Initial Clinical Experience with PerDUCER® Device: Promising New Tool in the Diagnosis and Treatment of Pericardial Disease

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Summary

Background: The idea to enter the normal pericardial sac safely was unrealistic until recently. The development of a novel instrument (PerDUCER® pericardial access device) for percutaneous access to the pericardium could potentially have a significant impact, not only on patients with pericardial diseases but even more, or primarily, on diagnosis and treatment of myocardial and coronary disease and arrhythmias.

Hypothesis: The overall objective of the present study was to evaluate the feasibility and safety of the percutaneous pericardial access with PerDUCER in patients with pericardial disease, and to analyze our initial experience with this new technique, with particular emphasis on sequential procedural steps.

Methods: The device was studied in five patients with pericardial disease (two men, mean age 50.4 years, range 30–68, four with normal body mass index). The procedure consists of two distinct techniques: (1) access to the mediastinal space, and (2) pericardial capture, puncture, and insertion of the guidewire. Access to the mediastinal space includes the introduction of a blunt cannula, a 0.038 guidewire, a dilator-introducer sheath set, and insertion of the PerDUCER device. Key points of the PerDUCER procedure are as follows: introduction of the blunt cannula without resistance, placement of the dilator-introducer sheath at the upper third of the heart, systolic movements of the PerDUCER device, successful vacuum and capture of pericardium, puncture and introduction of the intrapericardial guidewire.

Results: Access to the mediastinal space was accomplished in four of five patients, as were pericardial capture and probably puncture. However, despite numerous successful captures and probably punctures of pericardium, we were not able to confirm introduction of the intrapericardial guidewire into the pericardial cavity in any of our patients (0/5). The procedure was very well tolerated in all patients (5/5). No major complications developed during the procedure, bearing in mind that the intrapericardial placement of the guidewire was not achieved. Minor complications included pain at the dilator-introducer sheath entry site (5/5) and mild transient fever (2/5).

Conclusions: According to the present experience, we believe that, with minor modifications, the PerDUCER device could be successfully implemented for pericardial entry in patients with pericardial disease. Further studies are needed to evaluate the feasibility and safety of this new instrument in patients with a normal pericardium. This could open a most exciting spectrum of possible implementations of the device in the future.

Key words: pericardium, pericardiocentesis, pericardial effusion, new devices

Introduction

Since a Spanish physician, Romero, first performed successful closed puncture of the pericardium in 1803, various approaches to the pericardium have been attempted.1 Pericardiocentesis became a routine procedure worldwide because of its excellent clinical efficacy and prompt lifesaving effect. Although reported by numerous investigators as convenient, low cost, and less troublesome than surgery, it has been associated with a significant risk of complications, higher than during cardiac catheterization and a number of invasive procedures.2–4 The probability of both success and complications of pericardiocentesis are mainly related to the volume, location, and loculation of the pericardial effusion. The procedure is most likely to be successful when performed in patients with an echocardiographically free space of 10 mm or more, and with anterior effusions.5
Until recently, the idea of safely entering the normal pericardial sac or pericardium with minimal effusion was only a dream. The potential diagnostic and therapeutic implications of such an approach have fascinated cardiologists for more than a century. A new concept in approaching pericardial space has been developed, and a novel instrument (PerDUCER® Pericardial Access Device, Comedicus Inc., Columbia Heights, Minnesota) for percutaneous access to the pericardium was introduced. After meticulous experimental evaluation of this device in the animal setting, it became clear that this technique could potentially have a tremendous impact not only on patients with pericardial diseases, but even more, or primarily, for diagnosis and treatment of myocardial and coronary disease and arrhythmias. If this technology meets expectations, the pericardial space may be employed to apply therapeutic agents directly on the epicardial surfaces of the heart and coronary arteries. Such implementation could provide more effective and extended drug action, no agent loss into the circulation, and few side effects.

Before routine use of this device in humans, various technical aspects of its practical application need to be clarified. Therefore, the overall objective of the present study was to evaluate the feasibility and safety of percutaneous pericardial access with the PerDUCER device in patients with pericardial disease and to analyze our initial experience with this new technique, with particular emphasis on sequential procedural steps.

**Methods**

**Patients**

The baseline characteristics of the patients in whom the PerDUCER device was employed are demonstrated in Table I. In June and July 1998, five patients (two men, mean age 50.4 years, range 30–68), four with normal body mass index, underwent the pericardial access procedure using the PerDUCER device. The mean duration of pericardial disease was 55 days (range 14–90 days). Two patients had idiopathic pericardial effusion, in another two pericardial effusion was due to an acute viral illness, and one patient suffered from neoplastic pericardial disease. Pericardial effusion assessed by echocardiography anterior to the right ventricle (RV) ranged from 0.8 to 2.2 cm (mean 1.6 cm). Four patients had no previous pericardial procedures, while the patient with a neoplastic effusion had emergency pericardiocentesis necessitated by cardiac tamponade (600 ml of hemorrhagic effusion evacuated, 32 days before the PerDUCER procedure). Subsequently, pericardial effusion recurred in this patient (range 0.6–0.8 cm). Therefore, at the time of the PerDUCER procedure, all five patients had moderate to large pericardial effusions, without signs of cardiac tamponade. In two patients pericardial thickness was measured by both transesophageal echocardiography (TEE) and magnetic resonance imaging (MRI). The values obtained were comparable for TEE and MRI and were 2–3 mm and 1.7–2 mm, respectively. Magnetic resonance imaging measurement of the pericardium thickness in patient No. 5 is shown in Figure 1.

**Abbreviations:** F = female, M = male, BMI = body mass index, RV = right ventricle, TEE = transesophageal echocardiography, MRI = magnetic resonance imaging.

**FIG. 1** Magnetic resonance imaging measurement of the pericardial thickness in Patient No. 5 revealing 2 mm in front of the right ventricle (black arrow).

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Age</th>
<th>Sex</th>
<th>BMI (kg/m²)</th>
<th>Duration of disease (days)</th>
<th>Etiology</th>
<th>Pericardial effusion by TEE (cm)</th>
<th>Pericardial thickness by MRI (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>56</td>
<td>F</td>
<td>18.1</td>
<td>90</td>
<td>Idiopathic</td>
<td>2.2</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>30</td>
<td>M</td>
<td>21.3</td>
<td>14</td>
<td>Viral</td>
<td>2.0</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>68</td>
<td>M</td>
<td>25.2</td>
<td>60</td>
<td>Neoplastic</td>
<td>0.8</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>50</td>
<td>F</td>
<td>27.5</td>
<td>21</td>
<td>Idiopathic</td>
<td>2.0</td>
<td>2 mm</td>
</tr>
<tr>
<td>5</td>
<td>48</td>
<td>F</td>
<td>26.4</td>
<td>90</td>
<td>Viral</td>
<td>0.9</td>
<td>2–3 mm</td>
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</table>

**TABLE I Baseline characteristics of patients with pericardial effusion who underwent PerDUCER procedure**
The PerDUCER Device: Features Related to Clinical Application

The device is essentially a sheathed needle, 35.6 cm (14") long, constructed of a 21 gauge stainless steel introducer needle located inside a stainless steel sheath. The proximal end of the PerDUCER device consists of a thermoplastic handle capable of counterclockwise rotation, which controls radial and axial movement of the introducer needle. Furthermore, the handle has both markings for rotation of the introducer needle and an integrated female luer vacuum side port. At the distal tip of the instrument there is a viewing tube with a hemispherically shaped side-hole cavity, where the pericardium is captured by vacuum and tangentially punctured by the introducer needle.

The PerDUCER Device: A Comprehensive Overview of Feasibility

All procedures were performed in the cardiac catheterization laboratory. Patients were extensively informed about the potential benefits and risks of the procedure and were requested to sign a written consent form.

Before approaching the pericardium, right heart catheterization and RV angiography were performed to reveal the RV contour, especially its inferior border. Such an approach, in most cases of standard pericardiocentesis, prevents the puncture or damage of the RV. The pigtail catheter remains in the RV for occasional manual dye injections, which improves orientation during the procedure. Therefore, such an approach was also followed before the PerDUCER procedures.

A pericardial access procedure with the PerDUCER device consists of two distinct techniques: (1) access to the mediastinal space, and (2) pericardial capture, puncture, and insertion of the guidewire.

Access to the Mediastinal Space

After administration of local anesthesia (20 ml 2% lidocaine), a small stab wound incision was made, just below the xiphoid process in the median line. The blunt cannula was introduced subsecnally until the mediastinal space was entered. At this point, it was important to perform RV manual injections from the previously placed pigtail catheter to improve the orientation and avoid possible complications. The use of the left lateral angiographic view was mandatory for optimal visualization of the cannula advancement and relations to the RV. Usually, entry into the mediastinal space was with minimal resistance, and therefore, if higher resistance is felt, caution should be exerted. The direction of the puncture should be as parallel as possible with the sternum. After placement of the cannula in the mediastinal space, an 0.038 guidewire was subsequently advanced and could be seen to move freely in the mediastinal space.

Instead of inserting and positioning the dilator-introducer sheath over the guidewire in one stage as recommended, we felt that it is more appropriate to perform gradual, subsequent dilation of the tunnel created with 8, 10, 12, 14, 16, and 19F dilators. Moreover, placement of large dilators could be painful in some patients, and therefore 2 ml thalamonal intravenously (IV) (fentanyl 0.05 mg + droperidol 2.5 mg/ml) was applied. Step-by-step dilation prevented difficulties during introducer sheath placement, particularly in obese patients, as we encountered in two cases (2/5). Figure 2 demonstrates the proper position of the 19F introducer in the mediastinal space, with guidewire inserted. Nonetheless, the current introducer sheath probably needs to be stiffer in order to provide more pushing force and to avoid kinking or collapse. Furthermore, sheath radio-opacity needs to be improved to facilitate its positioning. When the tip of the dilator-introducer sheath was placed at the upper third of the heart (left lateral angiographic view), both the dilator and the guidewire could be withdrawn. At this point, we found it very useful to inject 50% diluted angiographic contrast through the sheath to visualize its position in the mediastinal space and relation to the heart, as shown in Figure 3. This maneuver proved useful in three (3/5) of our patients, allowing the operator to achieve the desired sheath position and eventually to optimize the pericardial access site.

After loading of the intrapericardial guidewire and connection with the vacuum syringe, the PerDUCER device was inserted into the introducer sheath and advanced under fluoroscopic control until contact with the pericardium. Rarely, advancing the device can be difficult due to bending, kinking, or collapse of the sheath, a phenomenon we experienced in one case (1/5). Placement of the distal tip of the PerDUCER device over the correct pericardial access site is perhaps one of the key points of the procedure.

Pericardial Capture, Puncture, and Guidewire Insertion

Proper contact of PerDUCER device and pericardium was confirmed by its movements simultaneously with heart beats. This was an important sign of successful progress of the pro-
procedure and could be seen clearly from outside the chest. We observed this phenomenon in four of our patients (4/5). In achieving the optimal PerDUCER device position, it was essential to place the flattened surface of the viewing tube against the target pericardial site. Figure 4 reveals a correct device placement and its position in relation to the heart. After close contact with the pericardium was secured, a vacuum using the 20 ml syringe was drawn to capture a pericardial “bubble” into the hemispheric cavity of the viewing tube. A successful vacuum could be recognized as sustained tension on the syringe plunger, which we encountered in numerous instances in four of our patients (4/5).

Advancing the handle of the device moves the needle tangentially and punctures the pericardial “bubble” without risking of any damage. The puncture position of the needle can be seen easily on fluoroscopy, as depicted in Figure 5. After advancing the puncturing needle and the guidewire, the vacuum on the syringe is diminished or lost. The intrapericardial guidewire should then be inserted through the needle and placed into the pericardial space. The intrapericardial position of the guidewire is not easy to recognize, and therefore it should be verified in several angiographic views. When the guidewire is in the pericardium, the needle should be retracted and the PerDUCER device withdrawn. The intrapericardial guidewire can then be used to introduce other diagnostic or therapeutic devices.

All patients received a prophylactic antibiotic regimen (gentamycin 80 mg IV b.i.d., ampicillin 500 mg orally q.i.d. for 3 days) starting on the day of the intervention. Most patients could be discharged a day or two after the procedure.

**Results**

The most important procedural data are presented in Table II. Access to the mediastinal space was accomplished in four of five patients, as were pericardial capture and probably puncture. However, despite numerous successful captures and probable punctures of the pericardium, we were not able to confirm introduction of the intrapericardial guidewire into the pericardial cavity in any of our patients (0/5). Figure 5 illustrates a failed attempt of intrapericardial guidewire placement and its position in the mediastinal space.

The pericardial access procedure with the PerDUCER device was very well tolerated in all patients (5/5). No major complications developed during the procedure, keeping in mind that intrapericardial placement of the guidewire was not achieved. Minor complications included pain at the dilator-introducer sheath entry site (5/5) and mild transient fever (2/5). Pain was successfully treated with the above-mentioned IV analgesics.

Since two of five patients with a large pericardial effusion needed pericardiocentesis for diagnostic reasons, standard...
pericardial puncture was performed following the PerDUCER device study. The amounts of pericardial fluid obtained was 1200 and 700 ml.

Discussion

Cumulative experience with the PerDUCER device comprises animal experiments, studies on human cadavers, and clinical experience in patients undergoing cardiac surgery. Animal experiments were conducted mostly on pigs and were focused on procedural technique, hemodynamic considerations, the extent of myocardial and pericardial trauma, and therapeutic applications of the method. Studies on cadavers highlighted the technique performance within human anatomy and the potential technical drawbacks of the device. These studies are considered highly informative and successful, supporting the plans for clinical trials. Open-chest experience with the PerDUCER device has been conducted in eight patients, in whom the pericardium was captured, punctured, and the guidewire successfully inserted into pericardium without complications.

One of the key points of the procedural success in interventional cardiology is a proper indication for the particular method. The PerDUCER device is designed for puncture of both diseased and healthy pericardium. In patients with pericardial effusions, the device may replace standard pericardiocentesis as a more efficient and safer method. However, as already pointed out, the first experimental and open chest studies were designed and performed in subjects with a normal pericardium, highlighting new, more attractive diagnostic and therapeutic indications, unknown before in human medicine.

In contrast to previous experience, in the present study the PerDUCER device was used in patients with pericardial effusion, in a closed chest setting, with local anesthesia, and in the cardiac catheterization laboratory. Therefore, the conditions of our study corresponded to circumstances in which the device should be applied most frequently or exclusively in the future. In analyzing every sequential procedural step, some of the key points can be identified, as shown in Table III.

The use of RV angiography at this very early stage of application of the instrument was very instrumental in avoiding complications. Because of the simple design of the PerDUCER device, it is obvious that for the trained interventional cardiologist the learning curve will be rather short, and for other cardiologists very acceptable.

Despite several advantages of the instrument, introduction and placement of the intrapericardial guidewire was not accomplished. The potential reasons for failure can be classified into three groups: insufficient number of patients, erroneous patient selection, and the need for minor technical improvements of the device.

No definite conclusions about a new technology may be based on experience with five patients. Furthermore, all patients in this study had pericarditis of significant duration (mean 55 days) and associated with effusion (mean 1.58 cm). Taking into account these factors, one can hypothesize that in this patient cohort the thickness and/or elastic properties of the pericardium were increased abnormally, with augmentation of its fibrotic component. To elucidate this issue, we measured the pericardial thickness in two patients by both TEE and MRI and obtained values that were within the normal range. Nonetheless, significant effusion can produce tension on the pericardium, which is a clear impeding factor for capture and puncture. The same is true for pericardial fat that can easily obstruct the hemispheric side-hole cavity of the viewing tube and prevent capture. In addition, under the conditions of a thick and stiff pericardium, the side-hole cavity is inadequately small in both size and depth to enable capture. For the same reason, the vacuum intensity may not be sufficient to provide capture, and other means for generating a stronger vacuum, including electrical suction, may be needed.

| Table II | PerDUCER procedure: Procedural data |
| --- | --- | --- | --- | --- |
| Patient No. | Access to the mediastinal space | Pericardial capture and probably puncture | Insertion of the guidewire | Standard pericardiocentesis after the PerDUCER study | Pericardial effusion obtained by pericardiocentesis (ml) | PerDUCER complications |
| 1 | No | No | No | Yes | 1200 | No |
| 2 | Yes | Yes | No | Yes | 700 | No |
| 3 | Yes | Yes | No | No | — | No |
| 4 | Yes | Yes | No | No | — | No |
| 5 | Yes | Yes | No | No | — | No |

<table>
<thead>
<tr>
<th>Table III</th>
<th>Key points of the PerDUCER procedure</th>
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<tbody>
<tr>
<td>Introduction of the blunt cannula without resistance</td>
<td></td>
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<tr>
<td>Placement of the dilator-introducer sheath at the upper third of the heart</td>
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<td>Systolic movements of PerDUCER</td>
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<td>Successful vacuum and capture of pericardium</td>
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<tr>
<td>Puncture and introduction of intrapericardial guidewire</td>
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</table>
Conclusions

A new percutaneous pericardial access device, PerDUCER, was studied in five patients with pericardial disease. The procedure consists of two distinct techniques: (1) access to the mediastinal space, and (2) pericardial capture, puncture, and insertion of the guidewire. The access to the mediastinal space (the introduction of a blunt cannula, a 0.038 guidewire, a dilator-introducer sheath set, and the PerDUCER device) was successfully achieved in four patients. Pericardial capture and probable puncture were also accomplished in numerous instances in four patients, but despite this we were not able to confirm introduction of the guidewire into pericardial cavity in any of our patients. The procedure with PerDUCER device was very well tolerated in all patients (5/5). No major complications developed during the procedure, while minor complications included pain at the dilator-introducer sheath entry site (5/5) and transient fever. It is our impression that this procedure is as well tolerated as cardiac catheterization.

According to the present experience, we believe that with minor modifications the PerDUCER device could be successfully implemented for pericardiocentesis in patients with pericardial disease. Further studies are needed to evaluate the feasibility and safety of this new instrument in patients with a normal pericardium. This could open a most exciting spectrum of implementations for intrapericardial diagnostics and therapy in the future.

References