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A-Z Series article

The use and abuse of hypothesis tests: how to present P values.

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Abstract: This overview highlights some of the key issues involved in performing and interpreting hypothesis tests. We describe the general approach taken in performing a hypothesis test with a focus on how to state the null and alternative hypothesis, and why two-sided tests are usually more appropriate than one-sided tests.
We describe best practice techniques in performing and presenting the results of hypothesis tests. We recommend that, alongside any p-values, authors should also present estimates of the size of any treatment effects and their confidence intervals. Furthermore, they should specify the exact p-value rather than using terms such as 'NS' or the commonly used asterix notation. We discuss other pitfalls that are encountered at the analysis stage such as the use of repeated observations on individuals, the use of multiple tests on the data and the erroneous use of parametric tests when data are not normally distributed and vice versa. We highlight these points using two different examples: one looking at the use of compression stockings for preventing the occurrence of DVT on long-haul flights and a second hypothetical study comparing laser versus surgery techniques for the removal of varicose veins.

Review Article

The superficial venous system of the lower extremity: new nomenclature.

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Abstract: The phlebology in the area of lower limbs is the only medical field in which the terminological needs of clinicians were met. Ten years ago, the latest revision of the Latin anatomical nomenclature, Terminologia Anatomica (TA), was issued. But almost none of the chapters reflected the clinicians' need to be a relevant theoretical base for correct diagnostics and appropriate treatment. In 2001, during the 14th World Congress of the International Union of Phlebology, a consensus document (under the auspices of Federative International Committee on Anatomical Terminology and International Federation of Associations of Anatomists) was laid to expand the nomenclature of the lower extremity venous system. Some terms have been changed and several new have been added, corresponding to their clinical significance and anatomical positions. Sixteen new terms have been added in both Latin and English languages in the chapter concerning the superficial veins of the lower limb. This consensus document will be incorporated into the next version of the TA. The international anatomical nomenclature serves as a communication base for research, diagnostic, therapy and information exchange in phlebological sciences.

Keywords: nomenclature, terminology, anatomy, superficial veins of lower extremity.

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Original Article

Sclerotherapy of telangiectases and reticular veins: a double-blind, randomized, comparative clinical trial of polidocanol, sodium tetradecyl sulphate and isotonic saline (EASI study).

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Abstract:

Objectives: To assess the efficacy and safety of polidocanol (POL) in comparison to sodium tetradecyl sulphate (STS) and isotonic saline (placebo) for sclerotherapy of telangiectases or reticular veins by means of standardized digital imaging system, independent medical observers and detailed monitoring.

Methods: Of 316 randomized patients, 160 with telangiectases were randomly assigned to 0.5% POL, 1% STS or placebo, and 156 with reticular veins received 1% POL, 1% STS or placebo. Veins selected for injection were clearly visible telangiectases or reticular veins in a predefined treatment area (10x10 cm). Exact retrieval of the location was guaranteed by a newly established digital imaging system. Images were taken before first injection and 12 and 26 weeks after the last of three possible injection visits, and evaluated by the investigator and two blinded independent observers. The detailed safety monitoring included ultrasound screening for 'silent' deep vein thrombosis, electrocardiograms and clinical laboratory tests.

Results: POL demonstrated a statistically significant superiority versus placebo ($P < 0.0001$) for the primary criterion 'improvement of veins'. Significantly more patients were satisfied with POL at 12 or 26 weeks (84%, 88%) compared to STS (64%, 63%; $P < 0.0001$) and placebo (14%, 11%; $P < 0.0001$). POL was safe and well tolerated apart from expected local symptoms at the injection site.

Conclusion: Sclerotherapy of telangiectases and reticular veins with detergent-like sclerosants such as polidocanol (POL) or sodium tetradecyl sulphate (STS) is a well-established technique. However, evidence from clinical trials comparing these substances with a non-active solution is sparse and does not live up to expectations of modern clinical trial concepts necessary for authorisation purposes. The presented multicentre EASI study fulfils these requirements and clearly demonstrates that Sclerotherapy of C1 veins with POL is highly effective and deserves the adjunct 'gold standard'.

Keywords: telangiectases, reticular veins, sclerotherapy, polidocanol, sodium tetradecyl sulphate.

Original Article

Contact sensitization in patients with lower extremity dermatitis in the South Moravian region, Czech Republic.

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Abstract:

Objectives: The aim of the study was to determine the frequency of contact sensitization in patients with lower extremity dermatitis.

Methods: Between the years 2001 and 2007, the authors investigated 462 patients (mean age 49.1 years, 196 men and 266 women) with the eczema/dermatitis localized on their lower extremities, including feet. The patients were investigated with epicutaneous tests of the European Standard Series and also with other special patch tests.

Results: The most frequent allergens were balsam of Peru, 44/462 (9.5%); wool alcohols, 41/462 (8.9%); nickel sulphate, 39/462 (8.4%); propolis, 35/462 (7.6%); fragrance mix, 34 (7.4%) and colophony, 29/462 (6.3%).

Conclusions: In patients with lower extremity dermatitis the frequency of contact sensitization is still high, and therefore investigation with epicutaneous tests should belong to the routine dermatological diagnostic procedure in these patients.

Keywords: lower extremity dermatitis, allergic contact dermatitis, epicutaneous tests, most common contact allergens.

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Original Article

Sclerotherapy of voluminous venous malformation in head and neck with absolute ethanol under digital subtraction angiography guidance.

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Abstract:

Objectives: Venous malformation (VM) is the most common symptomatic low-flow vascular malformation, which predominantly occurs in the head and neck region. The aim of this paper was to evaluate the results of endovascular sclerotherapy of voluminous VM, when the lesion is either 15 cm in maximum diameter or the lesion invades more than one anatomical space, in the head and neck region using absolute ethanol under digital subtraction angiography (DSA) guidance.

Methods: A total of 23 patients with head and neck VMs between October 2005 and December 2008 were retrospectively reviewed. All patients received direct puncture ethanol sclerotherapy under DSA guidance. Follow-up assessments were performed at 3–25 months after therapies were completed, and complications were reported in some cases.

Results: All patients were satisfied with the results of therapy. Seventeen patients (73.9%) achieved excellent responses and six patients (26.1%) achieved good responses in magnetic resonance imaging assessments. Minor complications developed during the procedures, all of which were successfully managed with full recovery during follow-ups. Serious complications such as acute pulmonary hypertension, cardiovascular collapse and pulmonary embolism were not encountered.

Conclusion: It is concluded that sclerotherapy with absolute ethanol under DSA guidance is an important alternative therapy for voluminous and extensive VM, as the procedure is reasonably safe and offers good therapeutic results.

Keywords: sclerotherapy, voluminous venous malformation, digital subtraction angiography (DSA), ethanol, head and neck.

Original Article

Is low compression pressure able to improve venous pumping function in patients with venous insufficiency?

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Abstract:

Background: A too high resting pressure of compression devices is poorly tolerated and may cause skin defects, especially in patients with concomitant arterial occlusive disease.

Aim: To investigate whether low compression pressure will improve venous pumping function in patients with venous incompetence.

Material and methods: Venous pumping function was assessed in 20 patients with severe reflux in the great saphenous vein by measuring ejection fraction (EF) using strain-gauge plethysmography. Measurements were repeated after application of knee-high medical compression stockings and of inelastic bandages applied with a pressure of 20, 40 and 60 mmHg in the supine position.

Results: EF was significantly reduced compared with healthy controls. Compression stockings exerting a median pressure of 27 mmHg (interquartile range [IQR] 25–29) in the supine and 30.5 mmHg (IQR 28.25–34.25) in the standing position produced a moderate, non-significant improvement of EF of 17%. Inelastic bandages with a resting pressure of 20.5 mmHg (IQR 20–22) in the supine position resulting in a standing pressure of 36 mmHg (IQR 33–40.75) led to a significant increase of EF of 61.5% ($P < 0.01$). A further increase of the resting pressure to 40 and 60 mmHg achieved an increase of the EF of 91% and 98%, respectively ($P < 0.001$).

Conclusions: In patients with venous pumping failure, inelastic bandages produce a significant pressure-dependent increase of EF. A significant improvement in venous pumping function was achieved with inelastic bandages even at a resting pressure of 20 mmHg.

Keywords: chronic venous insufficiency, elastic stocking, inelastic bandage, ejection fraction, venous pumping function.

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Original Article

Conventional surgery and endovenous laser ablation of recurrent varicose veins of the small saphenous vein: a retrospective clinical comparison and assessment of patient satisfaction.

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Abstract:

Objectives: Recurrences of varicosities of the small saphenous vein (SSV) are common. Surgical reintervention is associated with increased complication rates. The aim of the study was to assess the feasibility of endovenous laser ablation (EVLA) in recurrent varicose veins of the SSV and to compare this technique with surgical reintervention.
Methods: All case files of patients treated for SSV varicosities between May 2006 and October 2008 were evaluated and recurrences were selected. Demographics, duplex findings, clinical, aetiological, anatomical and pathological classification, perioperative and follow-up data were all registered. Additionally, a questionnaire focusing on patient satisfaction was taken.
Results: Two hundred and eighty-one patients were treated for varicosities of the SSV, of which 42 were for recurrences. Twenty-six of these were treated with EVLA, all under local anaesthesia, and 16 were surgically treated. Most surgically treated patients were treated under regional anaesthesia (88%). Technical success was achieved in 94% of surgically treated patients and in all EVLA-treated patients. Complications in both groups were mostly minor and self-limiting. Sural nerve neuralgia appeared to be more frequent in the surgically treated group (20% versus 9%). After correction for length of follow-up, the incidence of rerecurrences was not statistically significant between groups.
Conclusion: EVLA is feasible in patients with recurrent varicose veins of the SSV with possibly a lower incidence of sural nerve injury. Patient satisfaction is high for both treatment modalities. Studies with larger samples are indicated to confirm these observations.

Keywords: small saphenous vein, recurrence, endovenous laser ablation, surgery, satisfaction.

Original Article

Post ambulatory phlebectomy: chronic peripheral lymphocoele.

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Abstract:

Objectives: Peripheral lymphocoele is a recognized complication after various forms of surgery. This is a case report of a calf lymphocoele after surgery for varicose veins by ambulatory phlebectomy.
Method: The reported incidence, pathology and possible treatment methods are discussed.
Conclusion: Phlebectomy practitioners need to be aware of the possibility of this complication.

Keywords: lymphocoele, complication, varicose vein, surgery, phlebectomy.