

time to healing of the reference leg, health-related quality of life, resource use, treatment change, adverse events, and ulcer recurrence. Health-related quality of life and resource use were measured at baseline and every 3 months thereafter by participant self-completion of the SF-12 and EQ-5D. Adverse events were classified as serious (death, life-threatening, or limb-threatening) or non-serious. After the reference leg ulcer healed nurses assessed ulcer recurrence on a monthly basis. There were 457 participants in the two treatment groups: 230 in the two-layer group and 227 in the four-layer bandage group. Of these, 230 in the hosiery and 223 in the bandage group contributed data for analysis. Median time to ulcer healing was 99 days (95% CI, 84–126) in the hosiery group and 98 days (95% CI, 85–112) in the bandage group. The proportion of ulcer healing was the same in the two groups (70.9% hosiery and 70.4% bandage). There was no evidence of a difference in the mental component summary score by treatment over 12 months. Patients allocated to hosiery had a higher physical component summary score than those assigned to four-layer bandages, suggesting better physical health in the hosiery group. This was after adjustment for ulcer area, ulcer duration, participant mobility, center and time. One hundred fifty of the 454 (33%) participants changed to a non-trial treatment before their ulcers healed, and more did so in the hosiery group (38%) than in the bandage group (28%; $P = .02$). Adverse event frequency was similar in both groups except that in the hosiery group there were more non-serious adverse events (67% vs 58%) than in the bandage group. In follow-up, 14% of the patients in the hosiery group had ulcer recurrence compared with 23% of patients in the bandage group: hazard ratio, 0.56; 95% CI, 0.33–0.94; $P = .026$. Mean average costs were £300 lower per participant in the hosiery group than in the bandage group with the difference ascribed to more frequent nurse consultations in the bandage group.

Comment: The data indicate that the two forms of compression tested are both quite effective in the healing of venous leg ulcers. The higher rate of treatment changes in the participants of the hosiery group suggests that hosiery may not be suitable for all patients with venous leg ulcers. Treatment modality is likely best individualized based on potential patient compliance and center expertise.

Compression Stockings to Prevent Post-Thrombotic Syndrome: A Randomised Placebo-Controlled Trial

Kahn SR, Shapiro S, Wells PS, et al. Lancet 2014;383:880-8.

Conclusions: Elastic compression stockings do not prevent post-thrombotic syndrome (PTS) after a first proximal deep venous thrombosis (DVT).

Summary: Two previous single center randomized trials have suggested that wearing elastic compression stockings for 2 years after proximal DVT can halve the risk of developing PTS. The trials, however, were small and not placebo controlled. It is obvious that stockings can be cumbersome to apply, can be hot and uncomfortable, and can itch in many patients. In addition, they can be expensive, up to \$100 or more per pair, and need to be replaced twice yearly because of wear and tear, and frequently are not covered by health care plans. PTS reduces quality of life and poses a substantial economic burden on patients and society. Therefore any technique to prevent post-thrombotic syndrome in patients with DVT would be welcome. The authors conducted a multicenter randomized placebo-controlled trial of active versus placebo elastic compression stockings used for 2 years in an effort to prevent PTS after first proximal DVT. Patients with an ultrasound confirmed first proximal DVT were randomly assigned to study groups with a web based randomization system. Any patient with a first symptomatic proximal DVT was eligible for the study. The patients were excluded if the use of compression stockings was contraindicated or they had an expected life expectancy of less than 6 months or geographic inaccessibility that precluded return for follow-up visits or if they were unable to apply stockings or they had received thrombolytic therapy as part of their initial treatment of acute DVT. The primary outcome was PTS diagnosed at 6 months or later using Ginsberg's criteria (leg pain and swelling of ≥ 1 month duration). Secondary outcomes included cumulative incidence and severity of PTS with Villalta's score, objectively confirmed recurrent venous thromboembolism, death, adverse events, venous valvular reflux, and quality of life. The authors used a modified intention to treat Cox regression analysis, supplemented by pre-specified per-protocol analysis of patients who reported frequent use of their allocated treatment. The active stockings were 30–40 mm Hg stockings whereas the placebo stockings provided only 5 mm Hg of compression at the level of the ankle. The stocking appeared similar and patients were asked not to wear their stockings to their follow-up visits which occurred at 1, 6, 12, 18, and 24 months. From 2004 to 2010, 410 patients were randomly assigned to receive active elastic compression stockings and 396 placebo elastic compression stockings. The cumulative incidence of PTS was 14.2% in the active ECS versus 12.7% in the placebos ECS group (hazard ratio adjusted for center, 1.13; 95% CI, 0.73–1.76; $P = .58$). Results were similar in the prespecified per-protocol analysis of patients who reported frequent use

of stockings. In addition the 2 year cumulative incidence of Villalta-defined PTS in both the active and placebo stocking groups in this study were similar to the control arms of previous trials that had reported benefit of stockings (Brandjes DPM et al, Lancet 1997;349:759–62, and Prandoni P et al, Ann Intern Med 2004;141:249–56).

Comment: Results of this trial do not support the routine use of elastic compression stockings after proximal DVT to prevent PTS. However, while the results suggest that elastic compression stockings might not affect the natural history of PTS development after DVT, whether compression stockings might be of benefit to improve symptoms of established PTS or of acute DVT remain open questions.

Endovascular or Open Repair Strategy for Ruptured Abdominal Aortic Aneurysm: Thirty-Day Outcomes from IMPROVE Randomised Trial

IMPROVE trial investigators, Powell JT, Sweeting MJ, et al. BMJ 2014;348:f7661.

Conclusions: In patients with ruptured abdominal aortic aneurysm (rAAA) a strategy of endovascular repair is not associated with significant reduction in 30-day mortality or cost.

Summary: Endovascular repair for rAAA has emerged as a treatment strategy for anatomically suitable patients with rAAA. This has been on the basis of observational studies which have suggested that repair of rAAA with EVAR may be associated with lower perioperative mortality than repair of rAAA with open techniques. However, observational studies do not consider individual center expertise and this potentially influences selection of patients and diagnostic criteria. A recent trial from The Netherlands found no difference in 30-day mortality between EVAR and open repair groups with mortality rates of 21% and 25% respectively in the Dutch trial (Reimerink JJ et al, Ann Surg 2013; 258:248–56). However, in the Dutch trial only patients anatomically suitable for endovascular repair were randomized to either endovascular or open repair. Investigators in the IMPROVE trial felt their method of randomization was more of a real world scenario. In IMPROVE, patients were randomized either to an endovascular strategy (immediate CT scan followed by EVAR if locally determined as anatomically suitable for EVAR and open repair when not suitable) or to immediate open repair with CT being optional. IMPROVE enrolled patients from 29 vascular centers in the UK and one in Canada from 2009 to 2013. There were 613 eligible patients (480 men) with a clinical diagnosis of rAAA. Three hundred sixteen patients were randomized to the endovascular strategy and the diagnosis of rAAA was confirmed in 275 (87%), 8 (3%) had repair of a symptomatic nonruptured AAA in the same admission, and 33 (10%) had other discharge diagnoses. Of the patients with ruptured or symptomatic AAA 272 had a CT performed and 174 (64%) were considered anatomically suitable for EVAR with local reporting of unfavorable anatomy at the aneurysm neck the most common reason for lack of suitability for EVAR (75/84 cases). EVAR was then attempted in 154 patients (four converted to open repair), open repair was attempted in 112 other patients (84 anatomically unsuitable for EVAR). There were 28 crossovers who were anatomically suitable for EVAR, 16 patients died before aneurysm repair, and 1 patient with a symptomatic aneurysm refused repair and was discharged. There were 297 patients randomized to open repair with the diagnosis of rAAA confirmed in 261 (88%). Fourteen (5%) had repair of a symptomatic intact aneurysm in the same admission and 22 (7%) had another discharge diagnosis. In this group EVAR was attempted in 36 (13%) patients and open repair in 220 (80%) patients, and 19 patients died before aneurysm repair. Main outcome measures were 30-day mortality and 24-hour and in-hospital mortality, costs, with and time and place of discharge as secondary outcomes. 30-day mortality was 35.4% in the endovascular strategy group and 37.4% in the open repair group: odds ratio, 0.92 (95% CI, 0.66–1.28, $P = .62$); odds ratio after adjustment for age, sex, and Hardman index, 0.94 (95% CI, 0.67–1.33). Endovascular strategy may have provided some benefit for women (interaction test, $P = .02$), odds ratio, 0.44 (95% CI, 0.22–0.91) versus 1.18 (95% CI, 0.80–1.75). Thirty-day mortality for patients with confirmed rupture was 36.4% (100/275) in the endovascular strategy group and 40.6% (106/261) in the open repair group ($P = .31$). There were more patients in the endovascular strategy than in the open repair group who were discharged directly to home (189/201 [94%] v 141/183 [77%]; $P < .001$). Average 30-day costs were similar between the groups.

Comment: The study indicates that an endovascular strategy for a rAAA has similar mortality as open surgical repair of rAAA. It also suggests, however, that an endovascular strategy may benefit women patients with rAAA and may result in a greater ability to discharge patients to home with less time in the ICU than open surgery for a rAAA. Observational studies previously reported improved mortality results with endovascular repair for rAAA have likely been subject to institutional bias, selection bias and perhaps reporting bias. Nevertheless, a strategy for repair of rAAA that includes possible endovascular repair may offer benefits for selected patients in terms of reduced time in the ICU and a greater ability to discharge home.