International Cross-Sectional Survey on Management of Type II Endoleak and the Role of Preemptive Embolization

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Background: Type II endoleaks (TIIELs) commonly occur following endovascular aneurysm repair (EVAR). There is a lack of unified consensus regarding the management of TIIEL. Preemptive embolization is a potential method to reduce the risk for TIIEL, but its role is debated. We performed a survey among aortic experts internationally to assess perspectives on TIIEL management and the role of preemptive embolization.

Methods: A questionnaire was prepared covering aspects on effect of TIIEL on EVAR outcome, strategies to manage TIIEL, and attitudes toward preemptive embolization techniques. The questionnaire was distributed using an online platform among vascular specialists across 80 specialized aortic centers worldwide.

Results: Of 80 survey recipients, 56 (70%) responded. Only 12% of participants did not believe TIIEL to affect the durability of EVAR. Nearly 82.2% of respondents believed TIIEL increases the likelihood of reintervention. One-quarter agreed that TIIEL increases aortic-related mortality post-EVAR. For established TIIEL, 12% find "any sac expansion" to be an indication for intervention, while 41% would intervene at >5 mm sac expansion, and 52% at >10 mm sac expansion. Majority (63%) perform selective embolization in this setting. Only 3.6% of participants reported routinely conducting preemptive embolization in over 30% of their EVAR cases, while 42.9% never performed this procedure, and 53.6% performed preemptive embolization in <30% of cases. A substantial 76.8% believed that existing literature lacked sufficient evidence to support the integration of preemptive embolization into their clinical practice. Additionally, almost 90% expressed interest in participating in a multicenter randomized controlled trial evaluating the safety and efficacy of preemptive embolization.

Conclusion: Management of TIIEL is highly diverse among aortic experts. There is a need for further evidence on when and how to best treat TIIEL, as well as robust studies with long-term data to assess the potential role of preemptive embolization in increasing the durability of EVAR.

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INTRODUCTION

Endovascular aneurysm repair (EVAR) ushered in a new era in treating abdominal aortic aneurysm with its improved short-term morbidity and mortality, shorter hospital stays, and faster recovery.[1] Durability and reintervention rates remain the main concern with EVAR, particularly when addressing aneurysms in younger patient cohorts.[1] Type 2 endoleak (TIIEL) is common post-EVAR, occurring in 10–15% of patients,[2,3] affecting the need for follow-up post-EVAR as well as resulting in most reinterventions.[4,5] Whereas type I and type III endoleaks are clear indications for reintervention, reintervention for TIIEL is still a controversial topic. Currently, societal guidelines have different recommendations for when to intervene on TIIEL, with the European Society for Vascular Surgery guidelines promoting reintervention in case of sac growth >10 mm,[6] while the Society for Vascular Surgery guidelines recommend reintervention at >5 mm sac growth.[7]

The predominant origins of TIIEL are typically from the inferior mesenteric artery (IMA) and lumbar arteries (LAs).[8] The prospect of preemptive embolization of the aneurysm sac or the aforementioned vessels has been suggested as a potential remedy for the risks associated with persistent TIIEL. However, it is noteworthy that the majority of relevant studies are characterized by a single-center, retrospective cohort design, often with limited sample sizes, and some findings lack conclusive outcomes.[9–13] Two randomized trials that have reported on the outcome of preemptive embolization of the aneurysm sac[14] or the IMA.[15,16] While these trials point toward potential positive effect of preemptive coiling in terms of sac dynamics and occurrence of TIIEL, they do not confirm that preemptive embolization strategies, either of side branches or of the sac, increase the durability of EVAR.[17] Additionally, there is no formal health economic evaluation of the techniques. Therefore, the recent European Society for Vascular Surgery guidelines recommend against routine preemptive embolization for TIIEL prevention.[6]

Considering the above uncertainties regarding TIIEL management and prevention, we conducted a cross-sectional survey inviting international experts in aortic surgery. The aim was to assess specific attitudes toward TIIEL treatment and the role of preemptive embolization as a preventative measure.

METHOD

The study group reached out to 80 vascular specialists renowned for their expertise in the aortic field. They were identified based on prior publications in high rank vascular scientific journals and/or from international conference presentations on EVAR procedures, and/or among researchers serving on guidelines committees relevant to the study practice. To investigate only once the endorsed practices at each aortic center or vascular division and avoid the potential bias derived from duplicate responses, only one physician per institution was allowed to participate in the survey process.

The formulation of the questions was guided by variances delineated in multiple guidelines and contemporary publications.[6–11,13] Certain questions provided participants with the opportunity to select multiple answers.

The survey was distributed to participants using an online questionnaire platform (Google Forms: Online Form Creator | Google Workspace). The survey link was sent individually via group email, with reminders sent 2 weeks later to ensure comprehensive participation. Subsequently, study data were collected and analyzed within the same platform.

In addition to demographic inquiries, participants were presented with 14 multiple-choice questions, as presented in Supplementary Table 1.

RESULTS

Of the 80 survey recipients, 56 aortic experts from 20 countries responded, reflecting a response rate of 70%. Fifty-four respondents were vascular surgeons, 1 cardiovascular and thoracic surgeon, and 1 interventional radiologist. Academic institution-affiliated participants constituted 89.3% of the total respondents. The majority of participants conducted over 20 standard EVAR procedures annually (98%), with a notable portion reporting more than 50 cases per year (75%).

The vast majority (88%) of participants believe that TIIEL affects EVAR durability in some way (Fig. 1). The belief that TIIEL has the potential to increase the rate of reintervention is shared by 82.2% of participants. Additionally, 51.8% of participants believe that TIIEL promotes aneurysm sac growth. One-fourth of the experts perceived that TIIEL increases aortic-related mortality.

With regards to when to intervene on an established TIIEL, over half of participants (58.9%) concurred that TIIEL associated with aneurysm sac expansion jeopardizing the proximal and distal seal would be deemed a robust indication for intervention. Furthermore, a portion of participants (51.8%) believed that TIIEL with aneurysm sac expansion exceeding 10 mm from baseline

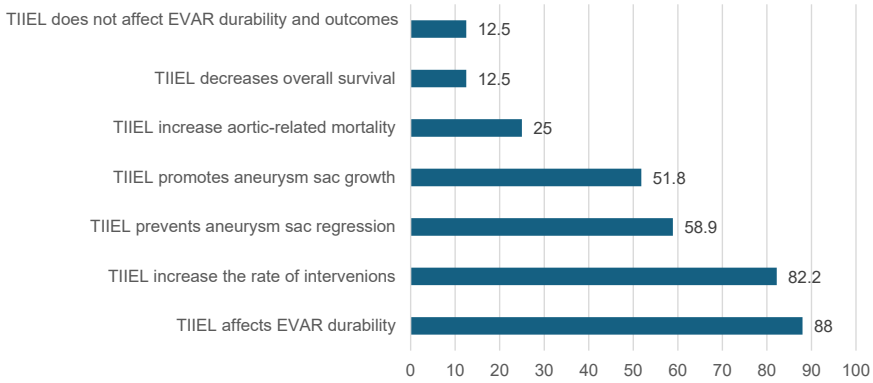

Fig. 1. Survey response to perception of type II endoleak (TIIEL) effect on durability and outcomes of endovascular aneurysm repair (EVAR). Percent respondent in each category is presented.

warranted intervention, whereas 41.1% regarded only 5 mm of sac expansion as a reasonable threshold. One in ten would intervene on any sac expansion, without a specific threshold.

Twenty-nine vascular surgeons (51.8%) conducted TIIEL embolization themselves, while 20 (35.7%) referred the cases to an interventional radiologist. The remainder (10.8%) stated that the procedure was conducted collaboratively between vascular surgeons and interventional radiologists, except for one participant who indicated that the procedure was not performed at their institution. Most participants (64.3%) favored a selective (transarterial) approach for embolization of IMA and LAs compared to other available approaches.

When queried about their preferred embolization material, the majority of participants (75%) favored using multiple materials during each session. The primary material chosen for initiating embolization was detachable coil/microcoil (46.4%), followed by nondetachable coil/microcoil (21.4%). Additionally, half of the participants selected Onyx (Medtronic, United States) as the preferred material for augmentation during the procedure.

With regards to preemptive intervention for prevention of TIIEL, only a minority of participants (3.6%) reported to have integrated such strategies into their routine practice. Approximately half (53.6%) of the respondents have employed it selectively, in less than 30% of their annual EVAR volume. Conversely, a substantial portion of participants (42.9%) have never performed preemptive embolization for TIIEL prevention (Fig. 2).

When asked about the persuasiveness of current literature to establish preemptive embolization as a routine method for TIIEL prevention, only a minority of participants (10.7%) expressed confidence in the existing literature to support its implementation in practice. Contrarily, the majority opined that current literature lacks conviction, indicating the need for further evidence before adopting such a strategy (Fig. 3). To strengthen this approach, 66.1% of participants designated the necessity of a randomized controlled trial (RCT) demonstrating a significant reduction in aneurysm sac growth compared to a control group. Furthermore, 48.2% and 23.2% of participants agreed that the preferred outcome measure in a study of preemptive embolization should be to assess reduction in late aortic deaths or overall mortality, respectively. Others expressed a desire for RCTs showcasing a reduction in reintervention for TIIEL (42.9%) and a decrease in the rate of TIIEL occurrence (28.6%). Notably, only one participant required an RCT demonstrating cost-effectiveness to endorse the implementation of this strategy.

To gain deeper insights from participants, we requested their input on criteria for implementing preemptive embolization in an RCT. A substantial majority (92.9%) of participants identified the diameter of the IMA or LAs as a reasonable criterion for inclusion in future trials. Additionally, over half (51.8%) also supported the consideration of the number of LAs as a potential criterion. Furthermore, a minority opted for the diameter of the aneurysm, aortic aneurysm thrombus load, and patients on anticoagulation as potential indications for inclusion in future studies (Fig. 4). Approximately, the same proportion of participants who opted for selective embolization for TIIEL treatment also favored the selective approach for preemptive embolization (55.4%) (Fig. 5). Over 89% of participants expressed interest in participating in an international RCT evaluating the safety and effectiveness of preemptive embolization for TIIEL prevention.

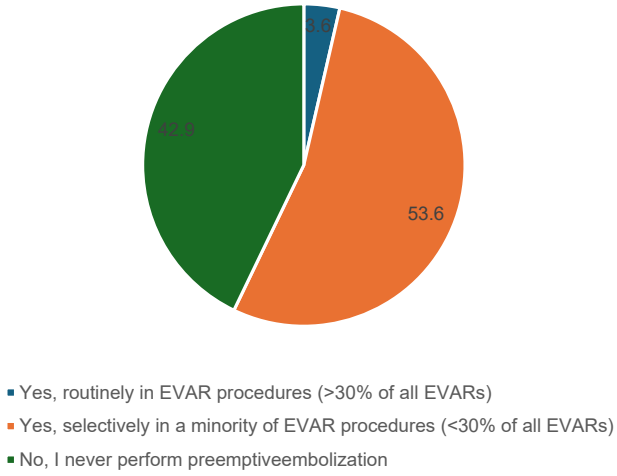

Fig. 2. Percentage of vascular specialists responding to the survey that performs preemptive embolization as a type II endoleak (TIIEL) prevention strategy.

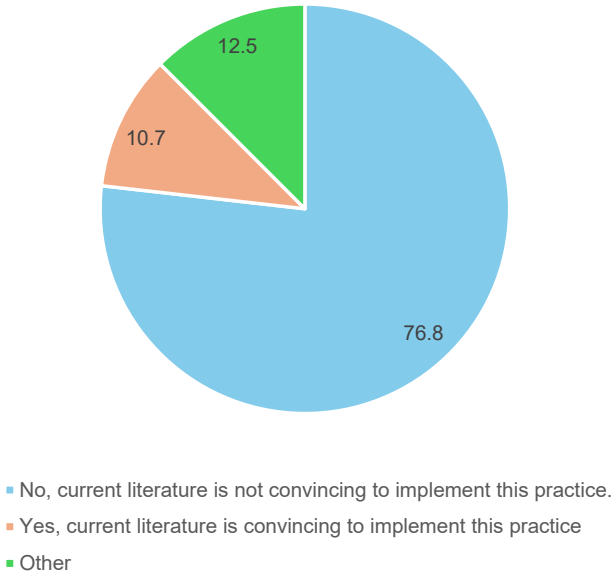

Fig. 3. Survey respondents' answer to ''Do you find the current literature convincing to establish preemptive embolization as a method that should be employed for prevention of type II endoleak.'' Percent respondent in each category is presented.

DISCUSSION

This survey underlines the diverse perspectives on TIIEL management and prevention among aortic experts internationally. Discrepancies in viewpoints regarding this matter are apparent throughout the literature.[9–11,13,15] For instance, no consensus exists regarding the threshold for change in diameter or duration of endoleak to warrant intervention.[6,7]

Most of the survey participants perceive persistent TIIEL as a long-term hazard after EVAR. Indeed, persistent TIIEL was associated with increased aneurysm related mortality as well as aneurysm rupture post-EVAR in a Japanese nationwide analysis reported by Seike et al. in 2022.[18] There are, however, different approaches to how TIIEL are managed and when intervention is performed within the expert group. The differences in responses may reflect the discrepancies between aortic guidelines. With regards to the method of reintervention for TIIEL, a variety of techniques are available, including transarterial selective embolization, translumbar or transperitoneal sac embolization, as well as more innovative techniques such as transcaval sac puncture or transgraft embolization. However, the clinical long-term success of TIIEL embolization is suboptimal, with one multicenter report suggesting a freedom from sac expansion of only 37% at 5 years after intervention for TIIEL.[19] Clearly, there is a need for further studies that support establishment of clear and accepted recommendations on when reintervention for TIIEL is indicated and how to perform this successfully.

Preemptive embolization could be a potentially interesting alternative to mitigate TIIEL.[15,20–23] Whether this translates into a notable clinical impact capable of reducing aneurysm-related mortality and enhancing survival remains uncertain. Interestingly, half of the respondents in this survey reported to perform preemptive embolization in a minority of EVAR cases, while 43% never performed this procedure, underlining the heterogeneity in current practice. The majority of the available evidence in this field stems from small, unblinded retrospective studies, with varying inclusion criteria and outcome measures. Most studies did not report comprehensively on complications, with only a few presenting their early complication rates.[20,21] Moreover, there is an inadequacy of information regarding late complications such as late rupture or infection.

Recently, 2 randomized trials have reported on outcomes of 2 different strategies for preemptive embolization. Samura et al.[8] conducted a single-center RCT of selective preemptive IMA embolization prior to EVAR, including 106 patients. The 5-year follow-up results from this study suggest that TIIEL occurred more frequently in the nonembolization group (28.3% vs. 54.7%; $P = 0.006$), and both freedom from TIIEL-related sac enlargement $\geq$5 mm and the cumulative incidence of sac shrinkage $\geq$5 mm were significantly higher in the IMA embolization group (95.5% vs. 73.6% at 5 years; $P = 0.021$ and 54.2% vs. 33.6% at 5 years;

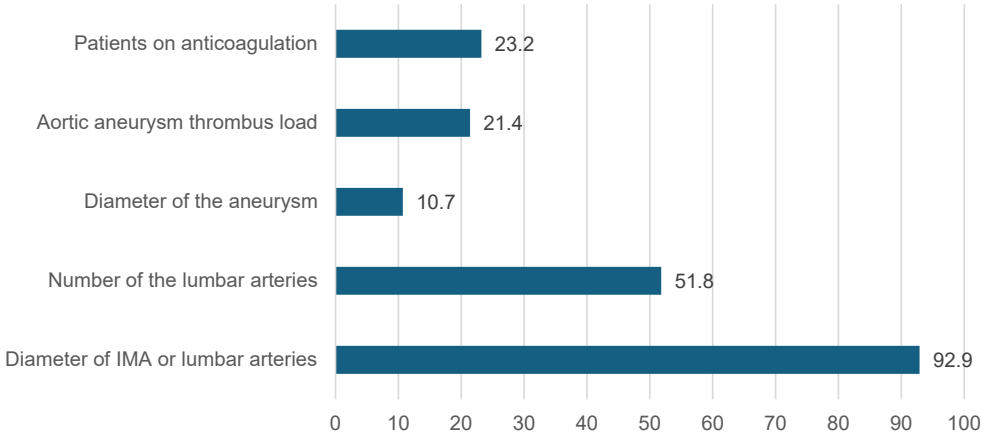

Fig. 4. Survey respondents' answer to potential criteria for implementing preemptive embolization in a randomized controlled trial. Percent respondent in each category is presented.

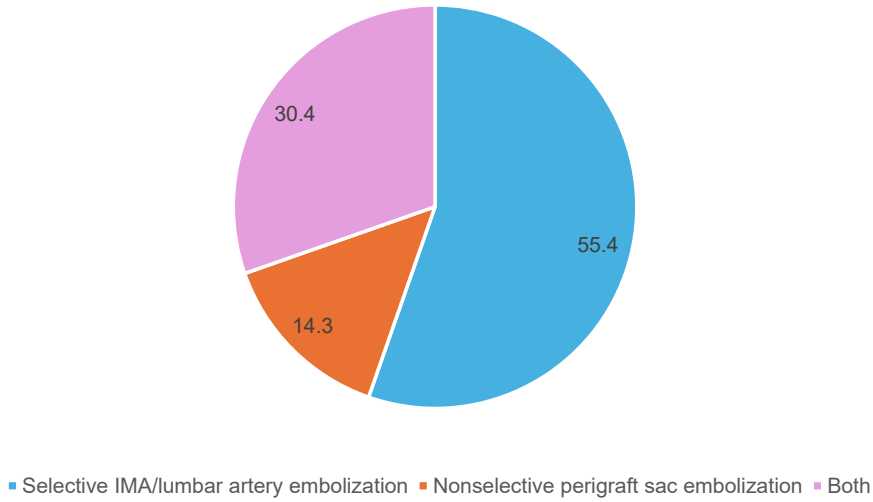

Fig. 5. Preferred strategy for preemptive embolization approach among survey participants. Percent respondent in each category is presented.

$P = 0.039$, respectively). However, the rates of overall reinterventions and TIIEL-related intervention did not differ significantly between the groups (9.4% vs. 11.3%; $P = 0.51$ and 0% vs. 1.9%; $P = 0.32$, respectively). Additionally, freedom from TIIEL-related sac enlargement $\geq$10 mm, an alternative indicator for TIIEL-related reintervention, favored the embolization group (100% vs. 90.4% at 5 years; $P = 0.019$).[16] Fabre et al. conducted an RCT including 94 patients at 2 centers, this time utilizing a nonselective approach involving coil embolization of the aneurysm sac in high-risk patients based on their inclusion criteria.[14] After 2 years of follow-up, the occurrence of TIIEL was significantly lower in the embolization group at 1 month (34% vs. 4.3%; $P < 0.001$), 6 months (41.7% vs. 4.26%; $P < 0.001$), and 12 months (40.5% vs. 14.3%; $P = 0.018$), but not at 24 months (25% vs. 6.5%; $P = 0.19$). Kaplan–Meier survival curves demonstrated a significant advantage for the embolization group in terms of freedom from TIIEL and reinterventions ($P < 0.001$). Additionally, at 24 months, there was a significant decrease in aneurysm sac volume in the embolization group ($P = 0.001$).

While these 2 trials add significantly to the body of knowledge on the potential benefit of a preemptive embolization strategy to reduce the risk with TIIEL, it is notable that they have not convinced the

participating experts, of whom 3 out of 4 reported that the current literature was not convincing. Of note, the current 2 RCTs, which in total include 200 patients treated with 2 inherently different strategies, do not support that preemptive embolization of side branches or the sac increase the durability of EVAR. To establish the potential benefit of preemptive embolization strategies for EVAR durability, robust trials with clinically relevant outcome are required. Optimally, randomized, multicenter trials to establish both the safety and effectiveness of preemptive embolization, with standardized outcome reported at long term (5 years and beyond) including late ruptures and endograft explantation due to noninfectious complications should be included. Additionally, a cost-effectiveness evaluation should be conducted as part of the trial to assess the prophylactic embolization's cost versus long-term follow-up and reintervention expenses. Fortunately, most of the partici pating experts expressed their interest in playing a role in such an RCT to enhance the evidence quality and establish the technique's value.

CONCLUSION

The current survey underlines the discrepancies in management of TIIEL in the aortic community internationally. While vascular specialists generally acknowledge the potential risks associated with TIIEL, there is no agreement on indications or method for intervention. The current evidence falls short in establishing the role of preemptive embolization in increasing EVAR durability, and hence the technique is not implemented in clinical practice in most centers. Randomized trials with long-term outcome data would be required to settle the potential value for preemptive embolization strategies.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT

Mohammed Habib: Writing — original draft, Validation, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Mario D'Oria:** Validation, Methodology, Investigation, Formal analysis, Conceptualization. **Jacob Budtz-Lilly:** Validation, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Kevin Mani:** Writing — review & editing, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.avsg.2025.02.027.

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