

**Randomized clinical trial comparing multiple stab incision phlebectomy and transilluminated powered phlebectomy for varicose veins**Chetter IC, Mylankal KJ, Hughes H, et al. *Br J Surg* 2006;93:169-74.

**Conclusion:** Transilluminated power phlebectomy (TIPP) compared with multiple stab incision phlebectomy (MSIP) results in fewer surgical incisions but has reduced early postoperative quality of life, with more extensive bruising and more prolongation of postoperative pain.

**Summary:** This was a randomized clinical trial at a university teaching hospital in Australia. Patients who were to undergo surgery for varicose veins were randomized to receive either TIPP or MSIP for treatment of the varicosities. For both groups, analysis consisted of operative times, number of incisions, and postoperative outcome. A quality-of-life analysis was conducted at 1 and 6 weeks after surgery using disease-specific (Aberdeen varicose vein questionnaire) and generic (Short Form 36 and EuroQual 5D) measures as well as the domain-specific Burford Pain Scale. The MSIP arm of the trial had 33 patients, and the TIPP arm had 29 patients. All patients had complicated or symptomatic varicose veins. In the MSIP group, 29 of the 33 patients were CEAP class II, and 27 of 29 patients in the TIPP group were CEAP class II.

Mean duration of surgery was 48 minutes (range, 41 to 63 minutes) in the MSIP patients and 50 minutes (range, 40 to 60 minutes) in the TIPP group ( $P = .717$ ). A significantly lower number of phlebectomy incisions were used in the TIPP group (mean, 5; range, 3 to 7), than the MSIP group (mean, 20; range, 11 to 25) ( $P < .001$ ). At 1 and 6 weeks, skin bruising was significantly higher in the TIPP group ( $P < .01$ ), and the Burford Pain Scale at 6 weeks was also significantly higher in the TIPP group ( $P = .019$ ). At 1 week after surgery, both groups had significant deterioration on the quality-of-life outcomes domains of physical function, role play, and social function of the SF36. The magnitude of deterioration was greater after TIPP. At 6 weeks, patients who had TIPP had no significant change in any SF36 quality-of-life domain compared with pretreatment values. Patients treated with MSIP at 6 weeks showed significant improvements in role play and in physical and bodily pain.

**Comment:** In this randomized trial of transilluminated power phlebectomy vs standard multiple stab incisions for varicose vein treatment, the only advantage of the transilluminated power phlebectomy was a decreased number of incisions. Surprisingly, there was no difference in operative time. If patient recovery is the issue, it therefore appears that standard multiple incisions provide a better outcome. If the patient is interested in fewer incisions for cosmetic concerns, transilluminated power phlebectomy will provide this but at the expense of a more prolonged recovery from the initial procedure.

**Slow-flow phenomenon during carotid artery intervention with embolic protection devices**Cassery IP, Abou-Chebal A, Fathi RB, et al. *J Am Coll Cardiol* 2005;46:1466-72.

**Conclusion:** Carotid interventions with emboli protection devices are frequently associated with slow-flow phenomenon. Slow-flow phenomenon is associated with an increased risk of periprocedural stroke.

**Summary:** Slow flow during carotid angioplasty and stenting is described as occurring when there is angiographic evidence of significant reduction of antegrade flow in the internal carotid artery proximal to the embolic protection device. The mechanism of slow flow during carotid percutaneous procedures is unknown, but it is hypothesized that particular debris-containing plaque elements may result in blockage of the filter, impeding antegrade flow. The authors sought to examine predictors of slow flow during carotid artery angioplasty and stenting with embolic protection devices.

Data were derived from a single-center carotid intervention registry that was maintained prospectively. Patients with normal flow during carotid intervention and those with slow flow were compared with respect to clinical procedure, lesion characteristics, and 30-day incidence of death and stroke.

There were 453 carotid interventions with embolic protection devices performed in 414 patients. Slow flow was observed in 42 patients (10.1%) and most commonly occurred after stent balloon dilatation (71.4%). Multivariate logistic regression analysis was used to identify predictors of slow flow. They included a recent history (<6 months) of transient ischemic attack or stroke (odds ratio, 2.8; 95% confidence interval, 1.4 to 5.6,  $P = .004$ ). In addition, increased stent diameter and increased patient age were also associated with slow flow. Among patients with slow flow, 30-day incidence of stroke or death was 9.5% compared with 2.9% in patients with normal flow ( $P = .03$ ).

**Comment:** It makes sense that if enough debris is trapped in the cerebral protection device, flow will be reduced through the ipsilateral internal carotid artery. However, it may be the increased debris in the protection device is also a marker of increased embolization at the time the lesion is initially crossed and that the strokes are therefore embolic rather than hemodynamic in origin.

**Bypass versus angioplasty in severe ischaemia of the leg (BASIL): Multicentre, randomised, controlled trial**Adam DJ, Beard JD, Cleveland T, et al; BASIL Trial Participants. *Lancet* 2005;366:1925-34.

**Conclusion:** Patients with critical limb ischemia secondary to infrainguinal occlusive disease and who are suitable for either angioplasty or surgery have similar short-term results with regard to amputation-free survival with either a bypass surgery-first strategy or a balloon angioplasty-first strategy.

**Summary:** The BASIL trial was designed to compare a surgery-first strategy vs balloon angioplasty-first strategy in patients with rest pain, ulceration, or gangrene of the lower extremity. There were 27 hospitals in the United Kingdom that participated in the study. Investigators randomly assigned 452 patients with severe limb ischemia secondary to infrainguinal disease to receive an angioplasty-first strategy ( $n = 224$ ) or a surgery-first strategy ( $n = 228$ ). Analysis was by intention to treat, and the primary end point was amputation-free survival. Patient follow-up ended when the patient reached an end point of either amputation of the trial leg above the ankle or died. Secondary outcomes were all-cause mortality, 30-day morbidity and mortality, health-related quality of life, use of hospital resources, and need for reinterventions. Patients had to be considered suitable for randomization by both consultant vascular surgeons and interventional radiologists.

The authors also audited patients from the six top recruiting centers who presented with critical limb ischemia and were thought to be suitable for randomization. After survival curves were examined, a post hoc analysis was done comparing risk of end points occurring between randomization and  $\leq 2$  years and end points occurring  $> 2$  years.

During the 6-month audit, 585 consecutive patients with critical limb ischemia presented to the top six recruiting centers, and 129 (29%) needed suprainguinal revascularization. Of the remaining patients with critical limb ischemia, 220 (48%) were treated without revascularization; therefore, 52% of the patients ( $n = 236$ ) presenting with critical limb ischemia underwent revascularization. Of these 236 potentially eligible patients, 70 (29%) were regarded as suitable for randomization into the trial, but 22 (31%) refused trial entry, thus leaving 48 for randomization. The audit results thus suggest  $< 10\%$  of the patients presenting with critical limb ischemia would be randomized into the BASIL trial.

Overall, 195 (86%) of 228 patients assigned to bypass surgery and 216 (96%) of 224 assigned to balloon angioplasty underwent attempts at their allocated intervention. At the end of the follow-up, 55% of the patients ( $n = 248$ ) were alive without amputation of the trial leg. Eight percent of patients ( $n = 38$ ) were alive with amputation, 8% ( $n = 36$ ) were dead after amputation, and 130 patients were dead without amputation (29%).

The immediate technical failure rate for the patients assigned to surgery was 3% (5 of 195). The immediate technical failure rate of the patients assigned to angioplasty was 20% ( $n = 43$ ). The difference in 30-day mortality between the two treatment strategies was not significant. Surgery was associated with a significantly higher early morbidity rate (53%) than angioplasty (41%). Morbidity events were primarily wound, infectious, and cardiovascular complications. No difference was noted in health related quality of life between the two treatment strategies. First year hospital costs were higher with a surgery-first strategy. At 6 months, the two strategies did not differ with respect to amputation-free survival (adjusted hazard ratio, 0.73, 94% confidence interval, 0.49 to 1.07). After 2 years, surgery seemed to be associated with a significantly reduced risk of future amputations, death, or both.

**Comment:** The article raises several interesting points. It is very difficult to recruit for trials of critical limb ischemic patients. The audit data suggests  $< 10\%$  of the patients screened for the trial would be eligible for randomization. In the short-term, results are similar in patients who are suitable both for angioplasty or surgery. Morbidity and expense are greater with surgery, but long-term amputation-free survival may be improved by a surgery-first strategy.

Overall, the trial results would appear to be as expected. If short-term results are what matter, and the patient can be treated with either angioplasty or surgery, angioplasty is the likely preferred strategy. However, in patients with suitable anatomy and a reasonable life expectancy, surgery may be a better alternative, accepting longer short-term morbidity as a price for greater long-term durability.

**Ethnicity and peripheral arterial disease: The San Diego Population Study**Criqui MH, Vargas V, Denenberg JO, et al. *Circulation* 2005;112:2703-7.

**Conclusion:** Black ethnicity is a strong and independent risk factor for peripheral arterial disease (PAD) independent of diabetes, hypertension, and body mass index.

**Summary:** There appears to be excess PAD in black patients and in non-Hispanic whites (NHWs). Little information is available for Asians and Hispanics. The San Diego Population Study sought to assess PAD prevalence rates in a defined population that included four ethnic groups: NHWs, blacks, Hispanics, and Asians. Patients in the study were randomly selected