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Late Open Surgical Conversion after Endovascular Abdominal Aortic Aneurysm Repair

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WHAT THIS PAPER ADDS

Late open surgical conversion following endovascular aneurysm repair is associated with significant morbidity and mortality. Although endograft preservation may be preferentially offered as a less invasive alternative to high risk patients requiring open surgical conversion, significant mortality was identified with this procedure. Adherence to device instructions for use (IFU) is markedly lower among EVARs requiring open surgical conversion than uncomplicated cases. There was a trend for decreasing interval to conversion; an association with liberalisation of EVAR outside of IFU is possible, but cannot be concluded from this study.

Introduction: Late open surgical conversion following endovascular aneurysm repair (EVAR) may occur more frequently after performing EVAR in anatomy outside the instructions for use (IFU). This study reviews predictors and outcomes of late open surgical conversion for failed EVAR.

Methods: This retrospective cohort study reviewed all EVARs performed at the Ottawa Hospital between January 1999 and May 2015. Open surgical conversions >1 month post EVAR were identified. Variables analysed included indication for conversion, pre-intervention AAA anatomy, endovascular device and configuration, operative technique, re-interventions, complications, and death.

Results: Of 1060 consecutive EVARs performed, 16 required late open surgical conversion. Endografts implanted were Medtronic Talent (8.50.0%), Medtronic Endurant (3.18.8%), Cook Zenith (4.25.0%), and Terumo Anaconda (1.6.2%). Eleven grafts were bifurcated (68.8%), five were aorto-uni-iliac (31.2%). The median time to open surgical conversion was 3.1 (IQR 1.0–5.2) years. There was no significant difference in pre-EVAR rupture status (1.4% elective, 2.1% ruptured, $p = .54$). Indications for conversion included: Type 1 endoleak with sac expansion ($n = 4$, 25.0%), Type 2 endoleak with expansion ($n = 2$, 12.5%), migration ($n = 3$, 18.8%), sac expansion without endoleak ($n = 2$, 12.5%), graft infection ($n = 3$, 18.8%), rupture ($n = 2$, 12.5%). Nine patients (56.2%) underwent stent graft explantation with *in situ* surgical graft reconstruction, seven had endograft preserving open surgical intervention. The 30 day mortality was 18.8% ($n = 3$, all of whom having had endograft preservation). Ten patients (62.5%) suffered major in hospital complications. One patient (6.5%) required post-conversion major surgical re-intervention. IFU adherence during initial EVAR was 43.8%, versus 79.0% ($p < .01$) among uncomplicated EVARs.

Conclusions: Open surgical conversion following EVAR results in significant morbidity and mortality. IFU adherence of EVARs later requiring open surgical conversion is markedly low. More data are required to elucidate the impact of increasing liberalisation of EVAR outside of IFU.

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INTRODUCTION

Endovascular aneurysm repair (EVAR) has steadily increased in popularity since its introduction two decades ago, and is now a well established treatment for abdominal aortic aneurysms (AAAs). Many reports have clearly demonstrated lower morbidity and 30 day mortality rates than open surgical repair,[1–4] although randomised control trials have not demonstrated long-term survival benefit.[3,4] Despite this, EVAR utilisation continues to rise and is becoming the intervention of choice for most patients with AAAs.[5,6] EVAR is being applied liberally to low and high risk populations, as well as patients presenting with anatomy outside instructions for use (IFU) guidelines.[7]

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The long-term success of EVAR is of concern, and requires long-term surveillance for complications that may arise as a result of inadequate sac exclusion by the endovascular stent graft device. Typically, the majority of problems can be addressed with secondary endovascular interventions, required in 9–15% of patients.[8–10] Late open surgical conversion following EVAR is a last resort, reserved to treat complications refractory to endovascular re-intervention; this is of particular relevance in those high risk patients who were deemed ineligible for open repair at the time of initial EVAR.

With increasing and wider application of EVAR, now including patients outside IFU, the number of complications requiring re-interventions and open surgical conversion is increasing.[7] The incidence of open surgical conversions is reported to range from 0 to 9% in various EVAR studies, with risk increasing over time.[8–12] The mortality rates of these conversions are remarkably high, ranging from 20–40%.[11–15] Worse outcomes occur with post-EVAR rupture and graft infection,[11,15,16] whereas elective open conversions are associated with mortality rates similar to primary open repair.[3,4,17]

With growing understanding of EVAR, operators are more often stepping outside device IFU to enable treatment for a larger patient population. Growing evidence suggests that this approach may have detrimental short- and long-term effects.[7,18–21] To mitigate these poor outcomes, it is important to explore the factors that may be leading to increased open surgical conversion, and to explore the morbidity and mortality rates of this procedure. Specifically, the relationship between operator adherence to device IFU and late open surgical conversion is not well studied.

The present study aimed to review the predictors and outcomes of late open surgical conversion for failed EVAR at the institution.

METHODS

The Ottawa Hospital is a tertiary care, university centre, which performs all AAA procedures in the local health integration network (LHIN). The Champlain LHIN is large, serving a population of 1.2 million people.[22] All AAAs presenting at peripheral centres are transferred to six vascular surgeons at the institution, all of whom perform EVAR. Turn down for ruptured AAA is less than 5%.

Ethics approval was obtained from the Ottawa Hospital Research before starting the study. Patient demographic data were obtained from the Division of Vascular Surgery's prospectively maintained database; custodians of this database are the division's research assistant and research nurse.

EVARs performed between January 1999 and May 2015 were reviewed. Patients that required open surgical conversion of previous EVAR more than 30 days after initial implantation were identified. The 30 day cutoff was selected as this excludes early complications of EVAR. The departmental database tracks all aortic procedures, endovascular and open, performed at the institution. Eligible cases were identified by searching the database for patients who first had EVAR followed by open surgical repair. For these patients, information from the division's database was supplemented by patient records from paper charts and the institution's electronic medical records (Telus vOacis 7.3.0, 2013), including those pertaining to hospital inpatient admissions, multidisciplinary team meetings, surgical consultations, clinical outpatient follow-ups, and surgical and radiological interventions. Furthermore, all imaging for these cases was reviewed (McKesson Radiology Imaging Software, Version 12.0, 2012. McKesson Corporation, New York, NY, USA) including pre- and post-operative imaging, as well as radiological reports.

Patients were included if they underwent an open surgical procedure involving complete or partial explantation of the endograft or open surgical modification (such as cerclage of the aortic sac around the endograft main body to treat a Type 1 endoleak, or ligation/clipping of lumbar vessels to treat a Type 2 endoleak). Endograft preservation was preferentially offered to patients with anatomy that would allow a simple ligation and/or cerclage, and was particularly considered in those for whom aortic clamping and explantation was prohibited as a result of their poor comorbid status. The depth of review was similar for open conversion cases and non-open conversion cases, except for the assessment of IFU criteria, which were retrospectively reviewed in more detail for the open conversion cases.

Data were collected on patient demographics (age, gender), diagnosis, initial EVAR date, EVAR type, EVAR device brand, pre-EVAR aneurysm diameter, indication of initial EVAR (elective vs. ruptured AAA), EVAR configuration (bifurcated, aorto-uni-iliac), number of EVAR components, EVAR device adjuncts (femoral–femoral bypass, ilio-femoral bypass, Palmaz stent [Johnson & Johnson Interventional Systems Co., Warren, NJ, USA]), intra-operative endoleak (type), IFU criteria (infrarenal neck angulation, neck length, neck calcification, neck thrombus, iliac tortuosity, iliac diameter), open surgical conversion date, indication for open surgical conversion, open surgical conversion technique (endograft preservation, explant), clamp position (supracoeliac, suprasuperior mesenteric, suprarenal, infrarenal), other open surgical conversion operative details, length of hospital stay, post-operative complications, intra-operative mortality, 30 day post-operative mortality, long-term post-operative mortality, and re-interventions post-operatively. The interval to open conversion was calculated as the time between initial EVAR and open surgical conversion. Major in hospital complications were defined as any life threatening sequelae following surgery or death. As a part of the EVAR surveillance program, all patients underwent ultrasound and computed tomography (CT) surveillance at 1, 6, 12, 18, 24 months, and annually thereafter. Over time, CT surveillance reduced, but regular ultrasound surveillance continued.

Adherence to endograft IFU was assessed by reviewing pre-EVAR axial CT images, as well as sagittal, coronal, and three dimensional reconstructions where available. IFU parameters were met if (a) infrarenal neck

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