ABSTRACT

Selected Abstracts from the September Issues of the Journal of Vascular Surgery and the Journal of Vascular Surgery: Venous and Lymphatic Disorders☆

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iTalian RegIstry of doUble inner branch stent graft for arch PatHology (the TRIUmPH Registry)

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Objective: The objective of this study was to assess early and midterm results after endovascular aortic arch repair using a double inner branch stent graft (DIBSG) in patients with aortic arch aneurysm or dissection unfit for open surgery.

Methods: Between 2012 and 2018, there were 24 patients with aortic arch disease who were treated with a single model of a DIBSG (Terumo Aortic, Glasgow, United Kingdom) in nine Italian cardiovascular centers. We investigated technical success, mortality, occurrence of major complications, and need for reintervention in a multicenter, nonrandomized, retrospective fashion.

Results: The in-hospital mortality rate was 16.7%. Cerebrovascular events occurred in 25% of patients and major strokes in 12.5%. Two patients experienced a retrograde dissection (8.3%), whereas none reported any type I or type III endoleak. During a mean follow-up of 18 months (range, 1-60 months), one patient died of a nonaortic cause and one reported a nonarch-related major stroke. No late secondary intervention was needed during the follow-up. Excluding from the analysis the first six patients treated until 2014 as part of the learning curve, in-hospital mortality, major stroke, and retrograde dissection rates were 11.1%, 11.1%, and 5.6%, respectively.

Conclusions: Endovascular aortic arch repair using this model of DIBSG is feasible, and results are acceptable for a new technique in a high-risk subset of patients. Operative mortality suffers the effect of a learning curve, whereas midterm aorta-related survival is promising. Endovascular repair of aortic arch disease with a DIBSG should always be considered to give high-risk patients a chance of repair. Large-scale studies are needed to assess the long-term durability of this technique.

False lumen embolization in chronic aortic dissection promotes thoracic aortic remodeling at midterm follow-up

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Objective: Failure of thoracic endovascular aortic repair (TEVAR) in chronic aortic dissections can be partially explained by retrograde false lumen (FL) flow through distal re-entry tears. After implantation of a thoracic stent graft, FL thrombosis occurs in less than 50% of the cases. The objectives of this study were to describe the feasibility and outcomes of FL embolization in patients with chronic aortic dissections.

Methods: Between June 2015 and January 2018, 27 patients (mean age, 61 $\pm$ 14 years) with chronic aortic dissection underwent FL embolization as an adjunct during or after TEVAR placement procedure. Indications for embolization were (1) symptomatic chronic aortic dissections with pain or rapid growth of aortic diameter ($\geq$5 mm/y) requiring rapid exclusion of the aneurysm, (2) aneurysmal dilatation with persistent FL retrograde flow after TEVAR, and (3) large FL aneurysms ($\geq$55 mm) that might lead to persistent retrograde flow. Twenty patients presented with type B chronic aortic dissections (74.1%) and seven presented a residual type A chronic aortic dissections (25.9%). Eight patients had a previous aortic arch replacement (29.6%). Six patients had previous repair with TEVAR (22.2%). The delay between the onset of dissection and the first endovascular repair was 47 months (range, 3-144). Spinal fluid drainage was used in 74.1% of cases (20/27 patients). Embolization devices included coils and vascular plugs.

Results: The technical success rate was 100% (27/27). Complete spinal cord ischemia was observed in one patient (3.7%). There was one hospital death from pneumonia after zone 1 supra-aortic trunk debranching with TEVAR and embolization. After the index procedure, FL thrombosis was observed in 81.5% of patients (22/27) on late phase computed tomography angiography. Five patients required two or more embolization procedures, leading to a high rate of complete FL thrombosis (92.6%). One patient presented a type IB endoleak and one patient presented a type II endoleak. Radiologic follow-up was 20 $\pm$ 10 months. The maximum thoracic aortic diameter significantly decreased from 63 mm to 54 $\pm$ 10 mm ($P < .001$).

Conclusions: Embolization of the FL of chronic aortic dissections is technically feasible with a low morbidity rate. The FL thrombosis is observed in the majority of case and promotes favorable thoracic aortic remodeling. Longer follow-up is needed to confirm these good results on the

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1078-5884/
http://dx.doi.org/10.1016/S1078-5884(19)31442-X

thoracic aorta and this technique may, therefore, improve the results of TEVAR in chronic aortic dissections.

Hybrid surgery for bilateral lower extremity inflow revascularization

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Objective: Aortobifemoral (ABF) bypass is the preferred method of bilateral inflow revascularization, with axillobifemoral (AXBF) bypass reserved for high-risk patients. Hybrid (HYB) surgery in the form of femorofemoral bypass and retrograde endovascular aortoiliac intervention is increasingly being used to achieve the same goal. This study compared the perioperative outcomes of HYB surgery with traditional surgery for bilateral inflow revascularization.

Methods: The American College of Surgeons National Surgical Quality Improvement Program files for the years 2012 to 2015 were reviewed, and all patients undergoing ABF bypass, AXBF bypass, and HYB surgery (femoral-femoral bypass and retrograde endovascular intervention) were included. Patients' demographics, comorbidities, and outcomes were compared between the three groups. A propensity-matched analysis was subsequently performed to compare HYB surgery with ABF bypass only. The χ^2 test and analysis of variance with post hoc analysis were conducted to evaluate between-group differences in risk factors and outcomes. SPSS statistical software (IBM Corp, Armonk, NY) was used.

Results: There were 1426 patients (ABF bypass, 976; AXBF bypass, 257; HYB surgery, 193). There were significant differences in the three populations of patients, with ABF bypass patients significantly more likely to have age <70 years (ABF bypass, 84.2%; AXBF bypass, 49.8%; HYB surgery, 58%; $P < .001$) and more likely to be independent (ABF bypass, 98%; AXBF bypass, 89.1%; HYB surgery, 93.2%; $P < .001$). Patients undergoing AXBF bypass were significantly more likely to be treated for critical limb ischemia (ABF bypass, 46.5%; AXBF bypass, 72.4%; HYB surgery, 51.8%; $P < .001$) under emergent conditions (ABF bypass, 0.9%; AXBF bypass, 5.1%; HYB surgery, 3.6%; $P < .001$). There was no difference in mortality between the three groups ($P = .178$). After propensity matching, a total of 571 patients with ABF bypass were compared with HYB surgery patients. HYB surgery patients had significantly less pneumonia (ABF bypass, 8.7%; HYB surgery, 1.6%; $P < .001$), unplanned intubation (ABF bypass, 7.7%; HYB surgery, 3.1%; $P = .032$), cardiac arrest (ABF bypass, 3.7%; HYB surgery, 0.5%; $P = .025$), transfusion (ABF bypass, 44.4%; HYB surgery, 18.1%; $P < .001$), and composite morbidity (ABF bypass, 55%; HYB surgery, 32.6%; $P < .001$). Patients undergoing ABF bypass had significantly higher mortality (ABF bypass, 4.2%; HYB surgery, 1%; $P = .043$) and 30-day reoperation (ABF bypass, 17.5%; HYB surgery, 9.3%; $P = .009$) and longer total hospital length of stay (ABF bypass, 9.79 ± 10.69 days; HYB surgery, 5.79 ± 9.72 days; $P < .001$). There was no difference in major amputation ($P = .607$) and readmission ($P = .495$) between the two groups.

Conclusions: ABF bypass is the most common surgery for bilateral lower extremity revascularization in the American College of Surgeons National Surgical Quality Improvement Program database and continues to have good outcomes. In selected patients, HYB surgery was associated with improved perioperative, 30-day outcomes compared with ABF bypass.

Using the Society for Vascular Surgery Wound, Ischemia, and foot Infection classification to identify patients most likely to benefit from revascularization

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Background: The Society of Vascular Surgery Wound Ischemia foot Infection (WIfI) classification system for chronic limb-threatening ischemia was intended to predict 1-year major lower extremity amputation (LEA) risk and to identify which patients benefit most from revascularization. We aimed to identify which WIfI presentations benefited most from revascularization to explore whether a cluster analysis could identify a more data-driven WIfI score, and to quantify which component of the WIfI score was most strongly associated with 1-year LEA after revascularization.

Methods: Composite multi-institutional nested cohort data from centers who previously validated WIfI were reviewed retrospectively. We collected each patient's WIfI component grades and whether LEA was performed. To examine the benefit of revascularization, the predicted LEA rates were subtracted from observed LEA rates. We used k-means cluster analysis to model predicted vs observed LEA rates after revascularization. Multivariable linear regression analysis was performed to quantify which WIfI score component(s) best predicted LEA.

Results: Data from 10 centers, accumulated between 2005 and 2015 were collated (2878 limbs at risk; 314 LEAs performed). The subset of patients who underwent revascularization comprised the study base (1654 limbs; 169 LEAs). Of 64 potential WIfI grade combinations, 15 were never reported and were excluded from the analysis. By original WIfI stages, the observed LEA rate after revascularization was: stage 1, 10.8% (14/130); stage 2, 4.9% (5/103); stage 3, 5.1% (25/487); and stage 4, 13.4% (125/934). Based on the difference between predicted and observed LEA risk for those who underwent revascularization, the WIfI scores were placed into quartiles from greatest to no benefit of revascularization. Cluster analysis identified four clusters with the following 1-year LEA rates: cluster 1, 4.4% (46/1038); cluster 2, 14.8% (66/447); cluster 3, 28.1% (36/128); and cluster 4, 51.2% (21/41). The between sum of squares/total sum of squares was 93.9%. Multiple linear regression revealed the wound grade most strongly predicted LEA (F-value, 17.25; $P < .001$). Ischemia (F-value, 6.51; $P = .001$) and infection (F-value, 5.7; $P = .003$) were similarly

associated with LEA risk. Interaction terms between each component of the WIfI score were not statistically significant.

Conclusions: WIfI can identify which patients with chronic limb-threatening ischemia are most likely to benefit from revascularization and may provide improved prognostication, risk stratification, and equitable outcome assessments. After revascularization, wound severity is most strongly associated with LEA risk. Ischemic and infectious grades confer additive, but not synergistic, risk. Future cluster analyses comparing specific WIfI presentations treated with and without revascularization will be required to further refine WIfI.

Multidisciplinary clinics reduce treatment costs and improve patient outcomes in diabetic foot disease

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Objective: Diabetic foot disease poses a significant and rising financial burden on health care systems worldwide. This study investigated the effect of a new multidisciplinary diabetic foot clinic (MDDFC) in a large tertiary hospital on patient outcomes and treatment cost.

Methods: Patients' records were retrospectively reviewed to identify all patients who had been managed in a new MDDFC between July 2014 and July 2017. The wound episode—the period from initial presentation to the achievement of a final wound outcome—was identified, and all relevant inpatient and outpatient costs were extracted using a fully absorbed activity-based costing methodology. Risk factor, treatment, outcome, and costing data for this cohort were compared with a group of patients with diabetic foot wounds who had been managed in the same hospital before the advent of the MDDFC using a generalized linear mixed model.

Results: The MDDFC and pre-MDDFC cohorts included 73 patients with 80 wound episodes and 225 patients with 265 wound episodes, respectively. Compared with the pre-MDDFC cohort, the MDDFC group had fewer inpatient admissions (1.56 vs 2.64; $P \leq .001$). MDDFC patients had a lower major amputation rate (3.8% vs 27.5%; $P \leq .001$), a lower mortality rate (7.5% vs 19.2%; $P \leq .05$), and a higher rate of minor amputation (53.8% vs 31.7%; $P \leq .01$). No statistically significant difference was noted in the rate of excisional débridement, skin graft, and open or endovascular revascularization. In the MDDFC cohort, the median total cost, inpatient cost, and outpatient cost per wound episode was New Zealand dollars (NZD) 22,407.465 (U.S. dollars [USD] 17,253.74), NZD 21,638.93 (USD 16,661.97), and NZD 691.915 (USD 532.77), respectively. The MDDFC to pre-MDDFC wound episode total cost ratio was 0.7586 ($P <$ .001).

Conclusions: This study is the first to compare the cost and treatment outcomes of diabetic foot patients treated in a large tertiary hospital before and after the introduction of an MDDFC. The results show that an MDDFC improves patient outcomes and reduces the cost of treatment. MDDFCs should be adopted as the standard of care for diabetic foot patients.

Practice patterns in arteriovenous fistula ligation among kidney transplant recipients in the United States Renal Data Systems

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Background: Arteriovenous fistulas (AVF) and grafts (AVG) have been associated with significant cardiac morbidity that often improves after ligation. However, AV access ligation after kidney transplant (KT) is controversial due to concern for potential long-term allograft failure. We investigated US trends in AV access ligation after KT and the association between ligation and allograft failure.

Methods: All adult Medicare patients on pretransplant hemodialysis with a functioning AVF or AVG who underwent first-time KT were studied using the United States Renal Data Systems (January 2011 to December 2013). Post-transplant AV access ligation was determined using current procedural terminology codes. The incidence of post-transplant AV access ligation was described, and characteristics for patients undergoing ligation vs no ligation were compared. Kaplan-Meier curves and Cox proportional hazard models were then used to determine the association of AV access ligation with long-term allograft failure and all-cause mortality after accounting for patient characteristics, donor characteristics, and variation in transplant center practices.

Results: A total of 16,845 patients with functioning AVF/AVG received a KT during the study period. Of these, 779 (4.6%) underwent post-transplant AV access ligation. The proportion of patients who underwent ligation varied substantially between transplant centers, ranging from 0% (43.0% of centers) to >10% (11.0% of centers). Transplant recipients who underwent access ligation were more likely to be female (40.4% vs 36.6%), had lower median body mass index (27.6 vs 28.4 kg/m^2), spent longer on dialysis pretransplant (4.2 vs 4.0 years), and were less likely to have renal failure secondary to diabetes compared with other etiologies (25.0% vs 34.9%) (all, $P \leq .03$). Patients who underwent ligation were also more likely to have steal syndrome (77.2% vs 4.1%) and AV access infectious or aneurysmal complications (2.7% vs 0.7%) (both, $P < .001$). After adjusting for donor and recipient characteristics, increasing age (adjusted hazards ratio [aHR], 1.01; 95% confidence interval [CI], 1.00-1.01), increasing years on dialysis (aHR, 1.06; 95% CI, 1.00-1.13), zero human leukocyte antigen mismatch (aHR, 1.82; [95% CI, 1.09-3.05), and steal syndrome (aHR, 41.00; 95% CI, 34.56-48.64) were associated with post-transplant AV access ligation. Black

race (aHR, 0.82; 95% CI, 0.69-0.98) and congestive heart failure (aHR, 0.66; 95% CI, 0.54-0.82) were negatively associated with ligation. Three-year allograft failure occurred in 4.9% ± 1.3% transplant recipients who underwent access ligation vs 9.5% ± 0.5% transplant recipients with functioning access (log-rank, *P* = .30), and was not significantly different between groups after risk adjustment (aHR, 0.81; 95% CI, 0.47-1.40). There was also no significant association between AV access and all-cause mortality after risk adjustment (aHR, 0.84; 95% CI, 0.46-1.54).

Conclusions: Post-transplant AV access ligation is uncommon and generally reserved for patients with steal syndrome. Importantly, ligation is not associated with post-transplant allograft failure, which occurs in less than 10% of patients at 3 years. There also appears to be no reduction in all-cause mortality with AV access ligation. These data suggest that AV access ligation after KT can likely be reserved for access-related complications because the systemic benefits appear to be minimal.