

## **A pilot study of the use of peripheral nerve blockade for percutaneous revascularisation in patients with critical limb ischaemia**

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### **Background**

The use of endovascular treatments for patients with critical limb ischaemia (CLI) continues to develop and expand. Patients with CLI frequently have intractable ischaemic pain that requires significant use of opiate analgesia in an increasingly frail and fragile patient cohort. In many cases this intractable pain excludes prolonged endovascular procedures without general anaesthesia. This pilot study aimed to investigate the potential use of peripheral nerve blockade to facilitate endovascular revascularisation in critical limb ischaemia.

### **Methods**

In conjunction with a vascular anaesthetist with a special interest in peripheral nerve blockade and pain management, a pilot study of patients requiring revascularisation under ultrasound guided peripheral nerve blockade to facilitate percutaneous endovascular reconstruction.

### **Results**

21 patients were included, 12 female, 9 male. The average age was 77 years. 12 patients had previously failed endovascular treatment due to technical reasons or symptoms. The procedures were tolerated in 20/21 patients. Procedure success was recorded in 15 patients 6 technical failures. On follow up 3 patients had undergone major amputation, 2 had minor amputations, and 16 had no amputation. Of the failed cases, only 1 patient required major limb amputation. No complications related to the nerve blocks were observed either peri- or post-operatively. 3 patients were deceased at the censor date.

### **Conclusion**

Peripheral nerve blockade for endovascular treatment is a safe and effective adjunct to allow treatment of critical limb ischaemia in an increasingly frail patient cohort. Investment is required to facilitate use of this adjunct to advanced endovascular procedures.

## **The use of antiplatelets and anticoagulants in patients undergoing endovascular revascularisation for peripheral arterial disease**

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### **Background**

Antiplatelet agents are usually prescribed following endovascular intervention to reduce adverse events and improve patency, but there are no firm guidelines about dose, type or duration of these medications. The aim of this study was to examine the protocols used in randomised controlled trials of peripheral endovascular intervention to assess patterns in practice.

### **Methods**

A systematic review and narrative synthesis was performed, searching MEDLINE, EMBASE and the Cochrane library from inception until November 2017 for randomised controlled trials (RCTs) of endovascular interventions for PAD. Peri-procedural and post-procedural antiplatelet and anticoagulant protocols were recorded and summarised.

### **Results**

103 RCTs of peripheral endovascular intervention were identified. From these, 69 different antiplatelet and/or anticoagulant protocols were identified. Sixty-nine percent of trials failed to clearly specify the antiplatelet and/or anticoagulant medications administered to trial participants. More than 20% of the trials did not specify the peri-procedural drug class. Thirty-one trials specified an intensive post-procedural antiplatelet protocol, with dual antiplatelet therapy in 28/31 cases. Fifty-four trials specified long-term antiplatelet and/or anticoagulant therapy, of which thirty-eight used aspirin. Newer interventions such as drug eluting stent trials had a higher tendency to use more aggressive drug regimens such as dual antiplatelet therapy.

### **Conclusion**

There is significant heterogeneity in the use of antiplatelet and anticoagulant therapy following peripheral endovascular intervention. Future trials should clearly specify antiplatelet and anticoagulant protocols to minimise the risk of confounding of outcomes due to divergent antithrombotic regimes.

## **First in man results from a novel device providing real time, quantitative feedback on tissue perfusion during peripheral intervention**

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### **Background**

Enormous amounts of resource are focused on determining the optimal method employed to improve perfusion to the lower limb. However, little time has been spent on determining how effectively we actually perform the procedure. Although some techniques exist for evaluating skin perfusion or oxygenation, these aren't widely adopted into clinical use because they interfere with clinical workflow or take too long to respond to perfusion changes.

### **Methods**

The IROAD study is a 40-patient trial evaluating changes in tissue perfusion seen during angioplasty or stenting. The device measures changes in photon scatter induced by improvements in capillary blood flow. The device produces real time numerical outputs, evaluating perfusion through the use sensors attached to differing angiosomes of the foot.

### **Results**

Data are currently available for 20 patients, with 11 having critical ischemia and 9 claudication. The device reliably demonstrated significant changes in tissue perfusion within 60s of a clinically significant event (balloon inflation etc). In patients who experienced a clinical improvement in their symptoms, there was a significant improvement in tissue perfusion after the intervention ( $p < 0.05$ ). The 2 patients in the study who showed no improvement in their tissue perfusion via the device had negative clinical outcomes.

### **Conclusions**

The novel monitor provided real-time feedback about tissue perfusion, without impacting on clinical workflow, and the device outputs correlated with clinical outcomes.

## **The relationship between gender and survival to discharge in people undergoing inflow procedures for aorto-iliac disease in the UK National Vascular Registry**

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### **Background**

Operative outcomes after lower limb revascularisation are frequently reported to be worse in women when compared to men. This study aimed to determine whether there was a significant relationship between gender and survival to discharge from hospital in people undergoing axillary or aortic based inflow procedures recorded in the National Vascular Registry (NVR).

### **Methods**

This was an analysis of NVR data relating to people over 40 years of age undergoing axillary or aortic-based inflow procedures between January 2014 and December 2016. Following univariate analysis, binary logistic regression was used to identify variables that were significantly associated with survival to discharge from hospital.

### **Results**

1766 inflow procedures were recorded (514 axillary and 1252 aortic) in 1191 men and 575 women. Women were older ( $p=0.006$ ), had undergone fewer previous interventions ( $p<0.002$ ), and presented with higher Rutherford scores ( $p=0.03$ ). Women had a higher prevalence of respiratory disease, but lower rates of IHD and stroke. Survival to discharge was associated with lower Rutherford scores (OR 1.75, 95% CI 0.74-0.412,  $p<0.001$ ), IHD (OR 2.1, 1.38-3.29,  $p=0.001$ ), chronic kidney disease (OR 0.15, 1.15-3.69,  $p=0.015$ ), elective versus emergency admission (OR 3.35, 1.02-5.53,  $p<0.001$ ) and lower age at time of surgery (OR 0.97, 0.95-0.99,  $p=0.009$ ), but not gender.

### **Conclusions**

Gender itself was not found to be a risk factor for survival to discharge after aorto-iliac revascularisation procedures. Risk factors for reduced survival such as age and higher Rutherford scores were greater in women, suggesting results showing poorer outcomes for women could be addressed by better and earlier diagnosis.

## **Interwoven nitinol stents vs. drug-eluting stents in the femoro-popliteal segment: two year outcomes in a propensity matched analysis**

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### **Background**

Percutaneous Transluminal Angioplasty (PTA) is a common procedure in patients with disease affecting the Femoro-Popliteal segment (F-P). Biomimetic nitinol stents (Supera Peripheral Stent – SPS) and Drug Eluting Stents (DES) were designed to improve the longevity of F-P PTA; however, their performance has not been compared in a pragmatic setting, taking atherosclerotic plaque-characteristics into account.

### **Methods**

296 patients (mean age: 73±11 years, 65 % male, 68% with critical limb ischaemia) undergoing F-P PTA using SPS or DES (2013-2018) were included. Patient and plaque data, including F-P plaque analysis to assess degree of calcification based on computed tomography, were collected; 121 case-matched pairs were created using a propensity score based on patient/plaque characteristics.

### **Results**

During a median 2 year follow-up, 28% of the cohort (32% SPS vs. 24% DES,  $p=0.07$ ) developed Target Lesion Restenosis (TLR) >50%. Amongst the 121 case-matched pairs, those with SPS vs. DES were not significantly more likely to develop TLR >50% (31% vs. 27%,  $p=0.34$ ), stent occlusion (13% vs. 12%,  $p=0.85$ ), have a major amputation (10% vs. 6%,  $p=0.16$ ), require reintervention (14% vs. 9%,  $p=0.12$ ), or die (7% vs. 4%,  $p=0.31$ ). Plaque calcification did not predict restenosis or occlusion in either stent group. The main predictors of restenosis >50% on multivariate analysis were: female sex [Odds Ratio (OR): 2.05,  $p=0.01$ ], hypertension (OR: 2.10,  $p=0.04$ ) and previous F-P occlusion (OR: 1.35,  $p=0.04$ ).

### **Conclusion**

Medium term results following F-P PTA with either SPS or DES are comparable, regardless of plaque calcification and patient characteristics.

**Renal injury is common after aortic intervention: Findings from the Midlands Aortic Renal Injury (MARI) cohort study, a Vascular and Endovascular Research Network (VERN) collaboration**

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The true incidence of acute kidney injury (AKI) after aortic or open endovascular procedures is unknown, even though AKI is known to be associated with worse outcomes. Current relevant literature suffers from inconsistencies such as lack of uniform AKI reporting.

A prospective cohort study was performed in 11 vascular centres (England and Wales) between September 2017 and December 2018, recruiting patients undergoing open or endovascular aortic surgery. Serum Creatinine (SCr) and urine outputs were measured to define post-operative AKI using Kidney Disease Improving Global Outcomes (KDIGO) criteria. Renal decline at 30 days was calculated using estimated glomerular filtration rate (eGFR) and the MAKE30 composite endpoint (death, new dialysis, >25% eGFR decline).

A total of 300 patients (mean age: 71 years, SD: 4 years; 27 females, 9%) were included, who underwent: infrarenal endovascular aneurysm repair (EVAR) 139 patients, fenestrated EVAR (fEVAR) 30, branched EVAR (bEVAR) 7, infrarenal open aneurysm repair (OAR) 98, juxtarenal OAR 26. Overall, 24% developed stage 1 AKI, 2.7% stage 2 AKI and 1% needed transient filtration before discharge. AKI proportion per intervention were: infrarenal EVAR 18%; fEVAR 27%; bEVAR 71%; infrarenal OAR 41%; juxtarenal OAR 63%. Age, baseline eGFR and ischaemic heart disease were the main predictors of AKI for infrarenal EVAR and OAR. Overall, 24% developed the MAKE30 endpoint.

AKI and short term renal decline after aortic intervention are very common. Age, baseline renal function and pre-existing cardiovascular disease are the main risk-factors. Research should now focus on AKI prevention in this high-risk group.

## **Acute kidney injury in association with acute type B aortic dissection**

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### **Introduction**

Acute Kidney Injury (AKI) following acute type B aortic dissection (AAD) may be associated with increased in-hospital and late mortality. Currently available evidence consists of small series using inconsistent non-validated AKI reporting criteria. This study examined the proportion of patients with AAD who develop AKI and detected associations with outcomes.

### **Methods**

Consecutive patients with AAD referred to a tertiary referral centre between January 2014-December 2018 were included. Clinical and biochemical data during in-hospital stay were recorded. AKI was defined according to the "Kidney Disease Improving Global Outcomes" (KDIGO) criteria, as recommended by National Institute for Health and Care (NICE) guidance.

### **Results**

A total of 96 patients were included (median age: 65 years; 31% female). Forty (41%) patients developed AKI, 19 had stage-1 AKI (20%), 15 stage-2 (16%), and 6 stage-3 (6%). A total of 3 patients required renal replacement therapy during their inpatient stay. Those with AKI had a longer stay in-hospital (17.5 days vs 9.5 days,  $P < 0.001$ ) and a 7-fold higher likelihood of death after 30 days (15% vs. 1.8%,  $p = 0.02$ ). The increased mortality was evident irrespective of stage (stage 1 AKI mortality at 30 days vs no AKI 17% vs. 2%,  $p = 0.04$ ).

### **Conclusions**

This study, using contemporary validated AKI reporting criteria, has shown that AKI is very common after AAD and that it is associated with worse short-term outcomes. Further work to understand the mechanisms of renal injury is warranted in order to guide management strategies in this setting.

## **Frailty factors and outcomes in vascular surgery: A systematic review and meta-analysis**

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### **Background**

Increasing evidence shows negative impacts of frailty on outcomes in vascular surgery patients. Review aims were to describe and critique tools used to assess frailty in vascular patients, and investigate its associations with patient factors and outcomes.

### **Methods**

Systematic review and meta-analysis of studies reporting frailty in vascular patients (PROSPERO registration: CRD42018116253) searching Medline, Embase, CINAHL, PsychINFO and Scopus. Quality of included studies was assessed using Newcastle-Ottawa scores (NOS) and quality of evidence assessed using GRADE criteria. Associations of frailty with patient factors were investigated by difference in means (MD) or expressed as risk ratios (RR), and associations with outcomes expressed as odds ratios (OR) or hazard ratios (HR). Data were pooled using random effects models.

### **Results**

Fifty-three studies (>160,000 patients) were included in the review and only 8 (15%) were both good quality (NOS ≥7) and used a well-validated frailty measure. Eighteen studies (62,976 patients) provided data for the meta-analysis. Frailty was associated with increased age (MD 4.05 years; 95% confidence interval [CI] 3.35, 4.75), female sex (RR 1.32; 95%CI 1.14, 1.54), and lower body-mass index (MD -1.81; 95%CI -2.94, -0.68). Frailty was associated with 30-day mortality (adjusted [A]OR 2.77; 95%CI 2.01-3.81), post-operative complications (AOR 2.16; 95%CI 1.55, 3.02) and long-term mortality (HR 1.87; 95%CI 1.29, 2.72). Sarcopenia alone was not associated with any outcomes. Quality of evidence was moderate to very low.

### **Conclusion**

Frailty, but not sarcopenia, is associated with worse outcome in vascular patients. Few studies use well validated frailty assessment tools, and prospective research using such tools is required.

## **Assessing digital and e-health literacy amongst patients attending vascular surgery clinic; a questionnaire study**

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### **Objective**

Despite a shift to communicate health information to patients through digital platforms, there has been no assessment of the digital and e-health literacy of vasculopathic patients. This questionnaire study aims to assess such literacy in this patient cohort.

### **Methods**

A multi-questionnaire study of consecutive patients attending vascular surgery clinics at a London tertiary centre was undertaken. The questionnaires consisted of a baseline demographic survey and two validated tools; the Mobile Device Proficiency Questionnaire (MDPQ-16) and the eHealth Literacy Scale (eHEALS).

### **Results**

75 arterial and 25 venous patients completed the survey (mean age 60 years; 53% male). 85% owned a smartphone, however, only 44% "strongly agreed" that they possess the skills to use a mobile device effectively. This correlated with age ( $r=-0.516$ ,  $p<0.05$ ) and level of education ( $r=0.247$ ,  $p<0.05$ ) but not gender ( $p=0.154$ ). 41% stated they could use 'app' and 'picture-based' modalities (e.g. WhatsApp), whereas 65% preferred SMS. When asked for the optimal method of transfer of health information, patients ranked SMS and "secure e-mail" as high as a formal consultation with a clinician. Regarding e-health literacy; 60% stated that they perceive digital health resources to be useful in guiding their own health choices, however, only 40% stated they were confident in distinguishing between high- and low-quality digital health resources themselves.

### **Conclusion**

The drive to incorporate digital health into healthcare is highly appreciated by patients. There is, however, a lack of digital and e-health literacy amongst a vasculopathic cohort. This requires consideration upon incorporation of such technology into care pathways.