Commentary

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Caution is Required when Considering Standard EVAR in AAA Patients with Anatomic IFU Violations

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Since its introduction in 1991 [1], endovascular aneurysm repair (EVAR) has replaced open techniques in most centers for the repair of infrarenal abdominal aortic aneurysms (AAAs) [2]. Over the years, many endovascular devices have appeared on the market with manufacturer specific instruction for use (IFU) guidelines in order to maximize short and long-term device performance. IFU parameters often include infrarenal neck angulation, neck diameter, neck length and iliac diameter and length.

Available randomized controlled trials (RCTs) evaluating long-term survival for infrarenal AAA have compared open surgical repair (OSR) to endovascular repair in patients with suitable aortic anatomy for EVAR and have shown an early survival advantage of EVAR over OSR [3]. All patients included in these trials met the individual device manufacturers' IFU with respect to anatomic criteria. However, in real world practice, patients who do not meet IFU criteria are often still treated by standard EVAR. According to the literature, IFU non-adherence is high, ranging from 39 to 69% [4-6] in published studies. In a publication evaluating patients undergoing EVAR at three vascular centres we have previously shown that 44% of patients undergoing EVAR had device specific IFU violations and that IFU violations were associated with device failure [6]. While these conclusions are supported by many studies in the current literature other studies have not shown a relationsip between IFU deviation and adverse outcomes.

For example, Schanzer et al identified a 41% rate of sac growth post-EVAR amongst patients who had deployments outside IFU [7] and Abbruzzese et al found a higher rate of graft related adverse events in a group of patients treated outside the IFU, particularly higher rates of limb thrombosis [4]. AbuRahma et al found IFU non-adherence to be associated with higher rates of early and late type Ia endoleaks, early reinterventions, and worse long-term survival [8]. In a systematic review of 16 observational studies, EVAR with hostile neck anatomy falling outside the IFU was associated with a higher risk of reinterventions and type Ia endoleaks [9].

In contrast to these studies which demonstrated an adverse relationship with EVAR outside IFU and outcomes, Lee et al in a single center review found non-IFU neck anatomy to have no impact on endoleaks, sac regression, migration and reinterventions after EVAR [10]. Similarly, Walker et al., in a multicenter registry with a median follow-up of 3 years, found that IFU non-adherence had no impact on mortality, aneurysm related mortality, sac growth, reinterventions or endoleaks [11]. Beckerman et al found only 31% of grafts were deployed within the IFU at their center, and that IFU adherence had no impact on early or late outcomes including mortality, reinterventions, and endoleaks [5].

The conflicting results are likely a result of several limitations in the published literature. Firstly, most of these studies have looked at isolated clinical endpoints with low event rates rather than composite endpoints thereby decreasing the likelihood of attaining statistical significance. Secondly, most studies suffer from short follow-up, with many limited to 3 years or less. This is particularly relevant as a recent publication about long-term results of the EVAR-1 trial have shown worse mortality in the EVAR group beyond 8 years, primarily related to an increased

rate of secondary aneurysm sac rupture [12]. The authors have suggested that the number of adverse outcomes could have been reduced if the follow up of these patients was better. It should be noted that all patients in the EVAR-1 trial had anatomy within EVAR IFU criteria, and one would assume that the effects of non-adherence to IFU would only increase these risks of long-term EVAR failure.

Many surgeons choose to push EVAR IFU limits to avoid performing a more invasive open or endovascular intervention despite some studies showing higher graft-related adverse events. This led to our recently published study evaluating the long-term survival of EVAR and OSR in patients with anatomy outside IFU criteria for EVAR [13]. Our multicentre retrospective cohort study included 426 patients with at least one anatomic IFU violation for EVAR undergoing either elective EVAR or elective OSR for AAA. Our survival analysis revealed a significant association between patients undergoing OSR and increased long term survival. Aneurysm related mortality was 3.5% in the EVAR group and 2.2% in the OSR group during long-term follow-up ($P < .001$). Our study identified that patients with IFU violations have higher overall long-term survival with open treatment compared to EVAR. It could be speculated that with longer follow up this difference in mortality would even increase since most complications from OSR repair occur early in follow up. Although we could not adjust for all differences between both groups, the results of this study certainly contribute to concerns regarding EVAR performed outside of IFU.

While further research is needed to confirm these results, caution should be applied when considering standard EVAR in a AAA patients with anatomic IFU violations. An alternative therapy such as OSR or complex endovascular treatment should be evaluated as a potential solution for those patients. Given this uncertainty, we feel that at the very least if patients are treated with EVAR outside IFU they warrant more intense and strict follow up until further study ca n clarify this issue.

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