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Official Title: LSA Reconstruction With Laser Fenestration During the TEVAR

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- Study Protocol
- Objective This study aimed to prospectively evaluate the safety and efficacy of left subclavian artery (LSA) revascularization via in-situ laser-assisted fenestration during thoracic endovascular aortic repair (TEVAR) for type B aortic dissection (TBAD).
- Design This was a prospective, single-arm, multicenter study that enrolled patients with complicated or high-risk acute TBAD. The LLTEVAR (LSA Revascularization With Laser-assisted Fenestration During TEVAR) study is a prospective, single-arm, multicenter trial that planned to enroll 100 patients at 5 vascular centers (NCT03845829). Patients presenting with complicated or high-risk acute TBAD with a proximal entry tear originating in zone 2 or zone 3, who were deemed appropriate candidates for TEVAR in conjunction with LSA revascularization, met the included criteria, and consented to participate were enrolled. The distance from the proximal edge of LSA orifice to the intended proximal landing location should be >5 mm. Patients were excluded if they were pre-procedurally scheduled to have proximal aortic arch coverage in zone 1 or zone 0. Other main exclusion criteria included patients who were inappropriate for TEVAR due to unfavorable anatomic characteristics (no commercially available aortic stent for the size of the aorta, no available access for TEVAR, both LAS and left vertebral artery originated from aorta, et al), previous open surgery for aortic arch and connective tissue disorders. The primary safety endpoint was freedom from composite major adverse events (mortality, stroke, myocardial infarction, rupture, paraplegia, type Ia endoleak) within 30 days after the procedure. Univariate and multivariate analyses determined the risk factors of composite major adverse events. The primary efficacy endpoint was freedom from all-cause death, LSA in-stent restenosis, and reintervention due to dissection progression, growth, and endoleak at 1 year after the procedure.
- Methods Once diagnosed, all patients received optimal medical therapy, consisting of close intensive care unit monitoring and control of blood pressure, heart rate, and pain. TEVAR procedures were performed for patients with complicated and high risk TBAD. Patients not responding to medical therapy or presenting with rupture or impending rupture, malperfusion were treated emergently; otherwise, TEVAR procedures were performed 2 weeks later. The procedure of TEVAR in adjunct with in-situ laser-assisted fenestration for LSA revascularization has been previously described in detail [19-21]. Briefly, the TEVAR procedures were performed under local or general anesthesia, and aortic stent-grafts were deployed through femoral access, and the LSA fenestration stents were inserted through brachial artery. The diameter of the aortic stent-graft was based on the diameter of the proximal healthy landing zone of the aorta with approximately 5% oversizing. If the diameter of the stent-graft mismatched the diameter of the distal attachment site of the aorta (e.g, > 20% oversizing of the total aortic diameter), a distal restricted stent technique was used [24]. After aortic stent-graft deployed, a 6F steerable sheath combined with a balloon catheter (Mustang, Boston Scientific, 4mm in diameter and 4cm in length) allowed the laser tip to be placed in the intended fenestration site outside of the aortic stent-graft. After the

fenestration was established, the balloon catheter was pushed forward and through the fenestration hole, and after the balloon angioplasty for the established hole, the laser tip was exchanged with a 0.035-inch guidewire. Then the fenestration hole was subsequently dilated up to the reference diameter of the subclavian artery, and a balloon-expandable (Lifestream, BD) or self-expandable (Fluency, BD) covered-stent (10% oversizing of the LSA in diameter) was deployed inside the fenestration. Post stent dilation was always required for the LSA stent. At the end of the procedure, arteriography was performed from the ascending aorta to assess the success of the procedure and to identify potential endoleak and residual stenosis of the LSA stent.

- Statistical Analysis Plan (SAP): Continuous variables are presented as mean with standard deviation, and categorical variables are summarized using counts and proportion. Univariate logistics regression analysis was performed to determine the potential risk factors of major adverse events (mortality, stroke, myocardial infarction, rupture, paraplegia, type Ia endoleak, major bleeding, acute kidney injury, limb ischemia, bowel ischemia, retrograde dissection, stent-induced new entry (SINE), access site complications and unplanned reinterventions), and only factors being found statistically significant in the univariate analysis were included in the multivariate analysis. The patency rate of LSA and the all cause related mortality were estimated using the Kaplan-Meier method. SPSS version 26.0 (SPSS, Inc., Chicago, IL, USA) was used for the statistical analyses. Differences with a P value < 0.05 were considered statistically significant.
- Informed Consent Form (ICF): attachment
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