Μεταπτυχιακή εργασία

Factors Predisposing to Endograft Limb Occlusion after Endovascular Aortic Repair

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Φύλλο Εξέτασης

Ο συγγραφέας βεβαιώνει ότι το περιεχόμενο του παρόντος έργου είναι αποτέλεσμα προσωπικής εργασίας και ότι έχει γίνει η κατάλληλη αναφορά στην εργασία τρίτων, όπου κάτι τέτοιο ήταν απαραίτητο, σύμφωνα με τους κανόνες της ακαδημαϊκής δεοντολογίας.

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Περίληψη

Εισαγωγή: Ανευρυσματική κοιλιακή αορτή ,ορίζεται ως η αυξηση της διαμέτρου περισσότερο από 50% της φυσιολογικής ή διάμετρος μεγαλύτερη απο 30 χιλιοστα , και απαντάται σε ποσοστό 2-12 % σε ασθενείς άνω των 65 , ιδίως άντρες καπνιστές. Η χειρουργική αντιμετώπιση, ενδαγγειακή ή ανοικτή , ενδείκνειται σε μεγιστη αορτική διάμετρο 5-5,5 εκ.

Η ενδαγγειακή αντιμετώπιση ανευρυσμάτων κοιλιακής αορτής αποδεδειγμένα έχει επιδείξει καλύτερα βραχυπρόθεσμα αποτελέσματα σε συσχέτιση με την ανοικτή αποκατάσταση. Ωστόσο έχει συσχετιθεί με αυξημένη συχνότητα επανεπεμβάσεων. Ο σκοπός αυτής της μελέτης είναι να επιδείξει τη συχνότητα των επιπλοκών, όπως η θρόμβωση σκέλους και να διερευνηθούν οι προδιαθεσικοί παράγοντες - χαρακτηριστικά τα οποία φαίνεται να συνεπικουρούν στην εμφάνιση της θρόμβωσης (ELO after EVAR).

Υλικά και Μέθοδος: Πραγματοποίηθηκε μέλετη της διεθνούς βιβλιογραφίας και αναζητήθηκαν μελέτες στις οποίες διερευνούνται

τα πιθανά άιτια θρόμβωσης σκέλους ενδομοσχευμάτος. Εν συνεχεία πραγματοποιηθηκε σύγκριση αυτων των αποτελεσμάτων με σχετική αναδρομική μελέτη που διενεργήθηκε στην Αγγειοχειρουργική Κλινικη του Καποδιστριακού Πανεπιστημίου Αθηνών. Κατα την οποία συνελέχθησαν πληροφορίες από όλους τους ασθενείς που παρουσίασαν θρόμβωση σκέλους ενδομοσχεύματος από τον Ιανουάριο 2010 έως και Ιούνιο 2013.

Μελετήθηκαν τα δημογραφικά στοιχεία-ατομικό αναμνηστικό , οι αθηροσκληρωτικοί επιβαρυντικοί παράγοντες και τα προεγχειρητικά ανατομικά χαρακτηριστικά του ανευρύσματος και των λαγονίων με αξονική αγγειογραφία (Computed Tomography Angiography -CTA)

Αποτελέσματα: έπειτα από ενδελεχή μελέτη 24 δημοσιευσεων που αφορουν τη θρόμβωση σκέλους ενδομοσχεύματος καταλήγουμε στο συμπερασμα ότι πρόκειτε για μια σχετικά συχνη επιπλοκή , η οποία κυμαίνεται στο 4 % , ενώ οι προδιαθεσικοί παράγοντες που εμφαινεται να συσχετίζονται με αυτή ειναι: η μικρή διάμετρος , η ελίκωση, η αθηρωματωση και η παρουσιά θρόμβου στις κοινές λαγονίους, καθώς επίσης και η κάλυψη ή ο εμβολισμός των εσω λαγονίων, το oversizing του ενδομοσχευματος και ο τύπος του ενδοσκελετου των προθέσεων (Z , κυκλικός ή σπειροειδής) .

Συμπέρασμα: προεγχειρητικά ανατομικά χαρακτηριστικά μελετημένα με CTA όπως η γωνίωση και η αθηρωμάτωση των λαγονίων και oversizing μπόρουν να χρησιμευσουν ως προγνωστικοί παράγοντες για πιθανή απόφραξη του σκέλους , ενω η επιλογή του κατάλληλου τύπου σκέλους και η αποφυγη κάλυψης της έσω λαγονίου με χρήση νεώτερων τεχνικών πιθανόν να ελαττώσουν την ποσόστωση αυτής της επιπλοκής.

Factors Predisposing to Endograft Limb Occlusion after Endovascular Aortic Repair

Mantas Georgios

Master of Science Thesis

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Abstract

Introduction: Abdominal Aortic Aneurysm is referred, the increase of the normal aortic diameter more than 50% , or diameter more than 30mm and occurs in 2-12% of 65 year old patients , specially men who are smokers. Surgical approach, open or endovascular, indicates in aortic diameter bigger than 5-5,5 cm. Endovascular AAAs Repair has better short-term results in comparison with open repair. In the other hand, increased rate of reoperations has been mentioned. The aim of this study was to be sawn the increased rate of complications, such as limp occlusion and to investigate risk factors for endograft limb occlusion after endovascular abdominal aneurysm repair (EVAR).

Material and Methods: A study of the international literature took part regarding trials investigating limb thrombosis after EVAR. Afterwards a comparison was done among these trials and a retrospective study that took part at the vascular department of University of Athens , which included data of all patients presenting with endograft limb occlusion after elective EVAR between January 2010 and June 2013. Along with

demographics – medical history, we investigated the impact of atherosclerotic risk factors, anatomic characteristics of the aneurysm, controlled with Computed Tomography Angiography -CTA.

Results: after a careful study of 24 published trials regarding limb occlusion after EVAR , we conclude that this complication isn't rare , with a rate about 4%, and the risk factors that seems to predispose to that are narrowed , angulated , atherosclerotic common iliac arteries , with precedence of endoluminal thrombus. Apart from that, internal iliac arteries embolization or being covered, endograft oversizing and the stent type (Z , circle or spiral) seem to be important.

Conclusions: The presence of significant angulation and calcification of the iliac arteries as well as excessive limb oversizing, based on procedural CTA control , may be risk factors for endograft limb occlusion after EVAR, whereas graft proper choice and avoiding of covering-embolization of internal iliac arteries with the use of new endovascular techniques may decrease the rate of ELO.

Prologue

My first approach of Vascular and Endovascular Surgery was at 2007 as a register in General Surgery at 401 Military Hospital. I took part in many Endovascular procedures since then and especially during my registry at the Vascular Department of Athens medical School in the head of Professor Ch. Liapis. After a 6 year study I realized that no technique is uncomplicated and a careful study of the risk factors may lead us to better results. In that point

, I would like to thank Professor Ch.Liapis , who urged me to investigated the risk factors that may are responsible for limb occlusion, and the rest of consultants and registers of the department that helped me collecting data and analyzing them, especially MD Constantinos Antonopoulos

Contents

Introduction

Abdominal Aortic Aneurysm is referred, the increase of the normal aortic diameter more than 50%, or diameter more than 30mm and occurs in 2-12% of 65 year old patients, specially men who are smokers. Surgical approach, open or endovascular, indicates in aortic diameter bigger than 5-5,5 cm.

Endovascular abdominal aneurysm repair (EVAR) has been widely used for the treatment of patients with infrarenal abdominal aortic aneurysms (AAAs). EVAR is considered to have fewer short-term complications than open reconstruction of AAAs. However, long-term durability of the technique is probably limited by the high incidence of late complications requiring re-intervention.

A well-known risk after EVAR is endograft limb occlusion, especially in complex iliac anatomy. It occurs in 2.6-7.4% of patients during follow-up and usually requires intervention to restore limb perfusion.

Several anatomical risk factors predisposing to limb thrombosis have been proposed, including common iliac artery diameter, calcification, angulation, and the presence of thrombus, whereas procedure related risk factors for limb thrombosis include endograft oversizing, type of stent and extension to the external iliac artery, whereas no significant association between the type of the endograft and limb thrombosis was proved.

After limb thrombosis, symptoms may necessitate additional interventions, including endovascular and direct surgical revascularization. These interventions have associated morbidity and often necessitate re-hospitalization. Much has been written on the treatment of graft limb thrombosis, but little regarding its prevention

The aim of this study was to present the experience with endograft limb thrombosis in order to identify potential anatomical and procedure related risk factors so as to avoid this complication.

MATERIALS AND METHODS

We performed a systematic review of the international literature between 2000-2014, at PUBMED system using as keywords: EVAR, limb occlusion, limb thrombosis, limb kinking, EVAR complication. There were 367 results and finally we concluded to 24 articles according limb thrombosis after EVAR that refer to possible causes of this complication. Patients presenting with ruptured or isolated iliac aneurysms or with a history of previous aortic surgery were excluded. We studied each study and located the possible risk factors that were referred.

Pre-operative factors extracted from patients' medical records included age, gender, commercial endograft type atherosclerotic risk factors (coronary artery disease; CAD, hyperlipidemia, hypertension, diabetes mellitus; DM, smoking), antiplatelet therapy at discharge (single, dual or other), preoperative maximum aneurysm diameter (cm), vascular access during EVAR indicating the side used to deliver the main body of bifurcated prostheses (right, left), pre-operative neck characteristics (length, diameter, angle $>45^{o}$, calcification > 50% of the circumference, presence of luminal thrombus > 50%) and preoperative characteristics of common iliac artery, ipsilateral to endograft limb occlusion (diameter, length, angle $> 60^{o}$, calcification > 50%, endograft limb oversizing > 15%,

extension to the external iliac artery). Post-operative follow up time was also considered as a potential confounder and an additional multivariate analysis was also performed in many studies.

Diameter and length measurements were performed with the use of a center lumen line. All diameters were measured from outer-wall to outer-wall. Aortic neck diameters were measured at the level of the lower border of the most distal renal artery and every 5 mm from this level until the start of the aneurysm. The calcification and thrombus in the aortic neck were measured at 10 mm below the most distal renal artery and were visually quantified and classified into groups of <25%, 25% to 50%, 50% to 75%, and >75% of the aortic circumference lined by thrombus or calcification. The aortic suprarenal and infrarenal neck angulations and AAA volumes were measured according to earlier published protocols. Diameters of the common iliac arteries were measured 1, 3, and 5 cm distally of the aortic bifurcation, and the diameters in the external iliac arteries were measured 1 cm distally of the iliac bifurcation.

Afterwards, there was a comparison among results of these reviewed studies and a prospective control match 1:3 study that took place at our department (Vascular Department- Athens MED School).

Between January 2010 and June 2013, 439 patients underwent elective EVAR for AAA using bifurcated endografts. All patients were treated with commercially available bifurcated endografts (n = 439): Gore Excluder (n = 139), Cook Zenith (n=155), Vascutek Anaconda (n=111), and Medtronic Endurant (n=34). All four types of these commercially available endografts were used according to their instructions for use, based on anatomical criteria and the surgeon's preference. A review of prospectively collected data for all consecutive patients presenting with endograft limb occlusion after elective EVAR for infrarenal AAA repair

was performed. Patients presenting with ruptured or isolated iliac aneurysms or with a history of previous aortic surgery were excluded. Each patient with endograft limb occlusion (case) was matched for sex, age, and commercial type of endograft used to three patients having EVAR and no endograft limb occlusion (controls). Cumulative random sampling of controls was carried out, in which the controls were automatically matched on age (within 3 years), gender, and type of endograft with cases in the entire cohort of patients. In the next step, the fixed number (3) of control subjects for each case was randomly selected. Increasing the number of controls above the number of cases may be a cost effective way of improving the study. The number of controls for each case was increased to three in order to improve the chance of detecting important differences.

All procedures were performed in the operating theater using a C-arm with angiographic and road mapping capabilities (Philips BV Pulsera). All endovascular grafts were deployed below the renal arteries, whereas endograft limbs were deployed with a distal sealing zone in the common or external iliac artery, depending on the extent of the aneurysm. Balloon dilatation of the entire length of the endograft, and completion angiography assessing graft position and function was performed routinely without stiff wires in place in order to detect limb kinking that might predispose to thrombosis. At discharge, antiplatelet medication was prescribed to all patients. The follow up protocol included: history, physical examination and 1 mm slice computed tomographic angiography (CTA) scan with intravenous contrast at 30 days and 12 months post procedure and color duplex ultrasound yearly thereafter.

Continuous data were reported as mean ` SD. Distribution of categorical study characteristics was reported as percentage among cases and controls. Standard statistical procedures (non-parametric chi-square distribution and

Student's t-test with corresponding p values) were used to assess differences in categorical and continuous study variables among cases and controls, respectively. Univariate logistic regression analysis was performed to derive crude odds ratios (ORs) and 95% confidence intervals (95% CIs) for study variables among cases and controls from 2 -2 tables. Furthermore, multivariate logistic regression analysis and conditional logistic regression analysis for 1:3 matched pairs were modeled, to derive adjusted ORs with 95% CIs using patients with endograft limb occlusion as cases and patients with EVAR and patent endograft limbs as controls (dependent variable) and significant covariates in univariate analysis as predictor variables. All analyses were performed using STATA version 11 (STATA Corp., TX, USA).

Results

Matched control analysis resulted to a total of 18 patients (4%) with a mean age of 71.3 +- 5.8 years presented with endograft limb occlusion. The occlusion rate per commercially available endograft used was 2.2% (3/139) for Gore Excluder, 5.8% (9/155) for Cook Zenith, 2.7% (3/111) for Vascutek Anaconda, and 8.8% (3/34) for Medtronic Endurant. No statistical significance for occlusion rate was observed after all possible comparisons among the different types of endografts (all $p > .05$). The 18 patients with endograft limb occlusion and 54 age, sex, and type of endograft matched controls were included in the study. There was one case of limb occlusion during the first post-operative week, two cases of endograft limb occlusion between the first and the fourth post-operative week, while in the remaining 15 cases (83%) limb occlusion occurred after 2e34 months. Diagnosis was based on clinical examination and imaging findings from color duplex ultrasound and CTA. Seven of the 18 patients

(39%) with endograft limb occlusion presented with symptoms of acute limb ischemia and were treated as an emergency, whereas the remaining 11 patients presented with symptoms of buttock or leg claudication and were treated electively by femoral-femoral bypass. Thrombectomy was attempted in all seven patients who presented with acute limb occlusion. However, in three it was impossible to advance the catheter into the thrombosed endograft limb so they were treated by femoral-femoral bypass. As a result, in 14 cases (78%) limb reperfusion was achieved with a femoral-femoral bypass. In the remaining four patients, limb thrombectomy and 64 stenting with balloon angioplasty was successful. Lower limb perfusion was restored in all cases. During the 2-30 month follow up period after reoperation, one patient died from thoracic aortic aneurysm rupture, two patients with a previous femoral-femoral bypass required re-intervention with axillo-femoral bypass, and the rest remained free of symptoms. Statistically significant agreement was recorded between the two independent observers (k 1⁄4 0.65, $p < .01$) regarding the morphologic analysis and the pre-operative AAA measurements.

Table 1 presents differences among cases and controls with respect to the variables studied. No statistically significant differences were observed regarding demographic characteristics (matched variables), atherosclerotic risk factors, antiplatelet therapy, access side, pre-operative maximum aneurysm diameter and pre-operative neck characteristics. In only two patients (1 case and 1 control) was there significant thrombus in the common iliac arteries. Statistically significant differences were observed in the pre-operative characteristics of the common iliac artery ipsilateral to the occluded endograft limb, including angle $>60^{o}$ (50% vs. 14.8%; $p = .002$), calcification >50% (44.4% vs. 13%; $p= .004$) and endograft limb oversizing >15% (83.3% vs. 48.1%; $p = .01$), respectively. Common iliac artery angulation was evident in the post-operative CTA, but not in the

intra-operative final digital subtraction angiogram (DSA) in one patient.

Results of univariate analysis for endograft limb occlusion by study covariates are presented in Table 2. An angle >60^{o} (OR = 5.75, 95% CI = 1.75-18.91; p = 0.004), calcification > 50% (OR = 5.37, 95% CI = 1.58-18.24; p= .007) and endograft limb oversizing >15% (OR = 5.38, 95% CI = 1.39-20.76; p = .01) of the ipsilateral common iliac artery increased the risk for endograft limb occlusion. The significance of the findings remained robust in the conditional (matched pair case control) regression analysis (Table 3). More specifically, endograft limb occlusion was associated with angle >60^{o} (OR = 5.76, 95% CI = 1.24-26.74; p =.03), calcification >50% (OR = 5.87, 95% CI = 1.10-31.32; p = .04) and endograft limb oversizing > 15% (OR =5.54, 95% CI = 1.11-27.60; p = .04) of the common iliac artery, ipsilateral to endograft limb occlusion. Time since operation did not prove to be a significant covariate (OR = 1.04, 95% CI = 0.96-1.09).

Johan Mertens et al run a study of 143 patients that had EVAR with COOK Zenith endograft and concluded that the interrupted stent design of the Zenith device is thought to be associated with a higher risk of iliac limb kinking, stenosis, or occlusion. Iliac limb stenosis occurred in three patients (2.1%) in this series and occlusion in eight (5.6%). Most iliac limb occlusions occurred shortly after the EVAR procedure, which has been reported previously. Most of these complications related to the graft limb occurred in patients treated with the earlier generation of the device during the first 2 years of the treatment period. In the later stages, these iliac graft limb-related complications were prevented by more careful patient selection and the preferable use of other endografts in the treatment of patients with tortuous or narrow iliac arteries.

Jasper W. van Keulen, et al run a study of 100 patients that had EVAR

with Medronic Endurant endograft and mentioned 3 patients with ELO at follow up.

Alfio Carroccio, et al run a study of 702 patients that had EVAR and reported that twenty-six of 702 limbs (3.7%) had an occlusion develop. The risk of limb thrombosis was associated with a smaller limb diameter. Mean graft limb diameter was 14 mm in the occluded population, and patent limbs had a mean diameter of 16 mm. Thrombosis occurred in 16 of 291 limbs (5.5%) that were 14 mm or less and in 10 of 411 limbs (2.4%) that were greater than 14 mm (P = .03). Extension of a graft to the external iliac artery was performed in 96 of the 702 limbs. Eight of these 96 limbs (8.3%) had thrombosis develop as compared with 18 of 606 (3.0%) that extended to the common iliac artery (P = .01). No significant association was present between limb thrombosis and the contralateral or ipsilateral side of a device, the configuration of the iliac graft limb end (closed web, open web, or bare spring), or the degree of iliac graft limb oversizing. AneuRx, Ancure, Vanguard, and Talent grafts each sustained limb occlusions, with no occlusions seen among the Gore and Teramed devices. No significant increased risk of graft limb thrombosis was observed in unsupported grafts (1/16; 6.3%) versus supported grafts (25/686; 3.6%; P = not significant).

Nayan Sivamurthy, et al studied 248 cases treated with a COOK Zenith endograft and divided them to 2 groups : those that had initially a bare metal stent at the iliac arteries and those that hadn't. There were 13 instances of limb thrombosis in 13 patients (5.2% of patients, 2.7% of limbs), all in the un-stented group. No limb occlusions occurred in the presence of adjunctive bare metal stents. Seventy-three percent of the occlusions occurred <6 months of endovascular AAA repair.

Thomas R. Wyss et al 217 study indicated that Increased neck angulation

and calcification and common iliac thrombus and tortuosity are associated with higher rates of graft-related complications after EVAR. Increased neck thrombus and common iliac calcification appear to protect against complications. Adjusted hazard ratios (95% confidence intervals, *P* values) for complications per unit increase of variable were 0.96 (0.92-0.99, 0.018) for neck thrombus, 1.06 (1.00-1.12, 0.044) for neck calcification, 1.02 (1.00-1.05, 0.079) for neck angulation, 1.04 (1.01-1.06, 0.011) for common iliac thrombus, 0.96 (0.93-1.00, 0.033) for common iliac calcification, and 5.96 (1.53-23.28, 0.010) for common iliac tortuosity.

Frederico Bastos Gonçalves, et al studied 179 patients undergone EVAR with GORE Excluder endograft and reported 2 limb occlusions.

Laura van Zeggeren, MD et colleagues studied Data of consecutive patients treated with the Endurant from December 2007 to April 2012. Included were 496 patients (87.7% male), who were a median age of 74 years (range, 68-78 years). Median follow-up was 1.7 years (range, 0-4.6 years). Twenty graft occlusions (4.0%) occurred during follow-up. Median time between primary EVAR and detection of the occlusion was 1 month, with 55% occurring > 60 postoperative days and 90% >1 year. No association was found between occlusion and sex (P = .28), age (P = .96), or use of an aorto-uniiliac device (P = .66). Technical error was the considered cause of the occlusion in 12 patients (60%). As a result technical error may be consider also as an important risk factor.

F. Cochennec et al in a study of 460 patients undergone EVAR mentioned that 36 limbs in 33 patients (7.2%) were occluded. Multivariate logistic regression showed that kinking (odds ratio [OR] 11.9; confidence interval [CI] 3.39-42.1; p=0.0001), first graft generation (OR 2.87; CI 1.25-6.62; p=0.017) and younger age (OR 1.05; CI 1.00-1.09; p = .034) were independently related to the occurrence of graft limb occlusion. Statistical

analysis failed to show any significant association with clinical presentation of the aneurysm (symptomatic or asymptomatic), existence of thrombus in the infra renal neck, maximal transverse diameter of the aneurysm, diameter of the infra-renal neck and iliac anatomy pattern.

The Prospective European Trial of the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair (E.V. Rouwet, et al) early results showed 3 limb occlusions in an amount of 80 patients, whereas ENGAGED trial studied 1262 patient that had EVAR with the same graft included occlusion of one of the iliac limbs was reported in 23 patients (2.0%) and graft stenosis was detected in 16 (1.4%). Stent graft kinking occurred in 20 (1.7%) cases. The reports indicate distal iliac fixation site diameter <8 mm at 1.5% (19/1262) of patients.

Stephen O'Neill et al published a case report indicating the importance of the diameter of distal aorta and the possible connection with limb thrombosis.

Victor Z. Erzurum et al run a study of 823 patients that had EVAR resulted in 25 ELOs in 22 patients. ELO was significantly more common in the unsupported unibody graft design ($P < .024$) and with extension of the graft limb to the external iliac artery ($P < .001$). There were significant differences in the occurrence of ELO in various graft designs ($P = .024$; degrees of freedom, 6) . ELO in the Ancure graft was most common, occurring in 5.12% of limbs. Among grafts with ELO, the common iliac artery was used as a landing zone for endograft limbs in 17 of 25 (68%) whereas the limb extended to the external iliac artery in 8 of 25 limbs (32%). Among all grafts with a landing zone in an iliac artery, 106 of 1620 (6.5%) were extended to the external iliac artery. Thus, extension to the external iliac artery was significantly more common in limbs that ultimately presented with ELO ($P = .001$). Mean limb diameter was 14.6 - 2.1

mm, with 12 of 25 limbs (48%) having diameters less than 14 mm.

Lastly Maleux G et al study (288 patient undergone EVAR) indicated that Underlying causes of occlusion were kinking of the stent-graft (n = 5), small-diameter endograft limb with extension to the external iliac artery (n = 3), and migration and dislocation of an endograft limb (n = 2).

Discuss

A case-control design was used for the first time in order to investigate AAA characteristics which can be easily detected in the preoperative CTA and predispose to postoperative endograft limb occlusion. Our results suggested that angle ≥60˚, calcification ≥50% and endograft limb oversizing ≥15% of the ipsilateral common iliac artery may be presented with a more than 5-times higher risk for endograft limb occlusion. On the contrary, extension of endograft to the external iliac artery did not prove to be a significant factor. This was not in line with some of the previous studies, recognizing endograft extension to the external iliac artery as risk factor for limb thrombosis.. All the other factors investigated in our study, including medical history, preoperative maximum aneurysm diameter (cm), preoperative neck characteristics, and access site, antiplatelet therapy did not seem to have any impact on endograft limb thrombosis. It's important to comment that some reports and analysis indicate neck atherosclerosis and angulation also as possible causes.

The anatomic characteristics of the aorta and the iliac arteries must be carefully assessed when planning EVAR. Aortic bifurcation accommodates both limbs of the endograft. Mature thrombus or atherosclerotic disease can cause a narrow distal aortic lumen. In these

situations a small or rigid calcific distal aorta predisposes to limb kinking or thrombosis. EVAR in patients with anatomical characteristics of common iliac arteries that are outside the instructions for use (IFU) – technical errors, may be important risk factors for endograft limb compression and/or kinking and thrombosis. Among these characteristics, severe iliac artery angulation and /or tortuosity has been linked with early kink development. Kinking of the endograft limb may not be visualized when the completion angiography is performed with the stiff wire in place. As a result, it is recommended that final angiography should be performed without stiff wires. It has been our practice to perform final angiography without stiff wires, in order to recognize limb-kinking predisposing to thrombosis.

Patients included in this study were treated using four types of endografts. We did not observe a statistical significance on the incidence of limb thrombosis between the different types of endografts. However, some characteristics of the endograft may be associated with limb thrombosis. The main graft-related cause of limb occlusion is lack of support within the structure of the endograft. Occurrence of limb occlusion in the Ancure graft has been described several times. During the short-term follow-up, an unsupported graft will require a re-intervention because of kinking 15 times more often than a supported one. We have recognized excessive iliac oversizing as a predisposing factor for limb thrombosis in our study. It seems that excessive oversizing of the endograft may lead to enfolding of the endograft limb into the vessel lumen. This is also supported by the fact that oversizing of an iliac limb by 4 mm led to a 12-fold increase in graft limb dysfunction. Graft enfolding is more likely to occur in an unsupported graft due to its lack of radial force.
Lastly the stent type of the limb graft is worth to be mentioned. Oldest types of extension have biggest rate of occlusion, also ‘z’ stent seem to be

thrombosed easier than spiral.
Even if we had been able to stratify risk according the findings of high-quality preoperative and intraoperative imaging, it is possible that other tests would still be needed to further refine patient selection. Pullback pressure measurements, for example, can help identify hemo-dynamically significant lesions, but they are relatively insensitive, even after flow through the femoral arteries has been restored. Ultrasound may be more sensitive, but the test is expensive, time consuming, and of un- known predictive value.

The current routine follow-up regimen appeared to play little role in the prevention of limb thrombosis. We identified and treated only two cases of impending limb thrombosis, both in already-stented patients. The explanation may lie in the timing of routine follow-up. Most cases of graft thrombosis occurred <6 months of stent-graft insertion, during which time the patients underwent routine imaging only once at 1 month

Limited experience and lack of long-term follow up makes decision for optimal treatment of endograft limb thrombosis difficult. However, there are surgical and endovascular options. Surgical options include thrombembolectomy and extra-anatomic bypass graft. There are however concerns about the possibility of graft damage or dislodgment and endoleak. On the other hand, this argument was not validated by a series in which no endoleak or graft dislodgement occurred despite using thrombembolectoy in modular graft designs. Earlier experience tended towards extra-anatomic bypass, mainly femoral-femoral bypass. Endovascular options include thrombolysis and balloon angioplasty or stenting and recent reports have encouraged an endovascular approach with or without thrombolysis. In our experience, the majority of patients presented with a delayed (more than 15 days) limb thrombosis was treated

with a femoro-femoral bypass. In cases of early occlusion, endograft limb thrombectomy was initially performed and there after a stent placement was decided. During the follow-up period two patients required re-intervention and were treated with an axillo-femoral bypass graft.

Conclusion

Endograft limb thrombosis occurred in 4.1% of the patients who underwent EVAR in our department. The presence of significant angulation and calcification of the iliac arteries as well as excessive limb oversizing may be risk factors for endograft limb occlusion. In the other hand proximal neck angulation, atherosclerosis, extension to the external iliac arteries the support of the endograft and the type of the limb extension stent seems to be important. Therefore all these factors may be consider preoperatively so as to reduce the rate of ELO.

Tables

Table 1. Distribution of 18 cases with endograft limb occlusion and 54 age-, sex- and –type of endograft matched controls by risk factors

	Cases (n=18)		Controls (n=54)		p value
Categorical Variables	n	%	n	%	
Males	18	100.0	54	100.0	Matched Variable
Graft type					Matched Variable
Gore Excluder	3	16.7	9	16.7	
Cook Zenith	9	50.0	27	50.0	
Vascutek Anaconda	3	16.7	9	16.7	
Medtronic Endurant	3	16.7	9	16.7	
Coronary Artery Disease	5	27.8	22	40.7	0.41
Hyperlipidemia	12	66.7	28	51.9	0.27
Hypertension	14	77.8	47	87.0	0.45
Diabetes Mellitus	3	16.7	10	18.5	0.99
Smoking	7	38.9	17	31.5	0.56
Antiplatelet therapy					0.43
Single	13	72.2	36	66.7	
Dual	2	11.1	12	22.2	
Other	3	16.7	5	9.3	
Right Access	17	94.4	44	81.5	0.27
Preoperative neck characteristics					
Angle ≥45˚	3	16.7	9	16.7	0.99
Calcification ≥50%	1	5.6	5	9.3	0.99
Thrombus ≥50%	3	16.7	21	38.9	0.15
Characteristics of common iliac artery, ipsilateral to endograft limb occlusion					
Angle ≥60˚	9	50.0	8	14.8	0.002
Calcification ≥50%	8	44.4	7	13.0	0.004
Endograft limb oversizing≥15%	15	83.3	26	48.1	0.01
Extension to External Iliac Artery	4	22.2	7	13.0	0.45
Continuous Variables	Mean	SD	Mean	SD	p value
Age	71.33	5.77	71.67	5.43	Matched Variable
Preoperative maximum aneurysm diameter (cm)	5.54	1.16	5.51	0.80	0.89
Preoperative neck characteristics					
Length (cm)	2.42	1.46	2.41	1.04	0.96
Diameter (cm)	2.35	0.64	2.43	0.33	0.49
Characteristics of common iliac artery, ipsilateral to endograft limb occlusion					
Diameter (cm)	1.61	0.47	1.65	0.66	0.80
Length (cm)	5.47	1.05	5.63	1.30	0.64

Table 2. Univariate logistic regression–derived ORs and 95% CIs for endograft limb occlusion controlling by study covariates

		Univariate Logistic Regression Analysis	
Variable	Category or increment	OR (95%CI)	p value
Access	Right vs. Left	0.26 (0.31 - 2.18)	0.21
Coronary Artery Disease	Yes vs. No	0.56 (0.17 - 1.79)	0.33
Hyperlipidemia	Yes vs. No	1.86 (0.61 - 5.67)	0.28
Hypertension	Yes vs. No	0.52 (0.13 - 2.04)	0.35
Diabetes Mellitus	Yes vs. No	0.88 (0.21 - 3.63)	0.86
Smoking	Yes vs. No	1.39 (0.46 – 4.20)	0.56
Antiplatelet therapy	1 Level more	1.06 (0.49 - 2.30)	0.88
Preoperative maximum aneurysm diameter (cm)	1 SD among controls	1.04 (0.57 - 1.90)	0.89
Preoperative Neck characteristics			
Angle	≥45˚ vs. <45˚	1.00 (0.24 - 4.18)	0.99
Calcification	≥50% vs. <50%	0.58 (0.06 - 5.29)	0.63
Thrombus	≥50% vs. <50%	0.31 (0.08 - 1.21)	0.10
Length (cm)	1 SD among controls	1.01 (0.64 - 1.61)	0.96
Diameter (cm)	1 SD among controls	0.66 (0.20 - 2.17)	0.50
Characteristics of common iliac artery, ipsilateral to endograft limb occlusion			
Diameter (cm)	1 SD among controls	0.88 (0.34 - 2.27)	0.80
Angle	>60˚ vs. <60˚	5.75 (1.75 - 18.91)	0.004
Calcification	≥50% vs. <50%	5.37 (1.58 - 18.24)	0.007
Length (cm)	1 SD among controls	0.90 (0.58 - 1.40)	0.63
Endograft limb oversizing	≥15% vs. <15%	5.38 (1.39 - 20.76)	0.01
Extension to External Iliac Artery	Yes vs. No	1.91 (0.49 - 7.52)	0.35

Table 3. Multivariate logistic regression and Conditional logistic regression (matched pair case-control) - derived ORs and 95% CIs for endograft limb occlusion controlling for significant study covariates

		Multivariate		Matched-pair Case-Control	
Characteristics of common iliac artery, ipsilateral to endograft limb occlusion	Category or increment	OR (95%CI)	p value	OR (95%CI)	p value
Angle	≥60˚ vs. <60˚	6.38 (1.57 - 25.93)	0.01	5.76 (1.24 - 26.74)	0.03
Calcification	≥50% vs. <50%	4.53 (1.11 - 18.43)	0.04	5.87 (1.10 - 31.32)	0.04
Endograft limb oversizing	≥15% vs. <15%	6.89 (1.46 - 32.59)	0.02	5.54 (1.11 - 27.60)	0.04

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