RELAY Branched device: The story of an aortic arch device

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Abstract

Background: The management of aortic arch pathologies represents a great challenge and is associated with high rates of mortality and morbidity. A superior endovascular approach via thoracic endovascular aortic repair (TEVAR) has been introduced to treat arch pathologies with specifically designed endografts. This approach was shown to benefit patients who are deemed 'high risk' for undergoing OSR as it is a greatly less invasiveness option and thus, yields lower rates of morbidity and mortality. Aims: This commentary aims to discuss the recent study by Tan et al. which reports original data on the neurological outcomes after endovascular repair of the aortic arch using the RELAY Branched device. Methods: We carried out a literature search on multiple electronic databases including PubMed, Ovid, Google Scholar, Scopus and EMBASE in order to collate research evidence on the neurological outcomes of endovascular aortic arch repair with TEVAR. Results: Tan and colleagues showed through their original clinical data that the RELAY Branched device has a high rate of technical success and favourable neurological outcomes. There were no reported neurological deficits in patients who received the triple-branched RELAY Branched device. Conclusion: The RELAY Branched endograft is well-established for candidates for aortic arch endovascular repair with favourable neurological outcomes. Multiple considerations can help control the incidence of stroke following endovascular repair. These include optimization of the supra-aortic vessels' revascularization, weighting the embolic risk in patients with atheromatous disease, and careful preoperative assessment to select the best candidates for arch endovascular repair

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Abstract

Background: The management of aortic arch pathologies represents a great challenge and is associated with high rates of mortality and morbidity. The invasive and radical open surgical repair (OSR) is the standard of care for this group of patients. A superior endovascular approach via thoracic endovascular aortic repair (TEVAR) has been introduced to treat arch pathologies with specifically designed endografts. This approach was shown to benefit patients who are deemed 'high risk' for undergoing OSR as it is a greatly less invasiveness option and thus, yields lower rates of morbidity and mortality.

Aims: This commentary aims to discuss the recent study by Tan et al. which reports original data on the neurological outcomes after endovascular repair of the aortic arch using the RELAY Branched device.

Methods: We carried out a literature search on multiple electronic databases including PubMed, Ovid, Google Scholar, Scopus and EMBASE in order to collate research evidence on the neurological outcomes of endovascular aortic arch repair with TEVAR.

Results: Tan and colleagues showed through their original clinical data that the RELAY Branched device has a high rate of technical success and favourable neurological outcomes. There were no reported neurological deficits in patients who received the triple-branched RELAY Branched device.

Conclusion: The RELAY Branched endograft is well-established for candidates for aortic arch endovascular repair with favourable neurological outcomes. Multiple considerations can help control the incidence of stroke following endovascular repair. These include optimization of the supra-aortic vessels' revascularization, weighting the embolic risk in patients with atheromatous disease, and careful preoperative assessment to select the best candidates for arch endovascular repair.

Commentary

The treatment of aortic arch pathologies remains a great challenge due to the associated high rates of mortality and morbidity. Open surgical repair (OSR) is considered as the first-line treatment strategy in patients with dissections or aneurysms involving the aortic arch. The high invasiveness and the radical approach in replacing the aortic arch via the frozen elephant trunk (FET) procedure predisposes the patient to disabling complications including stroke, organ malperfusion, and coagulopathy [1, 2]. The interest in the use of thoracic endovascular aortic repair (TEVAR) as an alternative to OSR in the treatment of arch pathologies has been continuously rising since its introduction. Still, it presents a challenge in the control and deployment of the endograft around the arch and poses the omnipresent risks of supra-aortic vessels malperfusion [3]. However, specialized TEVAR endografts complementing the anatomy of the arch have been developed. One major example is the RELAY Branched (Terumo Aortic, Scotland) which comes in single-, double-, or triple-branched configurations to preserve patency of the supra-aortic vessels. The endovascular approach to treating arch pathologies is reserved for high-risk patients who meet certain criteria to optimise the proximal deployment and sealing of the endograft. These require the presence of primary entry tears more than 20 mm distal to the sinotubular junction and a proximal landing zone diameter of more than 38 mm [3, 4].

We read with great interest the recent original study by Tan and Colleagues [5] which discussed the neurological outcomes after endovascular aortic arch repair using the RELAY Branched device. The authors presented original perioperative data on the clinical use of RELAY device in patients with arch pathologies. This study's great scientific value comes from the highly robust methodology which includes comprehensive statistical analyses performed and very well-presented clinical data. Also, the authors delineated where the

evidence in the literature stand in terms of neurological outcomes after endovascular arch repair. A total of 148 patients underwent endovascular aortic arch repair using the RELAY Branched device, out of whom 107 suffered of proximal aortic aneurysm and 41 patients had aortic dissection. Sixty-eight patients, representing 46% of the cohort, underwent the procedure in the acute setting whilst the remaining 54% (n = 80) were treated electively. Additionally, the majority of patients (73%; n = 108) received the double-branched configuration of the RELAY device. The single-branched and tripe-branched devices were only employed in 11.5% (n = 17) and 15.5% (n = 23) of patients, respectively. The authors also reported comprehensive follow-up data for all patients after 30 days, 6 months, 12 months, and 24 months post-operatively.

The primary reported outcome in Tan et al. [5] is the presence of neurological deficit as patients were screened for the presence of disabling or non-disabling stroke. The authors used the VARC-2 criteria which define a disabling stroke with a modified Rankin scale (mRS) score > 3 and a non-disabling stroke with a modified Rankin scale score < 2. After 24 months of follow-up, a total of six patients (4%) suffered from disabling stroke, out of which 2 occurred within the first 30 days post-TEVAR. On the other hand, a non-disabling stroke was documented in 8 patients (5.4%) over 24 months of follow-up, yet, 5 cases were identified during the first 30 days postoperatively. Whilst more than half of stroke incidences were recorded in the perioperative period, which is usually attributed to operative manipulation of the arch and the supra-aortic vessels, the authors highlighted that stroke, in a smaller percentage, can still occur even over an extended period postoperatively. Tan et al. [5] also highlighted further advantages of the RELAY Branched endograft including high technical success (99.4%) as well as a relatively short endovascular time during the procedure (100-150 minutes in 64% of patients). However, the authors noted that more extensive disease might lead to longer procedural duration and more extensive manipulation, hence this should be assessed pre-operatively to optimise results in suitable candidates.

The neurological results yielded by the RELAY Branched device can be considered superior to its market competitors. For example, Tazaki et al. [6] observed a combined stroke rate of 33% in patients who received the Inoue double-branched endograft, which is substantially higher than the combined rate of 9.5% reported by Tan et al. [5] (9.5%) in patients who received the double-branched configuration of the RELAY device. In addition, Tan et al. [5] reported a 0% rate of stroke in patients who received the triple-branched RELAY Branched device. In contrast, Tazaki et al. reported a 40% combined stroke rate in patients who received a triple-branched configuration of the Inoue device. Nonetheless, it seems there is no significant relationship between the incidence of stroke and the branching configuration of the graft.

The underlying mechanism of perioperative stroke in patients who receive TEVAR is yet not fully understood. Malperfusion and embolization are the main hypothesized mechanisms that drive the development of stroke. It is worth noting that the coverage of arch vessels during TEVAR may lead to cerebral malperfusion Control of each of these two factors could lead to superior neurological outcomes in this group of patients [7]. The left subclavian artery (LSA) is the most commonly covered supra-aortic vessel in TEVAR for descending aortic pathologies. This risk is even higher whilst stenting the arch without complete debranching of the supra-aortic vessels. Hence, the Society for Vascular Surgery guidelines recommend routine LSA revascularisation in elective TEVAR of the arch cases [8]. Moreover, atheromatous disease of the aortic arch has been linked to perioperative stroke in patients receiving TEVAR. This has been demonstrated by Katz et al. [9] who observed the strong association between >5 mm of atheromatous diseases in the aortic arch and the incidence of stroke following TEVAR (OR = 14.8, CI = 1.7 – 675.6, P = 0.0016). Therefore, following screening and evaluation, candidates with atheromatous disease in the aortic arch should be weighed for the risk of postoperative neurological insult. Unfortunately, Tan et al. [5] did not fully provide the baseline characteristics of their patients. This information could present the foundation to understanding the pathophysiology of perioperative stroke and should be addressed in future studies.

The RELAY Branched is a well-described devices for endovascular aortic arch repair, achieving highly favourable neurological outcomes. Multiple factors in the perioperative assessment can predict the risk of neurological outcomes in patients undergoing TEVAR. These include the presence of atheromatous aortic disease, the extent of the pathology and the technique of supra-aortic vessels revascularization.

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