Minimally Invasive Access of the Normal Pericardium: Initial Clinical Experience with a Novel Device

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Summary: The pericardial space is being investigated as a reservoir for local drug delivery to the heart and coronary arteries. Intrapericardial drug delivery is currently limited because the pericardial space is normally small and difficult to access by standard pericardiocentesis without invasive surgery or risk of cardiac injury. Clinical trials are being conducted to evaluate a novel, minimally invasive, pericardial access device (PerDUCER®, Comedicus Inc., Columbia Heights, Minn.). As of October 26, 1998, 12 clinical trials have been completed on patients undergoing cardiac surgical procedures. In all patients, a stab incision was made 1” subxiphoid and a 17G angled cannula, with preloaded guidewire, was advanced into the mediastinal space. After cannula removal, a 19F sheath/dilator was inserted over the wire. In eight patients, a median sternotomy was performed and the position of the sheath over the anterior pericardium (PC) was visually verified. Four patients underwent a closed-chest, fluoroscopy-assisted procedure. In all patients, the PerDUCER was inserted into the chest, via the sheath, and positioned over the PC. The PC was captured by suction and a bleb was formed within a side-hole on the PerDUCER tip. A sheathed needle was advanced, puncturing the isolated bleb of PC. A guidewire was advanced through the needle into the pericardial space and the PerDUCER was removed. Guidewire insertion was successful in 10 patients (7 on first attempt, 3 on second) without adverse hemodynamic effects or arrhythmia. Other than the guidewire insertion site, there was no evidence of injury to the PC or the heart. These initial clinical trials suggest that the PerDUCER may provide safe, rapid and effective percutaneous insertion of a guidewire into the normal pericardial space.

Key words: intrapericardial access, pericardiocentesis device, minimally invasive

Introduction

The pericardial space has been proposed as a new route for local drug administration and device insertion to the heart and coronary arteries. Angiogenesis,1, 2 antithrombotic,3 antiarrhythmic,4, 5 cardioprotective,6 and percutaneous transluminal coronary angioplasty restenosis7 therapies are being investigated. Intrapericardial drug delivery has not been utilized for heart-specific treatments where the pericardium is normal because the pericardial space is small and very difficult to access by standard pericardiocentesis techniques without invasive surgery or risk of cardiac injury. This report describes the initial U.S. clinical trials of a novel, minimally invasive pericardial access device (PerDUCER), designed specifically to provide safe and effective access to the normal pericardium.

Materials and Methods

The PerDUCER (Comedicus Incorporated, Columbia Heights, Minn.) is a percutaneous, sheathed-needle, pericardial access device that is designed to avoid injury of the heart during pericardial catheterization. The device consists of a 21-gauge needle housed inside a 12 French stainless steel sheath tube 20 cm in length. One end of the sheath tube is bonded to a plastic handle with a side-arm port that is connected to a suction syringe. The proximal end of the needle passes through a seal in the handle and is attached to a rotating assembly, on the outside of the handle, which controls the rotational and axial movement of the needle. A Tuohy Borst adapter is bonded to the rotating assembly and connects to the needle. A 0.018” J-tipped guidewire is preloaded into the needle and sealed by the Tuohy adapter. The distal end of the sheath tube is bonded to a
plastic tube with a tapered end and a half-moon shape (18.5 French maximum OD). The flat portion of the tube, intended to be placed on the pericardial surface, has a hemispherical-shaped, 4.8 mm OD side-hole which communicates with the suction lumen and also contains the travel of the needle point. Inside this isolation well is where pericardial capture and needle puncture are accomplished. The PerDUCER has “P” and “I” markings located on the rotating assembly to denote proper needle position for pericardial “Puncture” and guidewire “Insertion,” respectively.

Clinical trials of the PerDUCER pericardial access device have been conducted on 12 patients undergoing cardiac surgery under a Non Significant Risk Protocol from the IRB (Phase I Safety Study, open-chest, and Phase II Efficacy Study, closed-chest). The clinical study protocols were approved by the Institutional Review Board of Spring Branch Medical Center, Houston, Texas. Informed consent was obtained from all patients prior to surgery. Inclusion criteria included patients with no history of prior cardiac or thoracic surgery (sternotomy or thoracotomy); no active cardiac ischemia or arrhythmia; no myocardial infarction within 72 h of study; and stable cardiac, neurologic, pulmonary, coagulation, and renal function.

PerDUCER insertion was performed following induction of anesthesia with continuous hemodynamic and electrocardiogram (ECG) monitoring. In all patients, a small stab incision was made approximately 1” below the xiphoid process. A 17-gauge curved blunt cannula, preloaded with a 0.038” J-tipped guidewire, was inserted subcutaneously and carefully advanced, with the cannula curve directed toward the posterior surface of the sternum, through the diaphragm, and into the anterior mediastinal space. The guidewire was advanced through the cannula and observed to move freely in the mediastinal space. The cannula was removed and a 19 French sheath/dilator was inserted over the mediastinal guidewire. The dilator was unlocked from the outer sheath and withdrawn along with the guidewire, leaving the introducer sheath located in the anterior mediastinal space.

In eight patients a median sternotomy was performed, with minimal retraction, and the position of the sheath over the anterior pericardial surface was visually verified (Phase I studies). Four patients underwent closed-chest, fluoroscopy-assisted PerDUCER placement (Phase II studies). In all patients, the PerDUCER was inserted into the chest, through the sheath, and orientated with its tip located in the mediastinal midline approximately at nipple level. The side-hole on the flat plane of the device tip was placed against the pericardial target site. Using gentle downward force, the PerDUCER was moved in a back-and-forth motion in order to dissect a plane under the pericardial fat pad with the tapered end of the device.

The PerDUCER was first set in the “Puncture” position (needle retracted, needle bevel up) by aligning the “P” on the rotating assembly with the pin on the handle (Fig. 1A). Pericardial capture was accomplished by pulling back on the plunger of the suction syringe, connected to the PerDUCER handle, until resistance to further withdrawal was obtained. As suction was maintained, a pericardial bleb was formed within the side-hole well, thus isolating the pericardium away from the epicardial surface of the heart. Pericardial puncture was accomplished by briskly pushing the rotating assembly forward and advancing the needle (Fig. 1B). The rotating assembly was rotated 180° fully counter-clockwise to position the needle bevel opening (pointing downward toward the heart) for insertion of the intrapericardial guidewire (Fig. 2A). Suction was no longer required with the syringe because the pericardium is trapped in the side-hole bleb chamber by the full excursion of the needle (Fig. 2A). The Tuohy adapter was loosened by turning counter-clockwise and the guidewire was advanced 15 to 20 cm into the pericardial space (Fig. 2B). Proper placement of the guidewire was verified by observation of a characteristic loop defined by the margins of the pericardial sac. The rotating assembly was pulled back, aligning the “I” marking with the pin on the handle, thereby retracting the needle within the sheath tube (Fig. 2B). The PerDUCER was slowly withdrawn through the introducer sheath, leaving the intrapericardial guidewire in place. Following PerDUCER removal the chest was opened. The location of the intrapericardial guidewire was verified and photographed, and a small section of pericardium, at the guidewire insertion site, was excised for histologic examination.

Fig. 1 Illustration of the PerDUCER pericardial access device showing its handle, suction syringe, and cross section (close-up) of tip, pericardium, and myocardium during suction capture of the pericardium (A) and pericardial puncture (B).
Results

As of October 26, 1998, 12 clinical trials have been completed on patients undergoing cardiac surgical procedures at Spring Branch Medical Center, Houston, Texas. The patients (8 men, 4 women) ranged in age from 49 to 80 years (mean 66), and had an average height of 172 cm and weight of 90 kg. Guidewire insertion was successful in 10 patients (7 on the first attempt and 3 on the second attempt) without adverse hemodynamic effects (stable heart rate, aortic pressure, pulmonary artery pressure) or arrhythmia. The two technically unsuccessful procedures were both closed-chest cases. For the first, the guidewire was believed to be properly positioned intrapericardially, as determined fluoroscopically, but the guidewire was dislodged during the performance of the sternotomy. For the second, the guidewire was extrapericardial and located in the pericardial fat pad. The total procedure time from subxiphoid cannulation to intrapericardial guidewire insertion, via the PerDUCER, was < 15 min. Other than the guidewire insertion site, there was no evidence of injury to the pericardium or heart.

Discussion

Knowledge of the pericardium dates back to the time of Galen (129–200 AD), the Greek physician and anatomist who gave the pericardium its name. The pericardial sac surrounds the heart like a glove enfolds a hand and the pericardial space is naturally fluid-filled. The normal pericardium functions to prevent dilatation of the chambers of the heart, lubricates the surfaces of the heart, and maintains the heart in a fixed geometric position. It also provides a barrier to the spread of infection from adjacent structures in the chest and prevents the adhesion of surrounding tissues to the heart.8, 9 The normal pericardial space is small in volume and the fluid film within it is too thin to separate the heart functionally from the pericardium. When fluid is injected into the normal pericardial space, it accumulates in the atrioventricular and interventricular grooves, but not over the ventricular surfaces.10

Pericardiocentesis, or puncture of the pericardium, is indicated for (1) withdrawal of pericardial fluid for the treatment of cardiac tamponade, (2) diagnosis of pericardial disease(s) by study of the pericardial fluid, and (3) infusion of therapeutic agents for the treatment of malignant effusion or tumors. Clinically, drugs that have been injected into the pericardial space include antibiotic (sclerosing) agents,11–18 antineoplastic drugs,19–21 radioactive compounds,22 and fibrinolytic agents.23 The pericardiocentesis procedure is conducted by experienced personnel in the cardiac catheterization laboratory with equipment for fluoroscopy and ECG monitoring. Electrocardiographic monitoring of the procedure using the pericardiocentesis needle as an electrode is commonly employed.24–27 Use of an echocardiographic transducer has also been utilized to guide the pericardiocentesis needle.28, 29 Complications associated with conventional needle pericardiocentesis include laceration of a coronary artery or the right ventricle, perforation of the right atrium or ventricle, puncture of the stomach or colon, pneumothorax, arrhythmia, tamponade, hypotension, ventricular fibrillation, and death. The complication rates for conventional needle pericardiocentesis are increased in situations where the pericardial space and fluid effusion volume are small.

Intrapericardial drug delivery has, as yet, not been clinically utilized for heart-specific treatments where pericardial pathology is normal, because the pericardial space is small and very difficult to access without invasive surgery or risk of cardiac injury by standard needle pericardiocentesis techniques. Transvenous methods of pericardial catheterization have been investigated involving puncture of the right atrium with a needle-catheter assembly2, 30, 31 and puncture of the right ventricle with a helix-needle catheter.7, 32, 33 The major limitation of these methods, in contrast to the PerDUCER, is that the right atrial or ventricular wall is penetrated, which could lead to bleeding into the pericardial space. In addition,
these methods involve a bolus injection of drugs, rather than long-term delivery via an indwelling catheter.

Conclusion

The results from these initial clinical trials suggest that the PerDUCER may provide safe and effective percutaneous guidewire insertion into the normal pericardial space.

References

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