

Minimal- Invasive Transcutaneous Epicardial Pacemaker-Lead Implantation - A Novel Approach To Avoid Thoracotomy

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Introduction: In congenital heart disease (CHD) cardiovascular abnormalities, small vascular size and surgical procedures may preclude transvenous pacing. Surgical epicardial lead implantation is commonly used in these conditions. The objective of this study is to assess the feasibility of a newly developed minimal-invasive transcutaneous pacemaker-lead implantation technique to avoid thoracotomy and associated morbidity.

Methods: A preliminary pilot study using 5 German pigs was conducted. After femoral puncture RA-, LV- and aortic-root angiographies were performed to localize target sites. Epicardial access was established via a modified subxiphoidal approach: under fluoroscopy guidance a Tuohy-needle (18-22 G) was advanced retrosternally into the pericardial space. Contrast dye proofed correct location. Using coronary guidewires three 4-Fr. short-sheaths were introduced. Deflectable catheters (Medtronic C315) with a modified flat tip were positioned at the atrial and ventricular target site and stabilized by negative suctioning force. Through these 4.1 Fr. transvenous screw-in bipolar leads (Medtronic 3838) were implanted. After achieving acceptable sensing- and pacing-properties, sheaths and excessive air/fluid were removed. Leads were tunneled subcutaneously to a subcutaneously implanted 2-chamber pacemaker (Medtronic). Pacemaker was set to DDD to prevent interferences with intrinsic heart rhythm. First follow-up was at day 3-5.

Results: At implantation mean bodyweight was 28,2 (range 21,5-31) kg. Implant procedure was successful in all animals with establishment of a functional DDD-pacemaker system. Neither pericardial hemorrhage nor myocardial perforation occurred. One animal died unexpectedly in the post-procedural night. Remaining animals were euthanized due to pacemaker-pocket infection (without impairment of general-condition) (day 17, day 34), hind-leg fracture (not procedure-related) (day 18) and end-of-study (day 49). Lead-performance at first follow-up see table:

Mean (Range)	Impedance (Ohm)	Pacing-Threshold @1ms (V)	Sensing (mV)
Atrium			
unipolar	340 (240-430)	3,53 (0,5-7,5)	1,31-2,1 (0,25-1,4 to 2-2,8)
bipolar	465 (327-651)	3,17 (2-4)	1,6-2,4 (0,25-0,75 to 2,8-4,0)
Ventricle			
unipolar	313 (232-464)	4,3 (3-6)	3,1-4,4 (2,8-4 to 4-5,6)
bipolar	423 (347-568)	2,9 (1,25- 4)	1,6-2,5 (1-1,4 to 2,8-4,0)

Conclusion: Epicardial 2-chamber-pacemaker can be successfully implanted transcutaneously by this newly developed minimal-invasive pericardial approach. Satisfactory sensing- and stimulation-properties could be obtained during implant and short-term follow-up. Further research and procedural refinement may enable selective-site-pacing in CHD-patients avoiding thoracotomy.