Measurement of sternum-heart space in patients with and without median sternotomy

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**Introduction**: The Extravascular Implantable Cardioverter Defibrillator (EV ICD) as an innovational approach provides alternatives to commercially available ICDs in certain clinical situations. Previous clinical investigations have demonstrated the feasibility of applying an investigational lead under the sternum with a minimally invasive procedure to deliver lifesaving defibrillation and anti-tachycardia pacing therapy. Clinical information for the substernal space in patients with median sternotomy is needed to reveal the structure of the substernal space and guide the delivery of the lead.

**Methods**: CT images from patients with prior sternotomy (n=10, S-group) and without prior sternotomy (n=10, NS-group) were collected to measure the distance between the midline of sternum and the epicardial surface of the heart. Measurements were segmented into four regions: Region 1 between the xiphisternal junction (XJ) and xiphoid tip; Regions 2 to 4 along the midline of sternum, superior to the XJ, with distance from XJ of 20 mm, 50 mm and 60 mm, respectively (Figure 1A). In S-group, the measurements could be replaced with those between a sternal wire and the epicardial surface of the heart when the sternal wire was between the sternum and the heart, which was a result of the sternotomy procedure. Averaged distances were calculated and one-tailed t-test was utilized to compare the distances of four regions between the two groups.

**Result**: High quality CT images were collected from 20 subjects (70% male, aged 69.3±11.5 years) with slice thickness ≤1 mm and in-plane resolution ≤0.8 mm. Results (Figure 1B) showed significant difference of the averaged distances between sternum/sternal wire and the epicardial surface of the heart in Region 1 (S-group: 4.15±2.95 mm, NS-group: 8.09±3.58 mm, p=0.02). A trend of difference in the distances were observed in Region 2 (S-group: 5.87±4.28 mm, NS-group: 8.81±7.14 mm, p=0.15), Region 3 (S-group: 10.3±8.00 mm, NS-group: 15.34±8.42 mm, p=0.09) and Region 4 (S-group: 13.61±8.80 mm, NS-group: 15.72±5.90 mm, p=0.37).

**Conclusion**: Initial CT-image analysis in 20 patients shows a smaller space for post-sternotomy patients as expected, but there appears to be a narrow but viable space for lead position even in that...
specific patient group.