Video-assisted pericardioscopic surgery: refinement of a new technique for implanting epimyocardial pacemaker leads

Nima Hatama,⁎, Andrea L.A. Amerinia, Frederik Steiner a, Mark Lazeromsc, Karl Mischke b, Patrick Schauerte b, Ruediger Autschbacha, Jan Spillnera

⁎Department of Cardiovascular and Thoracic Surgery, Medical Faculty RWTH Aachen, Aachen, Germany
bDepartment of Cardiology, University Hospital, Medical Faculty RWTH Aachen, Aachen, Germany
cMedtronics Bakken Research Center, Maastricht, The Netherlands

Received 8 March 2010; received in revised form 8 June 2010; accepted 9 June 2010; Available online 2 August 2010

Abstract

Objective: Current alternative approaches for pacemaker lead implantation imply the breach of the pleural space. Recently, the feasibility of experimental lead implantation by rigid endoscopy has been described. The use of flexible endoscopes and a standardised application has not been realised yet. Our main goal was to compare rigid and flexible endoscopy and to establish a standardised protocol for the implementation of a closed-chest subxiphoid approach for epimyocardial lead implantation. Methods: Rigid and flexible endoscopes were used for placement of screw-in pacing leads (4-F). A total of 17 adult pigs (80 kg) were anaesthetised and a 10-mm subxiphoid axial incision performed. The pericardium was opened and entered under endoscopic vision. Epimyocardial electrodes were implanted through the endoscope onto all four chambers. Standard haemodynamic measurements and pacing measurements were carried out. Results: Both methods were deployed in the first three individuals. Superior endorsement of rigid endoscopy, due to better orientation and stability, led to its exclusive deployment in the remaining 14 individuals. Access to the implantation sites was quick (<10 min). A plastic cover had to be applied to reduce arrhythmia (VentricularExtrasystoles/cover: 17 ± 2.2 min−1 vs VentricularExtrasystoles: 5 ± 1.9 min−1; n = 4). Measured pacing parameters were comparable with classic endocardial-derived thresholds. Post-mortem examination revealed no relevant damage/injury and/or bleeding in the heart and circumjacent tissue. There was no evidence of injury at the implantation sites and the corresponding pericardium. The electrodes showed excellent anchorage inside the myocardial tissue (penetration depths: 3 ± 0.2 mm) and resisted high tractive forces. Conclusion: Flexible endoscopy is not suitable for exclusive deployment inside the pericardial space, whereas rigid endoscopy presented itself as a safe, fast and simple approach for epimyocardial lead implantation using an insulating trocar. Without cover, malignant arrhythmia constrains the implementation of video-assisted pericardioscopic surgery (VAPS). Subxiphoid VAPS permits optimal lead positioning under direct vision without fluoroscopy, without the breach of the pleural space and with a short procedural duration (<60 min). Our standardised minimal-invasive approach allows visualisation and intervention, potentially of all intrapericardial structures.

Keywords: Pericardioscopy; Subxiphoid; Pacemaker; Epimyocardial lead placement; Minimal invasive

1. Introduction

Since the spectrum of modern pacemaker therapy was expanded by cardiac synchronisation therapy (CRT), the numbers of patients receiving pacemakers and the consequent method-related peri- and postoperative complications have significantly increased using the standard transvenous technique [1]. Particularly in CRT, limited accessibility to the coronary sinus along with its branches and the mismatch between the region of latest left ventricular (LV) contraction and an adequate epicardial vein frequently lead to therapy failure and might even be responsible for the 30% non-responders, although this aspect has not been thoroughly investigated yet [2,3]. Further complications such as post-operative micro- (i.e., increased thresholds) or macro-dislodgement (i.e., loss of stimulation success) of the LV electrodes are frequent complications leading to re-operation or a change of strategy [4]. The current transthoracic epicardial approach through mini-thoracotomy circumvents the aforesaid obstacles and is regarded as the first-choice alternative approach. Direct vision and comparably
broad accessibility to the heart, combined with modern three-dimensional (3D) imaging of excitation dispersion, allows the selection of an optimal pacing site without long use of fluoroscopy added by the application of iodinated contrast. The surgical approach also allows active fixation of the lead to the epicardium that makes lead dislodgement very unlikely. The endoscopic approach by video-assisted thoracoscopic surgery (VATS) appears to find its way into clinical practice, but is only practised by a few centres, however [5—7]. Regardless of the type of surgery, the chest wall has to be penetrated and the pleural cavity opened, which is, compared with the transvenous approach, disadvantageous and is associated with increased postoperative morbidity, mortality and mean hospital stay [8]. The entrance into the pericardial space is limited by pericardial structures, such as the phrenic bundle, for instance, although both thoracotomy and VATS allow a much wider access to cardiac structures compared with the transvenous technique. Hence, the optimal alternative approach for lead placement would naturally be under direct vision through a small trauma, reaching all desired epicardial structures, but without breaching the pleural space and without using fluoroscopy. We believe that the use of video-assisted pericardioscopic surgery (VAPS) through a subxiphoid approach meets the above-mentioned requirements of an optimal approach. Moreover, it appears as a combination of individual advantages of both the transvenous and surgical approaches. Only a small number of experimental investigations have been published in the past describing initial experiences with endoscopy of the pericardial cavity in animals and humans for epidocardial lead placement with promising acute results concerning feasibility, yet with disappointing electrical properties, comparably major trauma and without any detailed description of adverse events [9]. Nevertheless, the scope was merely on the feasibility of rigid endoscopy in these studies. The main goal of this study was to analyse possible adverse effects of this subxiphoid minimal-invasive endoscopic approach and to establish a standardised protocol while evaluating the use of flexible and rigid endoscopy for epicardial lead implantation using a custom-made electrode. We anticipate finding out why this method has not been brought forward to clinical application.

2. Materials and methods

The appropriate local governmental institution approved the experimental protocol (LANUV No. 8.87.50.10.37.09.15). The experimental animals received humane care in accordance with the applicable National Institutes of Health (NIH) publication (No. 86-23, revised 1985).

2.1. Model

A total of 17 healthy adult female pigs (German Land-schwein) with a mean weight of 80 (±8) kg were included in this study. The size and topography of the thoracic organs are conditionally comparable to humans, although the porcine chest only offers a small mediastinal tissue bridge between the anteriorly anchored pleural spaces [10,11].

2.2. Preparations

Anaesthesia was induced and maintained by continuous infusion of fentanyl and isoflurane gas. All animals were positioned supine, intubated orally with an endotracheal tube and mechanically ventilated. Each subject was in sinus rhythm for the duration of the procedure.

Each animal was fitted with a peripheral arterial and a central venous catheter for continuous pressure documentation and drug administration as well as 12-channel electrocardiogram (ECG) and conventional surface ECG.

Each trial began with the distinct inspection of the pericardial cavity, followed by the sequential implantation of four epicardial leads (see Section 2.3). Pacing parameters were derived consecutively just after implantation and after a period of 10 h with sequential atrioventricular (delay: 120 ms) and synchronous ventricular stimulation (see Section 2.5). During the observation time, pacing was not conducted. After measuring all electrodes, the macroscopic in vivo assessment of the heart and its surrounding tissue was carried out. Finally, the animal was euthanised and the heart explanted for macropathological assessments (see Section 3.5).

The method in detail is as follows.

2.3. Operation

A 10-mm incision was performed in the median subxiphoid region and the pericardial sac displayed by blunt dissection. Subsequently, the endoscope (exemplified in Fig. 1), rigid and/or flexible (Hopkins 28295AA, length: 350 mm; outer diameter: 5.7 mm; working channel: 3.6 mm/Choledochoskop 11292DE1, length: 300 mm; outer diameter: 5.2 mm; working channel: 2.3 mm, Karl Storz®), Tutlingen, Germany), was advanced just before the pericardium. Then, the pericardial sac was opened at a vessel-free site by grasping the tissue with endoscopic forceps (Karl Storz®, Tutlingen, Germany) and retrieving it quickly through the working channel. A J-wire was forwarded through the created pericardial hole, guiding the introduction of the endoscope into the pericardial cavity where the anterior free wall of the right ventricle was displayed at once.

Fig. 1. A rigid endoscope is being deployed percutaneously via a small subxiphoid incision. The insert shows the endoscope used (HOPKINS, Karl Storz® Germany). (a) Optical shaft, (b) light supply, (c) plastic tube, and (d) already placed electrodes.
Fig. 2. Inspection protocol. This draft shows the standardised inspection of the pericardial cavity using the coronary vessels (red) as guiding landmarks starting with the exploration of the (1) right ventricular (RV) anterior facies, moving further cranial to the (3) superior vena cava (SVC) after spotting the (2) right atrial appendage (RAA) and the right coronary artery; then moving left towards the (4) left atrial appendage (LAA) and further to the left side then caudal towards the anterolateral facies of the left ventricle (LV) spotting branches of the left coronary arteries; then moving dorsolateral displaying the epicardial surface of the (5) left ventricle; afterwards moving to the right on the dorsal portion of the pericardium (6) towards the inferior vena cava (IVC). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of the article.)

2.4. Lead implantation protocol

Before beginning lead implantation, a systematic inspection of the pericardial cavity was carried out in a standardised manner (as seen in Fig. 2). After displaying all four chambers, systematic lead implantation was commenced, beginning at the anterior facies of the right ventricle (RV), going upwards to the right atrial appendage (RAA), then to the left atrial appendage (LAA) and finally to the posterolateral aspect of the left ventricle (LV) (see Fig. 3). The anticipated pacing site was chosen by circumventing any vessels or other structures, which could either compromise the conduction of the pacing impulse or presumably cause injury to the heart in the long run. The electrode used is a newly designed small-calibre steroid-eluting bipolar lead (4-F) with a special minimised screw at its tip. Unfortunately, detailed description cannot be revealed at this time, because of ongoing approval process by Medtronic®. Using the small-calibre rigid and the flexible endoscopes, the electrode was implanted directly into the epicardium by advancing it through the working channel and implanting it tangential, not transmural, in an anticipated angle of 35° (±10°) by clockwise turning of the whole electrode under direct vision. Endoscopy gave the ability to directly observe the electrical and mechanical behaviour of the lead and its surroundings before and during stimulation (Fig. 3). Therefore, direct verification of the position, efficiency and, particularly, safety of the lead’s position was possible avoiding injury to adjacent epicardial and opposite pericardial structures, such as vessels, for instance, in the long run. To implant the next electrode, a guiding wire was inserted into the endoscope just inside the pericardial cavity and both endoscope and the trocar slowly withdrawn, leaving the just-implanted electrode in situ. Again, the endoscope and trocar were easily inserted, guided by the deposited wire.

After implanting all four electrodes, fluoroscopy was performed to document the leads’ position (Fig. 4).

2.5. Stimulation protocol

Pacing parameters (sensing (mV); impedance (Ω); unipolar capture threshold (V) and pulse duration: 0.5 ms) were derived instantly after implantation of the particular electrode and paced with sequential atrioventricular (delay: 120 ms) and synchronous ventricular stimulation. After 10 h, the pacing parameters were evaluated again and the same stimulation mode deployed (see Table 2). During the observation time of 10 h, pacing was not conducted. Capture thresholds beneath 2.5 V were accepted. Stimulation-frequency was 10 beats above intrinsic heart rate.

2.6. Macroscopic analysis

After an observation period of 10 h post-implantation and deepened anaesthesia, the chest was opened by median sternotomy. The organs were initially examined in situ to detect any injury to the heart and its surrounding tissue. Then, the animals were sacrificed by an overdose of thiopental and potassium. Subsequently, the heart was explanted to assess the insertion sites of the leads (angle and depth) and their quality of anchorage inside the epicardium (Fig. 5), and the endothelium and endocardium. Histological assessment was not carried out.

2.7. Statistical analysis

Data are reported as mean ± standard deviation (SD) unless otherwise specified.

3. Results

The subxiphoid approach presented itself as very suitable for reaching the pericardial sac on the shortest way with the least technical effort. In each individual, the pericardium was easily reached by VAPS without any complications in less than 5 min from skin incision (see Table 1). Bleeding or injuries of cardiac and non-cardiac structures (i.e., pneumothorax) were not documented. With the use of an insulating cover, relevant haemodynamic depression and/or malignant arrhythmia did not appear. Minimal bleeding was caused by ruptured adhesions in the 14th individual.

3.1. Rigid endoscopy

The introduction of the bare-metal rigid endoscope into the pericardial cavity frequently led to ventricular arrhyth-
mimia (ventricular extra systoles (VESs)) with consecutive haemodynamic depression. This phenomenon was considerably reduced by the use of a semi-rigid plastic tube (see Fig. 1). Used as a trocar, the plastic tube insulates the metal instrument against the epicardial surface. Comparison of VAPS with or without the application of the plastic tube was assessed in four individuals. By the application of this tool, VES min\(^{-1}\) was reduced notably.

3.2. Flexible endoscopy

In principle, the application of a small-calibre flexible endoscope is advantageous regarding the triggering of arrhythmia due to its non-metallic surface and to its freedom of movement compared with rigid endoscopes. However, the soft and flexible instrument could not withstand the heart’s movement, making well-directed manoeuvring and orientation very time consuming and technically extensive. Additional biplane fluoroscopic imaging was necessary to obtain some kind of orientation. The incidence arrhythmia was comparable to the trocar-covered rigid endoscope (VES\(_{\text{flexible}}\): 3.8 ± 1.7 min\(^{-1}\) vs VES\(_{\text{trocar}}\): 5 ± 1.9 min\(^{-1}\), \(n = 3\)). The application of a larger flexible endoscope, where more stability would be expected, was not conducted due to the infeasibility of sterilisation and therefore making their clinical application inside the pericardial cavity unattainable. Hence, the deployment of flexible endoscopy was abandoned after three individual trials due to the lack of proper steering ability, necessity of additional tools and high time consumption. Rigid endoscopy was deployed solely for the remaining individuals because it endorsed superior.

3.3. Adhesions

The 14th animal demonstrated massive intrapericardial adhesions after entering the pericardial cavity, implying an ongoing or recently healed intrapericardial inflammation, possibly comparable with patients who had previous cardiac surgery. The adhesions could be easily loosened or detached by blunt dissection by the endoscope to reach the implanta-
tion sites. During this manoeuvre, the animal had to be defibrillated once due to ventricular fibrillation.

3.4. Lead implantation

The access to the pericardium (<5 min) and to the implantation sites was quick (<10 min) and without any complications. Orientation and navigation was solely feasible by rigid endoscopy requiring no additional working or imaging tools, thus being able to reach and identify all intrapericardial structures quickly, easily and safely.

Implanting the epimyocardial leads was quick (<20 s), unproblematic and reproducible. The anticipated tangential implantation angle of 35°±15° could be easily applied by direct implantation of the lead through the working channel into the epicardium without any additional tools. Although pacing parameters were adequate after every initial implantation, deliberate repositioning was carried out in one trial to document possible adverse effects. Altering the implantation site was uncomplicated and easy without any bleeding complications. Intentionally created bleeding of the epicardium was successfully met by the direct application of saline-diluted adrenaline (1:100) without any systemic effects such as tachycardia or hypertension. The electrodes fitted well inside the working channel and did not dislocate after retracting the endoscope. The position stability of the electrodes demonstrated itself as excellent and secure, confirmed by endoscopy after 10 h, just before sternotomy. Lead dislodgement did not occur during the observation period. The capture thresholds were stable or even improved after 10 h and are summarised in Table 2.

After several hours, a thin fibrinous covering of the heart was seen regularly, most likely due to inflammation that did not compromise thresholds.

3.5. Post-mortem analysis

Macroscopic post-mortem examination did not show any relevant damage/injury and/or bleeding to the circumjacent tissue from skin-level to the pericardial entry site, and there was especially no pneumothorax. The pericardium appeared virtually intact despite the diameter of the inferior pericardial opening of 13±4 mm. A look at the closed, transparent pericardial sac confirmed the parallel position of the leads to the heart seen by biplane fluoroscopy caused by the corresponding character of the pericardium to the epicardium. In spite of this fact, intrapericardial structures did not show any injury whatsoever. There was no evidence of

Table 1. Time measured in minutes (min) from skin incision to particular site according to inspection protocol (see Fig. 1) in 17 animals.

<table>
<thead>
<tr>
<th>Pericardium (inferior)</th>
<th>RV (anterior facies)</th>
<th>RA (appendage)</th>
<th>LA (appendage)</th>
<th>LV (posterolateral facies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 ± 0.7 min</td>
<td>6 ± 1.2 min</td>
<td>6.7 ± 1.5 min</td>
<td>7.2 ± 1.5 min</td>
<td>9 ± 1 min</td>
</tr>
</tbody>
</table>

Table 2. Pacing parameters derived unipolar (pulse duration 0.5 ms) in 17 animals; data as mean ± SD.

<table>
<thead>
<tr>
<th></th>
<th>LV Base 10 h</th>
<th>RV Base 10 h</th>
<th>LA Base 10 h</th>
<th>RA Base 10 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>R-P-potential [mV]</td>
<td>17.3 (±1.9) 21.1 (±1.3)</td>
<td>17.3 (±1.9) 17.9 (±2.0)</td>
<td>3.7 (±0.9) 4.0 (±0.2)</td>
<td>4.7 (±1.9) 5.0 (±0.5)</td>
</tr>
<tr>
<td>Impedance [Ω]</td>
<td>615 (±67.7) 527 (±29.5)</td>
<td>570 (±67.7) 498 (±14.2)</td>
<td>699 (±36.3) 687 (±47.3)</td>
<td>615 (±27.9) 406 (±28.4)</td>
</tr>
<tr>
<td>Threshold [V]</td>
<td>1.9 (±0.2) 1.5 (±0.7)</td>
<td>2.0 (±0.4) 1.9 (±0.2)</td>
<td>1.1 (±0.2) 0.9 (±0.7)</td>
<td>1.0 (±0.3) 0.8 (±0.4)</td>
</tr>
</tbody>
</table>
haematoma, rupture or perforation at the implantation sites and the corresponding pericardium, which the lead’s movement may have caused after the observation time of 10 h (see Fig. 2). The electrodes showed excellent anchorage inside the myocardial tissue (penetration depths: 3 ± 1 mm) and resisted high tractive forces to the point of eradicating the lead with myocardium, although they were only implanted tangential not transmural.

4. Discussion

The present study shows the feasibility, pitfalls and safeguards of VAPS and introduces a standardised protocol for minimal-invasive epicardial pacemaker lead implantation from a subxiphoid approach. The major advantages of this method are: (i) broad accessibility to intrapericardial structures, (ii) short procedural duration, (iii) small trauma, (iv) avoiding pleural breach and (v) abdication of fluoroscopy.

Since the late 1950s, closed-chest endoscopy of the pericardial cavity was described on very few occasions in the literature and almost exclusively used for diagnostic means [12–16]. Only recently have Zenati et al. actually demonstrated the feasibility of epicardial lead implantation by VAPS [9]. Given these promising initial results, this method has not established itself in clinical practice. In fact, an increasing number of recent publications report good acute and long-term results of LV epicardial lead implantation in humans by VATS as an alternative approach [5–7,17–21]. Despite the comparably minor trauma to thoracotomy, the disadvantageous fact of pleural breach remains in each of these reports. Beyond that, VAPS allows multilateral exposure inside the pericardial space without changing the patient’s position while VATS frequently necessitates repositioning to reach opposing cardiac structures such as pulmonary veins, for instance. As opposed to VATS, we were able to demonstrate a very broad accessibility to all intrapericardial structures by VAPS. We also revealed possible pitfalls and consecutive safeguards. Unlike previous findings, we experienced malignant ventricular arrhythmia when the “bare” metal rigid endoscope was introduced inside the pericardial cavity. The rate of arrhythmogenic events was clearly reduced by the subsequent application of a custom-made plastic trocar. Adhesions, due to prior surgery of inflammation, might be a possible pitfall using VAPS. The 14th animal did show massive adhesions between the pericardium and the epicardial surface, possibly comparable to patients who had prior pericardial inflammation, whether based on previous surgery or pericarditis. We demonstrated that these adhesions could adequately be loosened or detached bluntly by the endoscope to reach the implantation sites.

The comparison of perioperative unfavourable events of transvenous and transthoracic pacemaker lead implantation regarding trauma, postoperative pain, hospital stay or procedural duration, for instance, clearly presents the transvenous approach as the less invasive and, therefore, more beneficial method (see Table 3). Extending this comparison to VAPS, we believe it would find its place somewhere in-between the aforementioned approaches. In contrast to the transthoracic approach, subxiphoid VAPS avoids chest wall manipulation/penetration while sharing similar minor trauma and short procedural duration approximating the transvenous technique. Preliminary results from our ongoing chronic ovine model are very promising and uphold the suppositions made in Table 3.

4.1. Study limitations

The shape of the porcine chest and the cardiac axis differs from human beings. The thorax is slightly protruding and the axis of the heart is rotated counter-clockwise, leaving the apex caudo-sagittal. Hence, the subxiphoid approach in a porcine model allows a parallel alignment of the endoscope to the heart’s axis. By contrast, the diaphragm facies of the human heart mainly consists of the right ventricle with its main axis being orientated to the left. To exclude inadequate exposure of epicardial structures in humans by VAPS from a subxiphoid approach, human cadaver trials were carried out. Although all four chambers, especially the posterolateral aspect of the left ventricle, were reached easily, the more dorsolateral orientated heart’s apex could not be reached entirely.

We were able to evade one of the main limitations of prior studies by using a custom-made epicardial electrode with good short-term electrical performance. However, one still has to await the long-term results of this custom-made electrode, especially with regard to the intrapericardial inflammatory reactions of the epicardium and pericardium following this operation. In addition, the long-term electrode’s behaviour and stability in a moving individual has to be assessed, given the fact that the animals were immobilised during general anaesthesia. However, the majority of the animals used in this trial and previous studies were healthy (except animal number 14) with normally dimensioned hearts. Adverse effects on the dilated and diseased heart are yet to be assessed with regard to arrhythmia and haemodynamic tolerance as well as to possibly limited working space. Furthermore, to complete CRT, defibrillator electrodes have to be implanted, which was done neither in previous groups nor in our trial.

5. Conclusion

Small-calibre flexible endoscopy is not suitable for exclusive deployment inside the pericardial space. For the use of bare-metal endoscopes inside the pericardial cavity,
insulating coverage is mandatory to avoid malignant arrhythmia with haemodynamic depression. By doing so, rigid endoscopy presents itself as a safe, fast and simple approach for epimyocardial lead implantation. It permits optimal lead positioning under direct vision without fluoroscopy, without the breach of the pleural space and with a short procedural duration (<60 min). Our standardised minimal-invasive approach allows visualisation and intervention, potentially of all intrapericardial structures. Considering the precise allocation of the latest point of ventricular contraction by today’s 3D imaging techniques (whether by magnetic resonance imaging (MRI) or by echocardiography) and taking the broad accessibility and orientation by VAPS into account, one could target the optimal implantation site prior to surgery [22–25]. This fact could reduce the occurrence of non-responders in CRT by far.

References


Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ejcts.2010.06.016.