer recurrence rate.


RETIROSPECTIVE ANALYSIS IDENTIFIES INDEPENDENT PROGNOSTIC FACTORS FOR 2-YEAR LIFE EXPECTANCY IN CLI PATIENTS

Soga et al conducted a study to estimate the 2-year life expectancy (2YLE) in patients with critical limb ischemia (CLI) using the risk score based on predictors of all-cause mortality within 2 years. He and his colleagues performed a multicenter retrospective analysis of 995 CLI patients with a follow-up period of >730 days who underwent endovascular therapy between March 2004 and December 2011.

The study concluded that the independent prognostic factors for the 2YLE were age, body mass index, non-ambulatory status, hemodialysis, cerebrovascular disease, left ventricular ejection factor, and tissue loss. A 2YLE score of 28 points indicated a <50% probability of 2-year survival and seemed to be helpful in identifying CLI patients with a poor prognosis.


ADDITIONAL FACTORS SHOULD BE CONSIDERED IN CLI REVASCULARIZATION

In an editorial comment on “Two-Year Life Expectancy in Patients With Critical Limb Ischemia” (see above), Beckman and Creager note that the findings of Soga et al have improved the process of patient selection for revascularization. They believe having an awareness of the likelihood of intermediate-term survival can better inform discussions with patients about the benefits of a procedure, its risks, and potential intermediate-term outcomes. However, the authors suggest other important factors should be incorporated into the decision-making analysis, including the impact of the procedure on sustained functional recovery, independence, and quality of life.


PCB VERSUS DES: RESULTS FROM THE IDEAS TRIAL

A study by Siablis et al reported the results of the Infrapopliteal Drug-Eluting Angioplasty Versus Stenting (IDEAS) trial, a prospective randomized controlled trial comparing paclitaxel-coated balloon (PCB) vs drug-eluting stent (DES) in long
infraoplitel lesions for the treatment of critical limb ischemia. Within 14 months, 50 patients were randomized 1:1 to undergo infraoplitel PCB angioplasty or primary DES placement.

The authors concluded that compared with PCBs, DESs are associated with significantly better immediate residual postpro- cedure stenosis and reduced vessel restenosis at 6 months. PCBs may produce positive vessel remodeling. Larger-scale multicenter trials are needed to verify these results.


**PASSEO-18 LUX DEB PROVEN SAFE AND EFFECTIVE IN TREATING INFRAPOPLITEAL LESIONS**

Zeller et al reported 12-month results from the BIOLUX P-II first-in-man trial, which compared the safety and efficacy of a novel paclitaxel-coated drug-eluting balloon (DEB) vs an uncoated per- cutaneous transluminal angioplasty (PTA) balloon catheter for the treatment of stenotic, restenotic, or occluded infraoplitel arteries in patients experiencing claudication or critical limb ischemia (CLI).

Between July 2012 and June 2013, a total of 72 patients in six European centers were randomized 1:1 to either a Passeo-18 Lux DEB or Passeo-18 PTA. In this small patient population including claudicants and CLI patients, the Passeo-18 Lux DEB was proven to be safe and effective in infraoplitel lesions with comparable outcomes to PTA.


**DES THERAPY REDUCES RISK OF REINTERVENTION AND AMPUTATION IN ATHEROSCLEROTIC DISEASE OF INFRAPOPLITEAL ARTERIES**

Fusaro et al conducted an updated meta-analysis to investigate the outcomes of percutaneous revascularization with primary drug-eluting stenting in patients with atherosclerotic disease of infraoplitel arteries. They evaluated 611 patients from 5 trials who were randomly assigned to drug-eluting stents (DES) vs a control of plain balloon angioplasty/bare-metal stent (BMS) implantation.

The primary endpoint was target-lesion revascularization, with secondary endpoints of restenosis, amputation, death, and improve- ment in Rutherford class. At 1-year follow-up, DES therapy demon- strated reduced restenosis and greater clinical efficacy compared with plain balloon angioplasty or BMS therapy and reduced the risk of reintervention and amputation without any impact on mortality and Rutherford class.


**TBI MAY IMPROVE DIAGNOSTIC ACCURACY OF ABI IN EVALUATING CLI**

A study by Bunte et al described the relationship between ankle-brachial index (ABI), toe-brachial index (TBI), Rutherford-Baker classification, and angiographic findings among consecutive patients with critical limb ischemia (CLI). From July 2011 to February 2013, a total of 89 consecutive patients with CLI had non-invasive testing for indications of rest pain as well as minor and major ischemic tissue loss. They subsequently underwent ABI testing and lower-extremity angiography with visualization of the infragenicular arteries.

In the evaluation of CLI, nearly one-third of patients with ischemic tissue loss had a normal or mildly reduced ABI. The authors concluded that assessment of clinical severity and the use of TBI are likely to enhance the diagnostic evaluation of CLI over ABI alone, especially among individuals with tissue loss.


**INFRAPOPLITEAL SES MAY ACCELERATE WOUND HEALING AND IMPROVE QUALITY OF LIFE**

Katsanos et al reported the final 1-year results of wound healing outcomes, health-related quality-of-life changes, and quality- adjusted life years (QALY) gain in the two treatment arms of the ACHILLES trial. ACHILLES was a multicenter randomized study of 200 patients comparing sirolimus-eluting stent (SES) with percutaneous transluminal angioplasty (PTA) for the treatment of infrapopliteal arterial occlusive lesions.

Rates of complete wound closure were higher in the SES group - 72.9% closed wounds vs 55.6% with PTA; health-related quality-of-life scores improved significantly up to 1 year in SES, but not in PTA, and there was a trend of more QALY gain in SES up to 1 year after randomization. The study concluded that infrapopliteal SES accelerates wound healing and may improve quality of life compared with PTA.

CLINICAL BENEFITS OF SES IN INFRAPOPLITEAL ARTERIES REMAIN UNCLEAR

In this paper, Hawkins provides an editorial comment on the analysis by Katsanos et al of 1-year wound healing and quality-of-life outcomes from the ACHILLES trial (see above). He commended the authors for providing data that examine whether drug-elution technologies can affect such important, patient-centric endpoints in peripheral artery disease. However, Hawkins found some significant limitations with the principal findings of the analysis.

Taking a closer look at the purported benefits Katsanos et al found with sirolimus-eluting stenting (SES), he suggests percutaneous transluminal angioplasty (PTA) may be just as effective. Hawkins concluded that although ACHILLES demonstrated benefits in restenosis and patency with SES in infrapopliteal arteries, it remains unclear whether those results translate into meaningful clinical benefit for patients.