Video-Assisted Pericardioscopic Surgery for Epimyocardial Lead Implantation

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Purpose. Video-assisted pericardioscopic surgery (VAPS) for epimyocardial lead implantation has demonstrated positive acute results concerning the safety and degree of freedom inside the pericardium. We evaluated the employment of a newly developed trocar for pericardioscopy with regard to long-term effects and feasibility of reoperation.

Description. Eight adult sheep were divided into three groups. In two animals, VAPS was used exclusively. All other animals received four small-caliber epicardial leads through VAPS. After 6 and 12 months (n = 3 each), reoperation was conducted for reevaluation of entry site, intrapericardial adhesions, lead position, and morphology of the implantation site.

Evaluation. Reentry close to the previous entry site proves unproblematic. Adhesions were mild to moderate in the immediate area of the implanted leads. Throughout the follow-up, pacing parameters were satisfactory. Lead dislodgement occurred in 1 of 24 leads. The deployment of small-caliber flexible endoscopes through the new trocar provided sufficient navigation, stability, and maneuverability.

Conclusions. Reoperation from the same subxiphoid approach proved feasible. Lead removal and reimplantation were feasible at both 6 months and 12 months after initial implantation. The intrapericardial adhesions caused by VAPS alone are mild.


Technology

Animal Model
After approval from government institutions (LANUV 8.87-50.10.37.09.151), 8 healthy adult female sheep (Röhn) with a mean weight of 58 ± 3 kg were included in this study. The animals were treated in accordance with the applicable guidelines for animal care (National Institute of Health, No. 86-23, revised 1985).

General Preparations
After preoperative fasting, all animals received a premedication of 2 mg/10 kg xylazine intramuscular. Anesthesia was induced by injection of propofol (2.6 mL/10 kg intravenously). All animals were orally intubated and mechanically ventilated. Peripheral arterial and venous catheters were applied for continuous pressure documentation and drug administration, respectively.

Dr Lazeroms discloses a financial relationship with Medtronic.
VAPS Instrumentation

Based on our findings that insulation of a bare metal instrument diminishes malignant arrhythmia, and that small-caliber flexible endoscopy is not solely applicable for pericardioscopy, we designed a new trocar prototype, developed and manufactured by Karl Storz (Tuttlingen, Germany). It consists of two components. The first part of the device is a reusable solid metal cylindrical body (Fig 1) with two openings, the proximal end being the instrument “gateway” with an integrated shutter allowing suction or pressurization by a Luerlock at its side. The distal end is fitted with a large screw thread, where a corresponding screw anchors the second part of the device: a smoothed-surfaced, blunt, semirigid Teflon sleeve (Karl Storz). This single-use part of the prototype represents the mandatory insulation for rigid endoscopy or serves as a stabilizing guidance for flexible endoscopes.

We deployed both a rigid Hopkins (Karl Storz) endoscope (Fig 2) and a small-caliber flexible endoscope (Karl Storz) used in our previous study (length 40 cm, outer diameter 12 mm, working channel 3.2 mm, up/down angulation 210/100 degrees, left/right angulation 120 degrees) using the trocar prototype for VAPS. In particular, the employment of small-caliber flexible pericardioscopy and its intrapericardial stability, navigation, and maneuverability were assessed using the new trocar (Figs 1 and 2).

Technique

Operation and Lead Implantation
Briefly, VAPS was performed in all animals as previously described [4]. A 10-mm incision was performed in the median subxiphoid region and the pericardial sac displayed by blunt dissection. The trocar prototype containing the rigid endoscope was inserted just before the pericardium. The pericardial sac was grasped by endoscopic biopsy forceps at a vessel-free site and opened by quick retraction. The semiflexible end of the trocar was then forwarded through the pericardial hole into the pericardial cavity, dilating the hole and allowing the introduction of the rigid endoscope into the cavity.

All four chambers and the great veins were displayed by rigid endoscopy using the new trocar according to our previously described protocol [4]. Afterward, the intrapericardial stability and navigation of a flexible endoscope were assessed.

In 2 animals, pure diagnostic VAPS was performed to differentiate whether the intrapericardial adhesions were a result of the VAPS procedure or were intensified by lead implantation. Systematic lead implantation (Stingray; Medtronic, Maastricht, Netherlands) was performed in 6 animals (Fig 3). The electrodes were implanted under direct vision through the endoscope’s working channel, avoiding the vessels and fatty tissue. Implantation was performed at an anticipated angle of 35 degrees (±10 degrees) achieving tangential, intramural lead position. Endoscopy allowed for direct verification of the position, efficiency, and particularly the safety of the leads’ positioning. Fluoroscopy was performed to document the leads’ position for postoperative follow-ups.

Stimulation Protocol
Left-sided leads were representatively connected to a dual-chamber pacemaker (Sensia DR; Medtronic), for follow-up assessments after 1, 3, and 6 months. The pacemaker was programmed in DDD-R-mode with the following parameters: pacing-voltage 3.5 V, pulse duration 0.5 ms, atrioventricular delay 120 ms, mode-switch frequency 120 per minute. Pacing was conducted at an intervention frequency of 80 per minutes during the observation time.

Repeat Surgery
After 6 and 12 months (n = 3 per group), reoperation was executed evaluating feasibility of reoperation from the former entry site and severity of intrapericardial adhesions. The lead positions were visualized and their correct and intact position verified. The animals were humanely killed through an overdose of thiopental and potassium. The hearts were then explanted to assess the insertion sites of the leads and the quality of their anchorage. Both
entry and implantation sites were inspected. The occurrence of adhesions was classified in four degrees, depending upon the possibility of their dissection using a rigid endoscope.

Histology
For histologic assessment of the lead entry sides, hearts were immediately dissected after euthanasia. After careful unscrewing of the lead spirals, small cubes of tissue (1 cm³) were paraffin embedded and cut to identify the lead channel. Staining was performed using conventional hematoxylin-eosin and collagen dyes.

Clinical Experience
The combination of the trocar prototype with a rigid endoscope provided optimal conditions for exploration of the whole ovine heart: all structures could be reached within minutes without occurrence of ventricular fibrillation or notable extrasystoles. The prototype provided excellent stabilization, maneuvering, and navigation for flexible endoscopy. Intrapерicardial structures (ie, aorta and pulmonary artery, around pulmonary veins) were easily accessible using the flexible endoscope with the trocar. In all group 2 and group 3 animals, the described leads could easily be placed with a procedure lasting well under 60 minutes. All animals reached their specific endpoints in a generally healthy state. No wound infections or hemATOMA occurred.

Lead Properties
After the primary operation and lead implantation, all leads exhibited good pacing properties (Table 1). At the first control, after 1 month, we noted one dislodged lead in the LA position. The initial operative video recording made it evident that the lead had in fact been incorrectly implanted. Aside from this, all leads were functional until the end of study, and no further major device-associated complications have been documented.

A follow-up of 6 months was completed for all the animals. According pacemaker values revealed no significant differences between timepoints for the chosen variables (data not shown). Both macroscopic and histologic evaluation of the entry sites revealed no excessive fibrosis or scar formation, showing only a moderate collagen layer adjacent to the lead channel and proper intramural positioning of the lead helix (Fig 4).

Pericardial Adhesions
In all animals, reentry through the identical pericardial entry site was not feasible owing to scar formation. The immediate vicinity allowed for simple entry. The occurrence and density of adhesions differed markedly between the groups (after 6 months, the number of adhesions at or close to the entry side was higher as compared to the 12-month follow-up; Table 2). In both the 6-month and 12-month animals, the lead circumference of connected leads showed third-degree adhesions, although removal of the implanted leads by counter-rotation proved to be simple. Intrapерicardial adhesions were intensified by lead implantation.

Comment
The technique of endoscopic exploration of the pericardial cavity from a subxiphoid approach has been known for decades. Only a few investigations have assessed its diagnostic and therapeutic value, particularly for pericardial effusions [6]. Even fewer investigations have systematically assessed the interventional use regarding epicardial ablation or lead implantation [7]. Demaria and Poignet [8] pointed out the risks provoked by a rigid device, implying that subxiphoid VAPS is potentially dangerous and not well suited for clinical use [5, 7, 9]. In contrast to the results [5, 9] with the FLEXview system (Boston Scientific Cardiac Surgery, Santa Clara, CA), we observed no myocardial trauma at the implantation site.

Subxiphoid VAPS can be used as a safe, fast, and simple access to intrapерicardial structures, if the following aspects are considered: Using bare-metal, rigid endoscopes inside the pericardial cavity, insulating...
coverage, and gentle movement are mandatory to avoid malignant arrhythmia with hemodynamic depression. When aiming at the posterior and posterolateral wall of the heart (ie, pulmonary veins, left ventricle), leverage must not be applied to the rigid endoscope to avoid obstruction of venous return of the right-sided cavities. Here, flexible endoscopy is preferable. To prevent poor intrapericardial navigation and maneuvering, splitting a small-caliber flexible endoscope with a rigid trocar proves to be very useful. Finally, using a standardized protocol for intrapericardial navigation avoids additional imaging in this narrow, moving environment.

Subxiphoid VAPS provides direct vision with a short procedural duration, no manipulation of the thoracic wall and the avoidance of pleural breach. Yet to achieve optimal visualization while providing sufficient intrapericardial stability for secure interventions, a further improvement of the instrumentation is mandatory. Together with Karl Storz Endoskope GmbH&Co KG, we have designed a trocar that is blunt enough to avoid myocardial trauma, yet solid enough to allow for secure handling of both rigid and flexible endoscopes. The trocar insulates the rigid endoscope’s shaft and allows for good visualization and maneuverability, while providing a solid base for small-caliber flexible endoscopes.

Study Limitations

Our model is limited by the anatomic singularities of the sheep. The sheep’s heart is aligned in a cranio-caudal axis compared to the -directed cardiac axis in humans. Organ distribution and orientation is therefore only nearly comparable to human, where the accessibility of the apical region proves to be especially difficult by subxiphoid VAPS [4].

In conclusion, we have demonstrated that reoperation from the same subxiphoid approach is feasible, if the identical pericardial entry point is avoided. The intrapericardial adhesions caused by VAPS were found to be mild, whereas implanted leads generate more profound, deeper encircling adhesions, while still permitting lead removal if necessary. Adhesions are less marked and less solid after 12 months.

Table 2. Adhesion Degree (I through IV) at Different Locations for All Animalsa

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<th>Location</th>
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<th>12 Months</th>
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<td>Atrial lead position</td>
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<td>Subxiphoidal</td>
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<td>III</td>
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<td>Pericardium</td>
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a n = 3 per group. Adhesion degree: I = no relevant adhesions; II = minor adhesions, easily dissectible with endoscope shaft, no bleeding; III = moderate adhesions, partially dissectible with endoscope shaft, epicardial oozing; IV = severe adhesions, not dissectible with endoscope shaft. D = dislodged; Right = right-sided leads; Left = left-sided leads.

Disclosures and Freedom of Investigation

Medtronic (Maastricht, Netherlands) supported this study financially; Karl Storz (Tuttlingen, Germany) supported the instrumentation. The authors have performed a free and independent development and evaluation of this new technology.

References


Disclaimer

The Society of Thoracic Surgeons, the Southern Thoracic Surgical Association, and The Annals of Thoracic Surgery neither endorse nor discourage use of the new technology described in this article.