Chapter 4: Development of a New Introduction Technique for the Pulsatile Catheter Pump

Abstract

The Pulsatile Catheter (PUCA) pump is an intra-ventricular blood pump that can be introduced into the left ventricular cavity through a superficial artery (trans-arterially) or directly through the thoracic aorta during open-chest conditions. When positioned, the pump aspirates blood from the left ventricle and transports it into the ascending aorta. A pneumatic driving system allows the blood to be ejected in early diastole of every second or third heart beat.

The main goal of this study was to develop an easy, fast, and safe surgical introduction technique. Four different ways of catheter introduction were tested in 20 acute open-chest experiments with calves: without any guidance at all, by X-ray guidance only, by using a guide-wire plus X-ray guidance, and by using a guiding pressure catheter. Introducing the PUCA pump catheter into the LV cavity by using a pigtail guiding pressure catheter proved to be easy to perform. The large-bore pump-catheter followed the guiding catheter and passed the aortic valve well. The position of the PUCA pump could be monitored from the pressure patterns derived from the guiding catheter.

*Artificial Organs* 1997, 21: 425-427
Introduction

The Pulsatile Catheter (PUCA) pump is an intra-ventricular blood pump that can be used as a Left Ventricular Assist Device (LVAD). The device consists of an extracorporeally placed, pneumatically driven membrane pump connected to a valved 6-mm or 8-mm external diameter indwelling polyurethane catheter. The PUCA pump is ECG triggered and aspirates blood from the left ventricle (LV) and ejects it into the ascending aorta during the diastolic phase of every second or third heart beat. Thus the PUCA pump combines left ventricular unloading with counter-pulsation, creating a pulsatile flow. In case of severe cardiac arrhythmia or signal disorders, the pump driver switches automatically to an untriggered mode.

The aim of this study was to find an easy, fast, and safe introduction technique for the PUCA pump that can be used in open-chest conditions as well as in peripheral transarterial applications.

Materials and Methods

Twenty Frisian-Holstein calves of either sex, ranging in body weight from 59 to 78 kg were used for the animal experiments. A left thoracotomy was performed by removing the 5th rib. An 18-mm, 300-mm long woven Dacron graft, beveled to 60 degrees, was sutured end-to-side to the proximal part of the descending thoracic aorta by partial clamping. After placement of aortic and LV pressure lines the PUCA-pump catheter was placed into the graft and was secured in such a way that no blood loss occurred when the aortic clamp was opened. All experiments were performed with a 40-cm long, large-bore (8-mm external diameter) valved catheter connected to a 60-ml membrane pump (Polymedica, Aachen, Germany). The introduction of the PUCA-pump into the left ventricular cavity was attempted in four different ways (N.B. More than one introduction technique was tested in some experiments!): without any guidance at all (n=5), by X-ray guidance only (n=3), by using a J-tip guide-wire plus X-ray guidance (n=3) and by using a guiding pressure catheter only [7 French single lumen pigtail catheter, Cordis, Roden, The Netherlands, (n=14)] - Fig. 1. In the last group the blood pressure at the tip of the guiding catheter was continuously monitored. After introduction of the guide-wire or the guiding catheter within the LV outflow tract, the PUCA pump was pushed over the guide-wire/catheter to the LV until the tip of the PUCA pump reached the tip of the guide-wire/catheter (this position was marked on the wire/catheter). The guide-wire/catheter was then removed, the membrane pump was filled with saline, connected to the PUCA pump, and pumping was started.
Introduction Technique

Fig. 1. The PUCA pump with guiding pressure catheter and membrane pump

The position of the PUCA pump tip was controlled by:
1. Palpation of the PUCA pump valve system in the aorta
2. X-ray monitoring
3. Pressure recordings from the guiding catheter
4. Monitoring left ventricular and aortic pressure patterns during PUCA pump assist
5. Examination of the left ventricular outflow tract at the end of each experiment, after the animals were sacrificed.

Results

No guidance at all

Passing the aortic valve with the large-bore pump-catheter without guidance proved impossible. The tip of the PUCA pump catheter either blocked at the point of the arising of the brachiocephalic trunk, moved in a wrong direction (into the brachiocephalic trunk), or could not pass the aortic valve. In three experiments the left main coronary artery flow decreased rapidly when the PUCA pump catheter was blocked into the aortic valve. When the catheter was removed from the aortic valve, the coronary flow was restored immediately to the normal level. Verification of the position of the tip of the catheter by palpation of the left ventricle was very hazardous, since every ventricular palpation caused ventricular extrasystoles with a possibility of ventricular fibrillation.
Passage of the aortic valve using X-ray guidance only was difficult to accomplish. The position of the PUCA pump could be determined by X-ray examination: the valve housing showed good X-ray contrast, but the contrast of the metal cage at the tip of the PUCA pump was poor. Also, as in the experiments for introduction without any guidance at all, the tip of the PUCA pump either blocked at the point of the arising of the brachiocephalic trunk, moved in a wrong direction (into the brachiocephalic trunk) or could not pass the aortic valve.

Efforts to use a guide-wire with X-ray control to introduce the PUCA pump into the LV failed. Passing the aortic valve with the J-tip guide-wire was relatively easy, but keeping the tip of the guide-wire positioned when the PUCA pump was pushed towards the LV proved more problematical. Also, an excessively deep position of the guide-wire in the left ventricle caused ventricular arrhythmias. This technique required frequent X-ray monitoring to confirm that the tip of the guide-wire was still in the left ventricle.

After introduction of the guiding pressure catheter into the left ventricular outflow tract, the PUCA pump passed the aortic valve rather easily. The continuous monitoring of the pressure patterns derived from the guiding catheter offered a good control of the PUCA pump position.

We noticed that passing the aortic valve without any guidance at all was not possible. The PUCA pump could not pass the aortic valve and in three experiments the left main coronary artery flow decreased rapidly. When the PUCA pump was removed from the aortic valve, the left mean coronary flow was immediately restored. Presumably, the tip of the pump was located in the left coronary cusp obstructing the ostium of the left coronary artery. After five unsuccessful and time-consuming experiments we come to the conclusion that guidance for the introduction of the PUCA pump was necessary.

The question then arose: *Which type of guidance for introduction of a transarterial LVAD is optimal?* The standard peripheral implantation technique for trans-arterial blood pumps (e.g., the Hemopump) requires fluoroscopic guidance\(^2\)\(^-\)\(^4\). Image quality in fluoroscopy is an important consideration since small, low-contrast
objects such as guide-wires, catheters and stents must be visualized. Labbe and al.\textsuperscript{5} mentioned that the signal-to-noise ratio can be improved by using a high-level-control. Frequent use of high-level control increases the radiation dose substantially, but some physicians feel that the improved image quality is necessary. Our experiments demonstrated that passing the aortic valve in calves with a large-bore pump-catheter by using X-ray guidance only is a very difficult procedure. As in the experiments without any guidance at all, the tip of the catheter could not pass the aortic valve. During the introduction, high X-ray exposure was necessary, in order to improve the poor contrast of the catheter tip.

The combination of a J-tip guide-wire and X-ray control has more advantages: the guide-wire will pass the aortic valve relatively easy, the position of the guide-wire’s tip in the LV can be confirmed by X-ray, and the catheter/cannula of a trans-arterial LVAD can be introduced into the LV more easily. The experiments showed that in this case the problem is not to introduce the guide-wire into the LV, but rather to keep the tip of the wire within the LV outflow tract during introduction of the pump-catheter. This technique required frequent X-ray monitoring to confirm that the tip of the guide-wire was positioned in the left ventricle. Ensuring that the tip of the wire stayed in the LV required an excessively deep position of the guide-wire, resulting in frequent ventricular arrhythmias.

Like the guide-wire, the pigtail-guiding catheter passed the aortic valve well and the cannula of a trans-arterial LVAD could be introduced into the LV more easily. The advantage of the guiding catheter in comparison to the wire is that the position of the catheter tip in the aorta or in the LV can be controlled easily by examining the characteristic pressure patterns derived from the guiding catheter. In this way the tip of the pump-catheter/pump-cannula can be positioned accurately just within the LV outflow tract, thereby avoiding contact with arrhythmogenic cardiac tissues by penetrating too deep into the LV. In fourteen experiments we established that the position of the guiding catheter tip could be easily determined from the pressure patterns. The PUCA pump followed the guiding catheter and passed the aortic valve well, confirming that during the introduction the tip of the guiding catheter was still in the LV. The technique is inexpensive and uses widely available equipment. Furthermore the technique does not require X-ray guidance and in this way avoids radiation of the patient and the staff. The study established that this new implantation technique is easy, fast, safe and requires only temporary pressure monitoring.
Chapter 4

Acknowledgments

The PUCA-pump is part of EUREKA project EU 68211 and was supported by the Dutch Heart Foundation.

References


