Iliofemoral complications associated with thoracic endovascular aortic repair: Frequency, risk factors, and early and late outcomes

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Background: Risk factors and outcomes after iliofemoral complications after thoracic aortic endovascular repair remain poorly characterized. This study was performed to characterize factors influencing perioperative iliofemoral complications during thoracic aortic endovascular repair.

Methods: All patients undergoing transfemoral thoracic aortic endovascular repair since 2005 with adequate preoperative aortoiliac 3-dimensional imaging (n = 126) were identified. Assessment of imaging was blinded with regard to occurrence of iliofemoral complications, defined as anything other than successful transfemoral device delivery and primary closure of an arteriotomy.

Results: The complication rate was 12% (n = 15). Univariate analysis identified that female gender, preoperative ankle-brachial index, average and minimal iliac diameters, diameter difference between iliac artery and sheath size, and iliac morphology score (calculated by combining iliac tortuosity, calcification, and vessel diameter) were associated with iliofemoral complications (all $P < .05$). Multivariate analysis identified the (1) difference between average iliac diameter and sheath size ($P = .014$), (2) iliac artery morphology score ($P = .033$), and (3) ankle-brachial index ($P = .012$) as independent predictors for iliofemoral complications. Early mortality was higher in those with complications (13.3% vs 1.8%, $P = .069$). Four-year freedom from limb loss, claudication, or revascularization was 97.9%. Iliofemoral complications reduced late survival primarily as a result of increased mortality within the first year ($P = .047$).

Conclusions: Thoracic aortic endovascular repair can be performed safely via a transfemoral approach. Alternative access in patients with high preoperative iliac artery morphology scores and device delivery size requirements over the native iliofemoral size may reduce iliofemoral complications. If early complications occur, prompt repair results in low rates of ischemic limb complications at late follow-up. (J Thorac Cardiovasc Surg 2014;147:960-5)

Despite the successful introduction of thoracic endovascular aortic repair (TEVAR) as a minimally invasive therapeutic option for the treatment of descending thoracic aortic aneurysms, it is associated with access and device delivery challenges. Passage of large-bore sheaths through diseased iliofemoral access vessels often precludes safe transfemoral TEVAR in up to 30% of patients.[1] Although alternative access routes, including ascending aortic, iliac, and subclavian arteries, have been described, these options increase the morbidity, duration of hospitalization, and postoperative recovery of what is intended to be a minimally invasive approach to aneurysm repair.[2,3] Modifications to the delivery catheters and sheaths (including tapered tips, hydrophilic coating, device diameter reduction, and improved trackability) have helped overcome some aortoiliac anatomic limitations, but current series report a 9% to 22% incidence of access complications, thus contributing to perioperative morbidity in patients who are frequently elderly and debilitated.[4-6]

No previous study has fully evaluated these challenges with TEVAR, particularly with a rigorous 3-dimensional (3-D) analysis of preoperative imaging studies. With the advent of other minimally invasive cardiovascular therapies, including transcatheter aortic valve replacement, an examination of the incidence, risk factors for occurrence, and early and late outcomes of iliofemoral complications associated with large-bore diameter device delivery for TEVAR is timely and warranted.

MATERIALS AND METHODS

This single-center retrospective study was approved by the institutional review board of the University of Michigan Medical School (HUM 00053164). The primary outcome in this study was the incidence of iliofemoral access complications. The definition of an iliofemoral access complication was determined before beginning patient review and encompassed the following: (1) inability to successfully deliver the device into the aorta via a transfemoral approach; (2) rupture, dissection, tear, or thrombosis of the ipsilateral iliac artery or femoral artery, and (3) inability to achieve primary closure of the femoral artery. Secondary outcomes

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Abbreviations and Acronyms
ABI = ankle-brachial index
IMS = iliac morphology score
OR = odds ratio
TEVAR = thoracic endovascular aortic repair
3-D = 3-dimensional

included early mortality defined as in-house or 30-day death and freedom from limb loss, claudication, or revascularization.

All patients who underwent TEVAR from March 2005 to August 2011 were reviewed for study eligibility (n = 235). Before undergoing TEVAR, all patients underwent computed tomographic arteriography with 3-D reconstructions and modeling using M2S imaging software (M2S Inc, West Lebanon, NH). Eighty patients were excluded from analysis on the basis of available imaging for the following reasons: (1) emergency status where time did not permit 3-D reconstruction, (2) 3-D models that did not include the iliofemoral vessels, and (3) missing M2S hard-copy compact discs with images no longer available for immediate review from the M2S server. Twenty-nine patients were excluded from the analysis because of planned delivery of the endograft via alternative access routes, including the iliac conduit or aortofemoral limb (18), ascending aorta (10), and carotid artery (1). The final study cohort consisted of 126 patients. Preoperative demographics and postoperative outcomes were collected retrospectively.

In 2002, a grading scale to objectively define the severity of anatomic factors in abdominal aortic aneurysms was developed by the ad hoc Committee for the Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/American Association for Vascular Surgery.[7] This scale designates a numeric value or score to the morphology of the aortic neck, aortic aneurysm, and iliac artery. Specifically, the iliac morphology score (IMS) includes extent of vessel calcification, vessel diameter or presence of occlusive disease, and vessel angulation or tortuosity. All available 3-D reconstructions were reviewed for the purpose of evaluating iliac anatomy and calculating this IMS.

The 3-D models were reviewed in a blinded fashion, such that the investigator did not know the operative and clinical outcome of the patient in question. Because the IMS was initially conceived for the purpose of TEVAR and included a component accounting for the landing zone of the iliac limbs, we developed a modified version using 3 components to evaluate the morphology of the iliac artery (Table 1). For the sake of simplicity, the common and external iliac arteries were evaluated as a continuous structure from the aortic bifurcation to the inguinal ligament, thus allowing calculation of a single IMS. A numeric value was assigned on the basis of varying degrees of calcification, artery diameter, and artery tortuosity. Diameter was recorded as minimal luminal and representative (average) diameter of the vessel. Tortuosity was calculated as the ratio between centerline luminal distance and straight line distance measured from the aortic bifurcation to the distal external artery at the inguinal ligament (Figure 1). The total score was calculated for the accessed side only, with a maximal score of 9. To account for sheath oversizing, the outer diameter of the sheath used to deliver the endograft in each patient was recorded in millimeters. In patients who received more than 1 endograft, the largest sheath used was recorded. The difference between average iliac diameter and sheath outer diameter was recorded as sheath oversizing.

All TEVARs were performed in hybrid operating rooms under general anesthesia as previously described. Operative exposure of the femoral artery was performed via a 5-cm transverse infrainguinal incision. Percutaneous access was obtained in the contralateral femoral artery for placement of a 5F sheath and a marked flush catheter. When intravascular ultrasound was used, an 8F sheath was inserted. Ipsilateral femoral access was performed with a single wall puncture needle and a single Lunderquist wire (Cook Medical Inc, Bloomington, Ind) placed into the ascending aorta. Routine serial dilation of the ipsilateral iliofemoral vessel with hydrophilic dilators (Cook Medical Inc) up to a 24F size (or less if delivery sheath size was smaller) was performed before introducing the endograft. TAG (WL Gore & Associates, Flagstaff, Ariz), TX2 (Cook Medical Inc), and Talent (Medtronic Inc, Minneapolis, Minn) endografts were used in this study. After deployment and removal of all devices, the common femoral artery was repaired with interrupted 5-0 polypropylene sutures, taking care to tack down all intimal flaps. Distal arterial signals and Doppler interrogation of the vessels were performed before closure of the wound. Ankle-brachial indices (ABIs) were obtained routinely on the first or second postoperative day. Completion imaging of the iliofemoral segment was performed selectively for altered pulse or Doppler signal identified after repairing the femoral artery.

Statistical Analysis

Statistical analysis was performed with SPSS (SPSS Inc, Chicago, Ill). Dichotomous variables were evaluated using chi-square analysis or Fisher exact test; continuous variables were evaluated using Student *t* test. Multivariate models (binary logistic regression) were constructed using a forward conditional process to identify factors that were independently associated with each of the outcomes of interest. Factors used in multivariate analysis included those with a *P* value of .1 or less on univariate analysis. Survival analysis was performed by Kaplan-Meier methods.

RESULTS

Early Results

The mean age for the entire cohort was 68.7 years with a slight predominance of male subjects (54.8%). The demographics are listed in Table 2. Femoral artery exposure was made through a reoperative field in 12% of instances, and a mean of 1.9 stent grafts were used per patient. Indications for intervention included aneurysm (60%), aortic dissection (21%), blunt traumatic aortic injury (17%), and penetrating ulcer (2%).

In 126 patients, there were 15 iliofemoral access complications, yielding a complication rate of 12%. In 8 patients, there was a rupture or dissection of the iliac artery; in 6 patients, the femoral artery required patch angioplasty to achieve closure. The endograft was unable to be delivered into the aorta via the transfemoral route in 1 patient. The presence of iliofemoral complications significantly increased postoperative length of stay (no complication median length of stay 5 days vs complication length of stay 6.5 days, $P = .007$).

By univariate analysis, those patients who sustained an iliofemoral complication were more likely to be female, to have smaller iliac arteries, and to have higher preoperative ABIs (all $P < .05$, Table 3). These patients also demonstrated more challenging anatomy as defined by a higher IMS (no complication IMS 2.7 vs complication IMS 3.7, $P < .001$). Device delivery sheaths were, on average, more than 1 mm oversized in the complication cohort and slightly undersized in those patients who did not sustain a complication (Table 3). By multivariate analysis, independent predictors of iliofemoral access complications