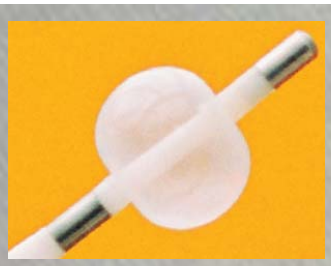


Hướng dẫn cấy dây tạo nhịp tạm thời với bóng không dùng x-quang

12/2007

Hướng dẫn cấy dây tạo nhịp tạm thời với bóng không dùng x-quang

Tài liệu tham khảo kèm theo bài hướng dân

- Schnitzler RN, Caracta AR, Damato AN. “Floating” Catheter for Temporary Transvenous Ventricular Pacing. *The American Journal of Cardiology* 1973; 31(3): 351-354 … thủ thuật củ đưa dây lên đường ra thất phải (RVOT) rồi kéo xuống mõm thất.
- Charuzi Y, Ganz W, Lebovitz JA, Swan HJC. Simplified Insertion of Flow-Directed Catheters for Ventricular Pacing. *Catherization and Cardiovascular Diagnosis* 1978; 4(3): 325-327.
- Mesiter SG, Banka VS, Helfant RH. Transfermoral Pacing with Balloon-Tipped Catheters. *JAMA* 1973; 225(7): 712-714.
- Lipp H, Ódonoghue K, Resnekow L. Intracardiac Knotting of a Flow-Directed Balloon Catheter. *NEJM* 1971; 284(4): 220.
- http://rnbob.tripod.com/transven.htm
- Instruction for Use – Vascor. Dây dài 110 cm, với khoảng cách điện cực 1 cm, và với đầu hình chữ S. Ngoài ra còn có dây hình chữ J. Đầu nối vào máy là loại kim 2mm Ø (không phải như trong hình trang bìa, trong hình là loại phích touch proof)

Bề dài dây điện cực đã được đánh dấu như dưới đây để bác sĩ có thể kiểm tra bề dài dây đã được luồn vào tĩnh mạch:

I	II	III	IIII	=	=I	=II	=III	=IIII	= =
10	20	30	40	50	60	70	80	90	100

Lượng hơi tối đa dùng để phòng bóng lên là 1,0 cc! Thường dùng khoảng 0,5 đến 0,75 cc. Nếu sợ bị air embolus (nghẽn mạch do bọt khí) thì dùng CO_2 thay vì hơi không khí. Triệt để không dùng nước để bơm bóng!

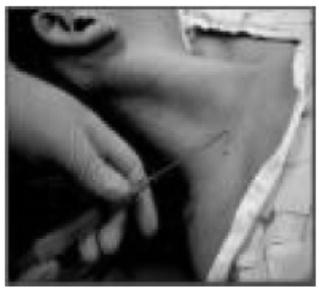
Trước khi dùng hãy kiểm tra bóng bằng cách bơm bóng lên và ngâm trong nước vô trùng. Nếu thấy bọt thoát ra từ bóng, thì bóng này không còn có thể dùng được và dây điện cực này nên bỏ đi vì một khi bóng không còn toàn vẹn, máu có thể nằm trong bóng ở nơi mà chất khử trùng không đến được.

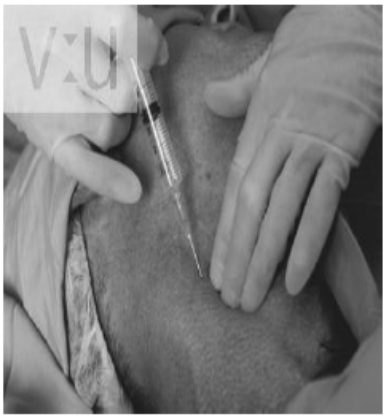
Trên nguyên tắc dây điện cực chỉ dùng một lần. Ở Việt Nam, dây thường được dùng nhiều lần. Sau khi rửa sạch, cần khử trùng lại bằng cách ngâm trong Cidex Plus 24 tiếng. Nhớ tháo ống chích ra. Vì cái bóng, nhớ khóa valve lại trước khi ngâm Cidex để tránh chất loãng vào trong bóng. Sau đó ngâm thêm trong nước muối vô trùng khoảng 1 giờ. Xong rồi bỏ cất trong một hộp sắt/nhôm đã được khử trùng. Trước khi dùng dây lại, hãy ngâm lại trong oxy già (hydrogen peroxide) khoảng 1 giờ. Trước khi dùng lại hãy thử bóng bằng cách bơm vào 0,5 cc hơi. Rồi hút xẹp bóng và kiểm tra là đã hút đủ 0,5 cc trở lại. Nếu hút thiếu hay dư nhiều, thì bóng này không còn dùng được vì không biết là có Cidex trong bóng hay không! … không thể đưa vào người bệnh nhân được!

Dây điện cực này có kích cỡ 5 French (1 French= 1/3 mm Ø). Để có thể dùng lại, nên dùng introducer khoảng 7 French để đừng làm tổn hại cái bóng ở đầu.

Vì dây điện cực đưa vào tận tim, cần phải sát trùng xung quanh điểm đưa dây điện cực vào tĩnh mạch, và bác sĩ cần phải tuân theo thủ tục phòng mổ. Ngoài ra vì dây điện cực dài, nên cần phải phủ bệnh nhân với khăn vô trùng, để có chỗ để thao tác dây bên ngoài.

- Subclavian vein
- Jugular vein
- Femoral vein

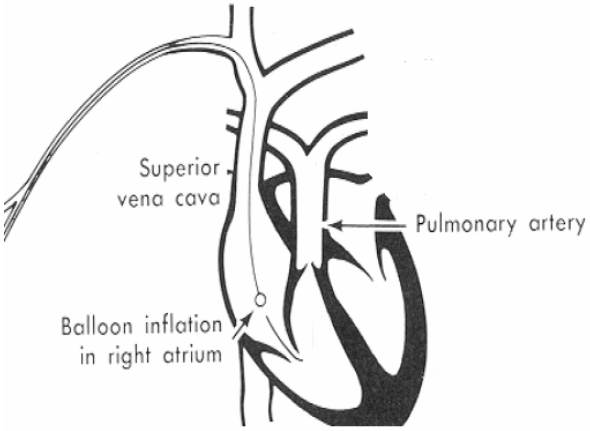




14

Thủ thuật giống như khi đưa ống thông Swan-Ganz, nhưng không đưa lên động mạch phổi. Đường vào tĩnh mạch dưới đòn (subclavian) trái có tỷ lệ thành công cao. Đường vào tĩnh mạch cổ nội (internal jugular) phải ít bị tai biến tràn khí màn phổi (pneumothorax). Ngoài ra còn có thể dùng tĩnh mạch cánh tay (brachial), hoặc tĩnh mạch đùi (femoral) (dễ bị nhiễm trùng). Xem phụ lục về ưu điểm và nhược điểm các lối vào.

Chống chỉ định: dùng thuốc kháng đông hay người bệnh thường chảy máu là chống chỉ định vào đường tĩnh mạch. Bệnh phổi hay dùng máy hô hấp là chống chỉ định đường subclavian và jugular.

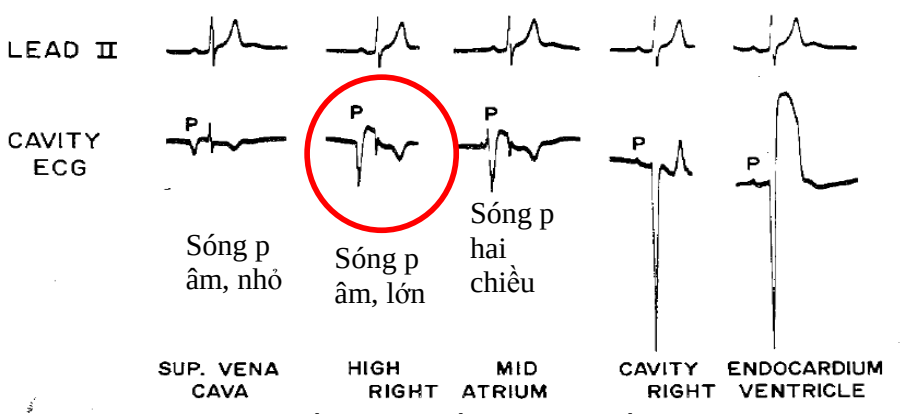


Sau khi đưa introducer vào tĩnh mạch, nên ước lượng khoảng cách từ điểm chọc tĩnh mạch đến nhĩ phải (xem bảng trong Phụ Lục).

Sau khi đưa dây điện cực khoảng ¾ khoảng cách ước lượng trên thì nối điện cực đầu (phích đen) vào kênh V1 của máy điện tâm đồ 12 kênh. **Vì an toàn của bệnh nhân máy điện tâm đồ cần phải được kiểm tra thường xuyên là kênh V1 an toàn để dùng với điện cực trong tim!**

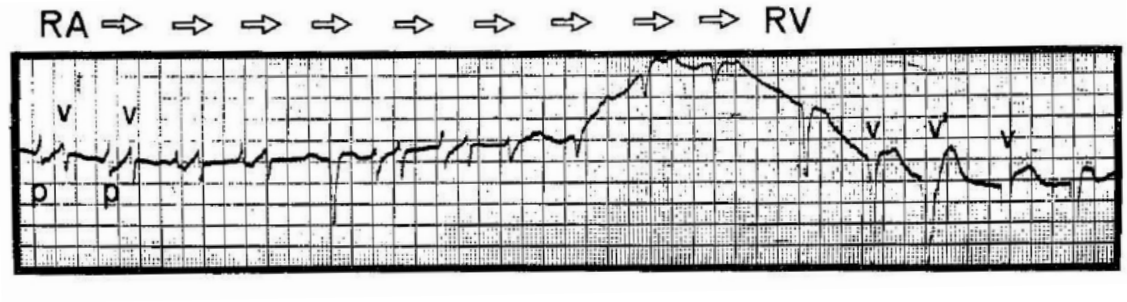
Với chuyển đạo II dùng để xác định thời gian các sóng p và QRS, hãy theo dõi sóng được phát hiện ở đầu dây điện cực theo mô hình dưới đây:

Khi đầu điện cực đã vào đến phần trên nhĩ phải (high right atrium), với sóng p lớn và âm, thì hãy bơm bóng lên. Nhớ đừng có bơm quá 1 cc! Nhớ ghi lại lúc đó dây đã được luồn bao xa trong tĩnh mạch. Trong trường hợp cần trở lại nhĩ, thì biết cần kéo lại bao nhiêu dây. Ngoài ra nên kiểm tra là bóng còn tốt, bằng cách bơm xong, khoá van lại, lấy ống chích ra và xả hết hòan toàn hơi trong ống chích, lắp vào lại, mở van, và hút ra hơi từ bóng. Nếu số lượng bơm vào và hút ra có khác biệt, đây là dấu hiệu bóng không còn hoàn chỉnh, vì vậy nên thay dây! Lý do cần kiểm tra lại là tại vì bóng có thể bị hư khi đưa qua introducer, nhất là trong trường hợp dây được tái sử dụng.



Nhớ là đầu dây có hình S. Trước khi luồn dây vào tĩnh mạch phần trên thân người, hãy thử xem nếu giữ đuôi dây bên ngoài cuộn lại theo chiều cuốn của dây, thì xoay cuộn dây thế nào để xoay đầu dây một cách thuận tiện hầu lèo lái các tĩnh mạch và đưa dây qua van ba lá! Các động tác này khác nếu đi từ bên phải (phải đổi hướng 1 lần, vì để xuống nhĩ dây cần phải cong về bên phải trước, khi xuống đến nhĩ thì cần cong về hướng trái) hay từ bên trái (không cần đổi hướng vì đầu dây chỉ cần cong về bên trái).

Sau khi bơm bóng lên, thì thả dây thêm khoảng 5 đến 10 cm qua van ba lá vào thất. Nếu sau khi thả dây nhiều mà không thấy sóng S lớn, thi hãy xẹp bóng lại, rút trở lại nhĩ phải, dựa theo chiều dài dây trong tĩnh mạch đã ghi lại ở đoạn trên khi bơm bóng, rồi bơm bóng lên và thả lại. Khi đầu dây vào thất, thường sẽ nhận thấy một số ngoại tâm thu thất.



Tín hiệu khi đầu điện cực đi từ nhĩ sang thất

Sau khi vào được thất thì hãy xẹp bóng và đưa dây từ từ (hầu tránh thủng thành thất) đến mõm thất. Khi đụng thành thất, thường sẽ có cảm giác mỗi lần tim đập ở đầu dây đang cầm và điện tâm đồ ở điện cực đầu dây sẽ có triệu chứng blốc nhánh trái như ở hình trên. Sau đó cho thêm chút dây vào để tạo hình "ghế" phía trên van ba lá. Đừng có thả quá nhiều dây và đừng có đình trễ xẹp bóng vì có thể đưa đến tình trạng dây bị rối (xem bài của Lipp – triệu chứng là nhịp nhanh thất khi rút dây trở lại từ thất và đầu điện cực ghi la đang ở nhĩ!) trong thất phải! Dây tạm thời cần được buộc/dán lại ở chỗ chọc tĩnh mạch và dây được cuộn lại (để tránh đoạn dây trong tĩnh mạch bị lôi ra khi đuôi dây bị kéo vì sơ ý) và buộc/dán lại ở một nơi gần đó.

Nối máy tạo nhịp tạm thời vào dây và kiểm tra ngưỡng tạo nhịp và sensing. Sau đó lập trình biên độ 2-3X ngưỡng tạo nhịp. Để kiểm tra điện cực, hãy kêu BN ho một vài tiếng xem có mất nhịp không. Ngưỡng cần được kiểm tra mỗi ngày và BN cần phải được nối với máy ECG 12 chuyển đạo trong cả thời gian tạo nhịp cấp cứu.

Vì nguy cơ nhiễm trùng, không nên để dây điện cực trong bệnh nhân quá 5 ngày.

Hãy cho bệnh nhân nằm trước khi rút dây điện cực ra. Rút dây ra hoàn toàn khi bệnh nhân đang thở ra để tránh nghẽn mạch do bọt khí (air embolism). Sau khi rút dây khỏi bệnh nhân, nên rửa cho sạch rồi ngâm Cidex như đã bàn ở trên. Nhớ cuộn dây theo đúng chiều trước khi khử trùng!

Nếu tái sử dụng dây điện cực (và introducer), thì lúc nào cũng cần có sẵn một dây (và introducer) mới dự phòng!

Đoạn trên bàn về dây điện cực được đưa vô tĩnh mạch ở phần trên người (tĩnh mạch cổ, tĩnh mạch dưới đòn, tĩnh mạch cánh tay). Còn một nơi khác có thể chọc tĩnh mạch đó là tĩnh mạch đùi (femoral vein). Bẹn phải là nơi thuận tiện nhất để đưa dây điện cực vào.Thường với tĩnh mạch đùi, các bác sĩ dùng loại dây hình chữ J. Các dây hình cữ S cũng có thể dùng nhưng không tiện bằng dây hình chữ J để vào mõm thất từ phía dưới. Nếu có bác sĩ nào quen dùng lối vào này, thi chúng tôi cũng có thể nhập dây hình chữ J. Thủ thuật nói chung tương tự như đã bàn ở trên.

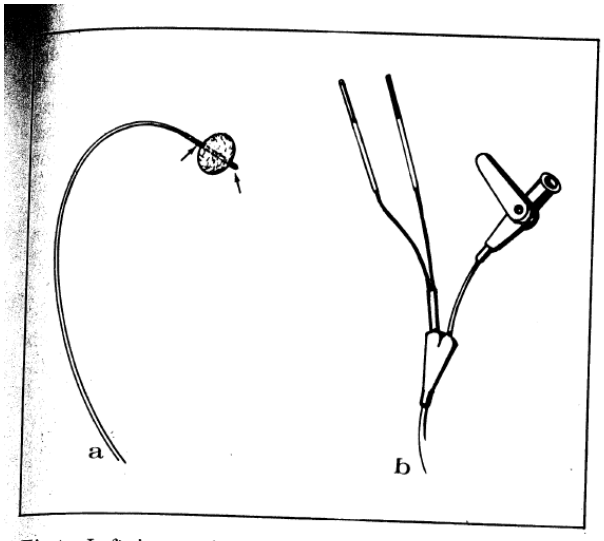


Fig 1.–Left, inverted J curve of the catheter tip, two electrodes (arrows), and balloon located between them. Right, two pacer terminals and two-way valve for balloon lumen.

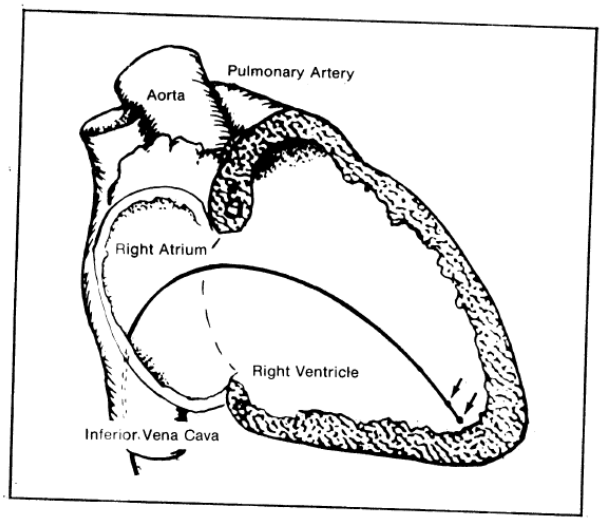


Fig 2.–A balloon-tipped catheter in optimal position for stable pacing with its tip wedged near the right ventricular apex.

Phụ Lục

Các lối vào cho dây tạo nhịp tạm thời

Ống thông central venous catheter (ống thông nội tĩnh mạch) dùng để đo huyết áp ở nhĩ và đưa thuốc vào tim, to hơn dây điện cực và vì vậy tỷ lệ sự cố cao hơn. Bài dưới đây, trích từ UpToDate, có chi tiết về cách chọc các tĩnh mạch để đưa CVC vào tim.

Comparison among PA catheter insertion sites

Insertion site	Distance (cm) to:			Advantages	Disadvantages
	RA	RV	PA		
Internal jugular	15-20	30	40	Easy to float, esp from right	Puncture of carotid relatively common
				Easy to cannulate	Risk of pneumothorax
Subclavian	15-20	30	40	Easy to float, esp from left	Higher risk of pneumothorax than with IJ approach
				Easy to cannulate	
Femoral	45	55	65	Easy to cannulate	More difficult to float catheter (may require fluoroscopy)
				Fewer major complications	
				Higher risk of infection	
				Risk of DVT	
Brachial					
Right	40	50	60	Few major complications	More time-consuming
Left	50	60	70	Safer if bleeding diathesis or coagulopathy	Difficult to float catheter
				May be easiest in morbidly obese patients	Lower rate of successful cannulation
					Limited to 72 hour duration due to phlebitis and infection risk

INSERTION CENTRAL VENOUS CATHETER

Site selection — Central venous catheters (CVC) can be inserted into the internal jugular (IJ), external jugular (EJ), subclavian (SC), femoral (FV), or brachial (BV) vein. The optimal site is determined by operator preference, operator experience, patient anatomy, and clinical circumstances

Internal jugular — Advantages of CVC placement in the IJ, compared to the SC, include a lower risk of pneumothorax and greater compressibility of the vessel, which is important when there is bleeding or arterial puncture. The straight path from the right IJ to the superior vena cava can be advantageous if insertion of a pulmonary artery catheter or temporary pacemaker become necessary. But, an IJ CVC is typically less comfortable for patients, more difficult to keep clean (especially if a tracheostomy is present), and associated with a higher rate of CVC-related bloodstream infections, compared to a SC CVC (show table 1). CVC insertion into the IJ can be difficult in obese or edematous patients if ultrasound guidance is not available, because anatomic landmarks may be obscured.

There are three common approaches to IJ cannulation: Medial approach — With the patient's head turned to the contralateral side, the sternal and clavicular heads of the sternocleidomastoid muscle are identified. The patient should flex his or her neck against resistance if these landmarks are not apparent, in order to better define the neck musculature. The needle is inserted inferior to the junction of the sternocleidomastoid muscle heads and advanced towards the ipsilateral nipple at a 30 degree angle with the skin. The IJ vein should be reached within 3 cm (show figure 1). Lateral (ie, posterior) approach — This approach begins as described for the medial approach. But, the needle is inserted posterior to the sternocleidomastoid — approximately 4 cm above the sternoclavicular joint — and directed at the contralateral nipple at a 10 to 15 degree angle with the skin. The insertion site is usually near the junction of the EJ vein and the posterior margin of the sternocleidomastoid muscle. Anterior approach — This approach also begins as described for the medial approach. But, the needle is inserted anterior to the sternocleidomastoid and lateral to the carotid pulse — at the level of the inferior margin of the thyroid cartilage — and directed toward the ipsilateral nipple at a 30 degree angle with the skin.

Subclavian — Advantages of CVC insertion in the SC include easily identifiable bony landmarks, greater patient comfort, easier dressing and maintenance, and a fewer CVC-associated bloodstream infections. Disadvantages include a greater risk of pneumothorax and inability to effectively compress the SC artery or vein if bleeding occurs . Despite this, observational studies have failed to demonstrate increased bleeding associated with CVC insertion in the SC, even when severe thrombocytopenia or coagulopathy exists [25,26].

Three approaches to subclavian cannulation are used: Infraclavicular medial approach - The needle is inserted 1 cm inferior to the junction of the proximal one-third and distal two-thirds of the clavicle. It is then directed toward the suprasternal notch at a 10 to 15 degree angle with the skin. Attention should be paid to avoid a steeper angle since this may lead to puncture of the lung apex and a pneumothorax (show figure 2). Infraclavicular lateral approach — The needle is inserted 1 cm inferior to the junction of the proximal two-thirds and distal one-third of the clavicle. It is then directed toward the suprasternal notch at a 15 degree angle with the skin. Unintentional catheter placement in the IJ vein is less common with this approach, but the risks of subclavian artery puncture and brachial plexus injury are increased. To bring the ipsilateral shoulder into optimal alignment during catheter insertion it is often helpful to have an assistant pull the wrist towards the feet. Supraclavicular approach — The needle is inserted cephalad to the clavicle and lateral to the junction of the clavicular head of the sternocleidomastoid muscle and the clavicle. The disadvantages of both the IJ and infraclavicular SC approaches are applicable to supraclavicular CVC insertion; therefore, it is not commonly done [24].

Femoral vein — A CVC can be inserted into the FV without risk of pneumothorax and without interfering with cardiopulmonary resuscitation (CPR). The needle should be inserted 1 cm medial to the femoral artery pulse and 1 to 3 cm below the inguinal ligament (show figure 3A-3B). Puncture above the inguinal ligament may result in peritoneal perforation or inadvertent puncture of pelvic vessels. The latter is problematic because applied pressure may be inadequate to limit bleeding. Disadvantages of the femoral vein site include a ten fold higher rate of CVC-related sepsis and thrombosis, inadequate delivery of medications to the heart during low flow states, and interference with patient mobility [27].

Brachial vein — Despite its popularity in the other settings, the peripherally inserted central venous catheter (PICC) — which is inserted via a BV — has little role in the ICU. PICC lines confer little risk of pneumothorax or uncontrolled bleeding, and are preferable to IJ CVCs in patients with elevated intracranial pressure [28]. But, PICC lines have high rates of malposition, thrombosis, infection, and displacement with arm movement. In addition, PICC lines are inadequate for volume resuscitation. Sonographic and fluoroscopic guidance may minimize the risk of malposition, but the cost-effectiveness of these strategies varies from institution to institution [29,30]. PICC lines are most appropriate for chronic ICU patients who are ready for transfer to a step-down unit or the medical or surgical ward.

Technique — The modified Seldinger technique is widely used to place CVCs. Briefly, the vein is cannulated with a needle and a guidewire is inserted through the needle into the vessel lumen. Once the needle is removed — leaving only the guidewire in position — a tract is dilated and the catheter is inserted over the guidewire. The guidewire is removed and the CVC is secured (show table 2 and show figure 4).

Catheter position — A chest radiograph should be obtained following a new SCL or IJ CVC insertion or attempt, to determine the location of the catheter's tip and to exclude pneumothorax or catheter malposition (show radiograph 1). In contrast, chest radiographs are not always necessary in hemodynamically stable, monitored patients after uncomplicated CVC exchanges over a guidewire [31,32].

IJ and SC CVCs should terminate proximal to the junction of the superior vena cava (SVC) and the right atrium to eliminate the risk of cardiac perforation and catheter associated arrhythmias. The junction of the SVC and the right atrium is approximately 14 to 16 cm from the skin puncture site for right sided CVCs, and 16 to 20 cm for left-sided CVCs. Insertion to a depth greater than 20 cm is rarely necessary [33].

COMPLICATIONS — Numerous complications are associated with CVC placement (show table 3). In an observational cohort study of 385 consecutive CVC attempts over a six month period, complications occurred in 33 percent of attempts [34]. Complications included failure to place the catheter (22 percent), arterial puncture (five percent), catheter malposition (four percent), pneumothorax (one percent), subcutaneous hematoma (one percent), hemothorax (less than one percent), and asystolic cardiac arrest (less than one percent).

Mechanical complications (eg, pneumothorax) tend to be detected at the time of catheter insertion, whereas infectious and thrombotic complications usually occur later. Mechanical complications detected at the time of catheter insertion are most common following attempted insertion in the SCL [34]. Despite this, the rate of mechanical complications is largely operator dependent and SC insertion may be preferred in experienced hands [14]. Infectious and thrombotic complications are discussed in detail elsewhere. (See "Diagnosis of central venous catheter-related bloodstream infections" and see "Prevention of intravascular catheter-related infections" and see "Pathogenesis of and risk factors for central venous catheter-related infections" and see "Catheter-induced upper extremity venous thrombosis").

CATHETER REMOVAL — Venous air embolism and bleeding are the complications most likely to occur when the CVC is removed.

Venous air embolism is a serious and poorly recognized complication of central venous catheterization. Venous air embolism can occur at the time of CVC insertion, while the catheter is in place, or at the time of catheter removal [35-37]. Patients should be placed in the supine position prior to CVC removal to decrease the risk of air embolism. The CVC should be removed during exhalation, when intrathoracic pressure is greater than atmospheric pressure. Air can be entrained into the venous circulation as the intrathoracic pressure decreases below atmospheric pressure if the CVC is removed during inspiration (See "Air embolism").

Firm pressure should be applied for at least one minute following removal and the wound should be dressed with dry sterile gauze. The tip of the catheter should be cut off using sterile scissors and sent for culture if a CVC-related infection is suspected. (See "Diagnosis of central venous catheter-related bloodstream infections").

"Floating" Catheter for Temporary Transvenous Ventricular Pacing

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A technique for the placement of a flow-directed balloon electrode catheter for right ventricular endocardial pacing was utilized successfully in 15 of 17 patients. The catheter is capable of being passed either percutaneously, or by cut-down procedure, at the bedside under electrocardiographic control. It was successfully positioned in 6 cases after other semifloating electrodes failed. This new catheter provides stable, reliable pacing and is an excellent alternative to X-ray image intensification for placement under urgent or emergent conditions.

In the clinical setting, the need occasionally arises for rapidly establishing effective ventricular pacing. At such critical times it may be difficult to move the patient to a conventional X-ray facility, and portable image intensification is often too costly or unavailable. As a result, several varieties of electrode catheters have been developed for blind passage under electrocardiographic control.[1-3] These catheters, at best, have had a success rate of approximately 70 to 80 percent.[1] Recently we have studied 17 patients with a new "floating" probe and have found it to be a fast, safe and reliable electrode with which to institute bedside ventricular pacing.

Materials and Methods

The catheter (Fig. 1) employed in this study is a 110 cm no. 3F bipolar catheter consisting of two 5 mm platinum ring electrodes. The distal electrode is located at the tip and the other 1.5 cm proximal to it. Between the 2 electrodes is a balloon which increases the diameter equivalent to that of a 5F catheter. The balloon is inflated by injecting approximately 1.5 cm of air into a valve at the proximal end of the catheter. At the time of insertion, the balloon is inflated under sterile conditions in a fluid medium to insure against any leaks.

Under local anesthesia the catheter is introduced into an appropriate antecubital vein, either percutaneously or by cutdown procedure. With the percutaneous approach, a needle or plastic cannula is used with an internal diameter large enough to accommodate the wider balloon portion. The catheter is then advanced to a previously determined length that would place the tip of the probe in the region of the superior vena cava. Occasionally, as is the case with catheters used in routine cardiac catheterization, some difficulty may be experienced negotiating the region of the shoulder. This problem may be overcome by rotating the catheter while gently advancing and retracting. Abduction of the arm has sometimes been helpful in our experience.

When the catheter is thought to be at the level of the superior vena cava, the pigtail extension of the proximal electrode (the shorter of the 2) is connected to the precordial lead of a well-grounded electrocardiograph. Care is taken to insure that the patient is not connected to any other electrical apparatus.

Unipolar recordings are made from the catheter tip. In the superior vena cava, the recordings will be similar to tracings from lead aVR. The catheter is then advanced several centimeters to the high right atrium where the re-

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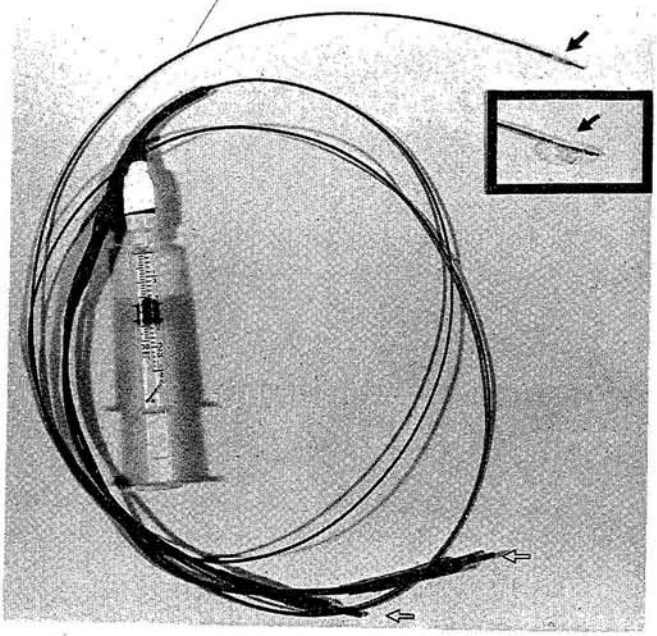

FIGURE 1. A no. 3F pacing electrode with a balloon located between the electrodes **(closed arrow)** and inflated (see inset) by a syringe attached to a valve at the proximal end of the catheter. The pigtail connectors for the battery generator are indicated by **open arrows.**

cordings show a large negative P wave. When this site is reached, the balloon is inflated with 1.5 cm of air through the valve at the proximal end of the catheter. The syringe is disengaged from the valve, trapping the air in the balloon. With the balloon inflated, the catheter is advanced 5 to 8 cm with constant monitoring of the intracardiac electrogram. The syringe is then reinserted into the valve mechanism and the air withdrawn.

For reference, recordings obtained at this time are presented in Figure 2. Panel A is a recording obtained from the superior vena cava before inflation of balloon. Panel B represents the recording obtained with the electrode in the high right atrium. It is at this time that the balloon is inflated. Panel C was recorded with the catheter in the right ventricle. Often this position is reached on a direct pass from the right atrium. In panel D the catheter has

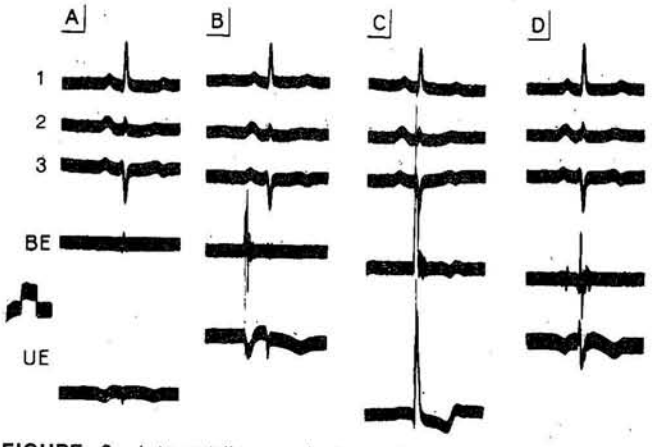

FIGURE 2. Intracardiac recordings from the probe in the superior vena cava **(A)**, high right atrium **(B)**, right ventricular apex **(C)** and pulmonary artery **(D)**. BE = bipolar electrogram; UE = unipolar electrogram. Standardization signal is 1 mv.

come to rest in the pulmonary artery. The recording in this instance often appears similar to that of a peripheral augmented lead but of greater amplitude. The catheter should be slowly withdrawn until a ventricular complex is obtained; at this time it will be in the right outflow tract of the right ventricle.

Figure 3 is an example of the sequence of events in positioning a balloon catheter in the apex of the right ventricle. The top panel was recorded with the catheter in the region of the high right atrium. In the middle panel, the catheter has been advanced to the mid-right atrium. The lowest panel demonstrates the passage to the right ventricle.

If the electrode does not pass to the right ventricle or pulmonary artery on the first attempt, it should be withdrawn to the region of the superior vena cava and the balloon reinflated. At this time the integrity of the balloon should be confirmed by injecting the air into the valve mechanism and demonstrating the ability to withdraw the same volume. If this is not accomplished, the catheter should be removed and discarded on the assumption that the balloon is leaking air. When the integrity is verified, the preceding technique is again employed.

Although the situation has not arisen, it is conceivable that some difficulty might be encountered with fibrillating atria. In our experience with studies in atrial fibrillation, differences in amplitude exist between the atrial signals recorded in the atrium and those recorded in the superior vena cava. Under these circumstances it would be appropriate to inflate the balloon in the superior cava.

The adequacy of the final position of the catheter was determined by 4 criteria: First, the electrogram from the tip electrode had to record a current of injury. This insured adequate contact of the tip with the endocardial surface.[4] Second, bipolar recordings (those obtained with the arm leads of the electrocardiograph connected to the 2 leads from the catheter while the leg leads remain on the patient) had to produce a deflection greater than 2 mv. This allowed for adequate sensing by the external battery generator. Third, the threshold for ventricular pacing (the minimal current that will produce consistent capture) was tested, using any one of a variety of battery-powered generators. In our laboratory we commonly used either a Medtronic no. 5837 or 5880A battery generator. The generator was subsequently set to deliver the current at levels of twice threshold. Fourth, the demand function of the system was determined by slowly decreasing the rate of firing of the generator until it was suppressed by the patient's own heartbeat; at this time there should have been no evidence of competition. Once reliable capture had been established and to insure the position of the catheter, it was fixed to the skin with a single nylon suture and the patient's arm was strapped to his side with an elastic bandage.

In this study portable chest X-ray films were subsequently obtained in each case to verify the proper position of the catheter electrode (Fig. 4). Figure 4 shows a typical X-ray film demonstrating the electrode low in the outflow tract of the right ventricle where it remained stable until removal 12 days later.

After removal of the electrode the integrity of the balloon and electrodes was routinely checked. The balloon was inflated in a liquid medium to determine the presence of leakage of air. The electrodes were checked by measuring the resistance with a volt-ohmmeter. No abnormalities in either the balloon or electrode systems were detected with these techniques.

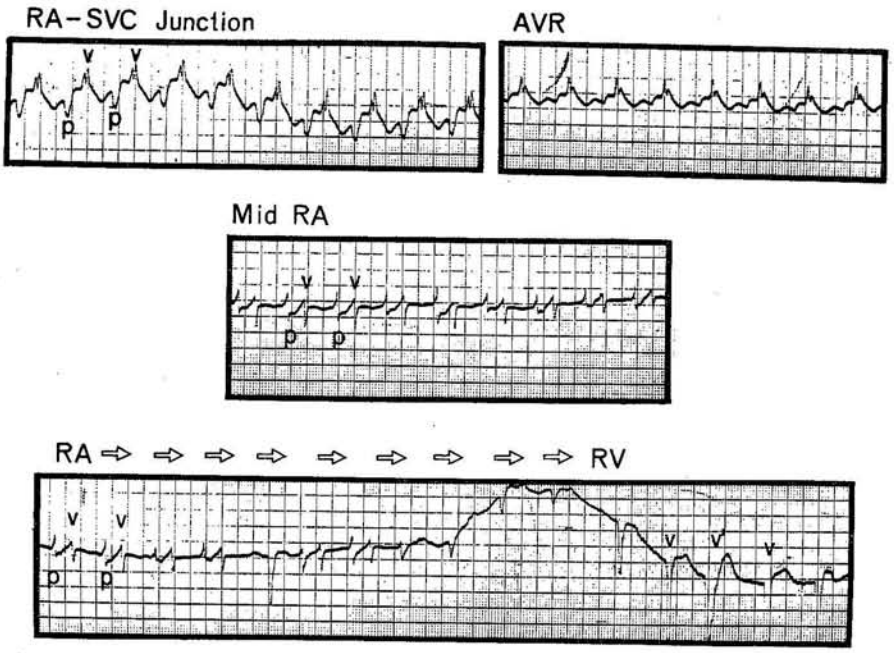

FIGURE 3. Demonstration of the sequential passage of the "floating" probe from the superior vena cava to the right ventricle. RA = right atrium; RV = right ventricle; SVC = superior vena cava.

Patients

The balloon electrode catheter was used in 17 patients. Eight patients were in the coronary care unit, and the catheter was placed for either the sudden development of an advanced degree of atrioventricular block either in the presence of an acute myocardial infarction (5 patients), sudden failure of a permanent generator (1 patient) or digitalis-induced A–V block (2 patients). Seven patients with various rhythm and conduction disturbances had the catheter positioned as a part of right heart catheterization. In 2 patients we were unable to pass the shoulder region with any form of semifloating catheter, and a standard U. S. Catheter and Instrument bipolar probe was inserted fluoroscopically.

Results

Successful placement of the catheter in the right ventricle was achieved in all patients within 3 to 5 minutes after the antecubital vein was entered. Thresholds, as determined by either an external demand generator or by an R wave-coupled generator, were usually less than 1 ma (1 patient had a threshold of 3 ma after 45 minutes of external cardiac massage). Of note, the catheter was successfully placed in the ventricles on 6 occasions after attempts with other forms of semifloating electrodes had failed. There was no appreciable difference in the positioning of the catheter electrode at the bedside from the ideal situation in the catheterization laboratory.

Two patients had ventricular premature contractions on passage of the catheter. This development was apparently related to the balloon as it entered the ventricle, since the contractions subsided spontaneously upon deflation of the balloon. Once positioned, the catheter was allowed to remain in place for 1 to 12 days. There was no evidence of thrombophlebitis at the site of insertion. Stable pacing without change in threshold was achieved over the entire period.

Discussion

With the rapid developments in cardiac pacemakers and intensive monitoring the occurrence of situations requiring the immediate placement of an electrode catheter has been appreciated.[1-3,5,6] When the circumstances permit, the insertion of a pacemaker electrode is still best carried out using image intensification. Since this is not always possible, several types of electrodes have been developed that may be

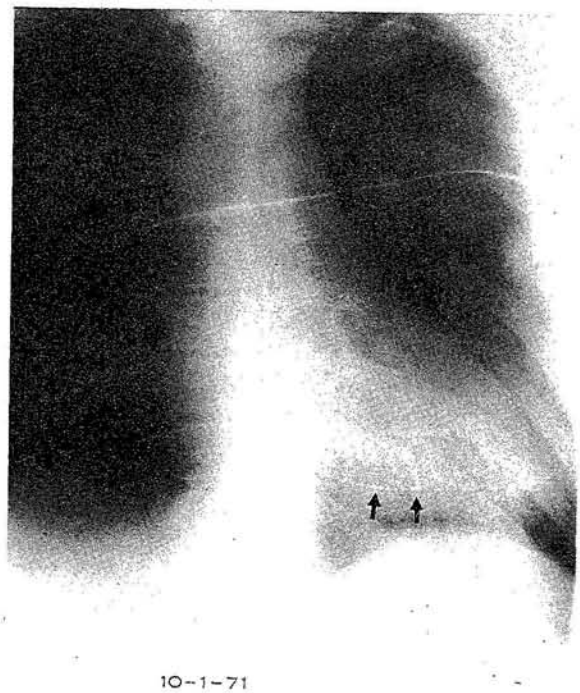

FIGURE 4. Portable chest roentgenogram showing the location of the catheter electrodes low in the outflow tract **(arrows)**. The catheter remained in this location for 12 days.

positioned at the bedside under electrocardiographic control. These are often placed easily and in a very short time, but even in the best hands there is only a 70 to 80 percent success rate.[1]

The theory behind our successful use of the balloon catheter is based on that of the flow-directed catheter employed by Swan and Ganz.[7] No complications were noted, and successful positioning in the right ventricular apex permitting pacing at a threshold less than 1 ma was obtained in each patient within 2 attempts.

Although we did not employ either the subclavian vein or femoral vein approach in this study, it is safe to assume that the success rate in these approaches will be as high since we never failed to enter the ventricle once the right atrium was reached.

The catheter electrode is no stiffer than any of the other semifloating electrodes currently employed. It has an advantage over other electrode catheters since the deflated balloon supplies a cushioning, accordion-like effect allowing the catheter tip to retract slightly when pressure is placed on it.

Stability of the pacing site is apparently due to the configuration of the catheter. The widening of the catheter in the region of the balloon might well allow better enmeshment under the trabeculae of the right ventricle. This would seem, therefore, to provide an advantage not present in the previously employed semifloat designs.

The possibility does exist, as with any probe of this kind, that complications might be noted as experience with the catheter grows. However, although Rosenberg et al.[1] reported a 16 percent incidence of complications arising from passage of a semifloating electrode, the majority of complications were caused by failure to produce consistent pacing. There is no reason to believe that the catheter technique used in our study would be associated with an increased incidence of complications. The use of air in the balloon is unlikely to cause difficulty since the quantity employed is small (1.5 cc) in relation to the capacity, and the balloon is tested before insertion to insure its integrity.

Reinflation of the balloon has produced no problems within the guidelines of our usage. Rupture of the balloon has not occurred and would not be expected to occur since the balloon is capable of holding a volume of 7 to 8 cc of air without rupturing.

Our experience with this new flow-directed catheter electrode suggests that it is passed to the ventricle more consistently and provides better stability than currently available semifloating probes. The technique requires little experience and does not necessitate moving the patient. It would therefore seem to offer an excellent alternative to portable image intensification in the positioning of a catheter electrode for ventricular pacing under urgent or emergent conditions.

Acknowledgment

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Catheterization and Cardiovascular Diagnosis 4:325–327 (1978)

Simplified Insertion of Flow-Directed Catheters for Ventricular Pacing

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Key words: temporary pacing, flow-directed pacing catheter, bedside temporary pacing

INTRODUCTION

The need for prompt and effective ventricular pacing has led to the development of a balloon-tipped flow-directed pacing catheter [1]. Such a catheter can be inserted at the bedside by floating the tip into the right ventricle using the electrocardiographic recording from the distal electrode as a location guide. In the method described, the tip of the catheter is floated first to the pulmonary artery and then pulled back to the right ventricle. In this presentation we describe a simplified method of placing a flow-directed balloon-tipped pacing catheter in the right ventricle for the purpose of temporary pacing.

MATERIALS AND METHODS

A No. 5 F-size flow-directed catheter (Swan-Ganz catheter, Edwards Laboratories, Santa Ana, California) without a pressure lumen but with platinum electrodes located at the tip and 1 cm proximal to it was used. An inflatable balloon was placed between the two electrodes (Fig 1).

The catheter was inserted into an antecubital vein and advanced into the superior vena cava or the right atrium. The distal electrode of the pacing catheter was connected to the V-lead of the electrocardiogram via an isolation circuit. The advancement was done under ECG control. Entry from the superior vena cava to the right atrium was indicated by a marked increase in the amplitude of the P wave (Fig 2). At this point the balloon was inflated with 1.5 cc of air and the catheter slowly advanced. Entry into the right ventricle was recognized by a marked decrease in the amplitude of the P wave and marked increase in the amplitude of the

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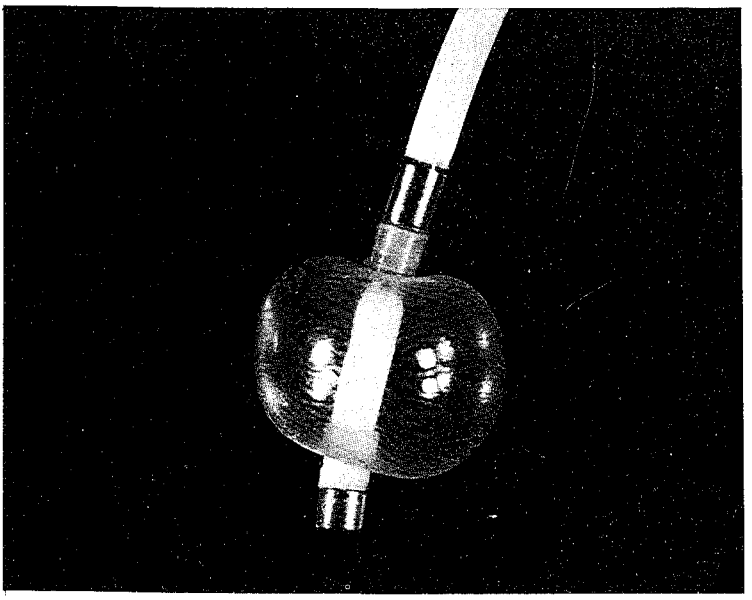

Fig 1. The distal end of the flotation pacemaker showing two platinum electrodes 1 cm apart, and the inflated balloon between them.

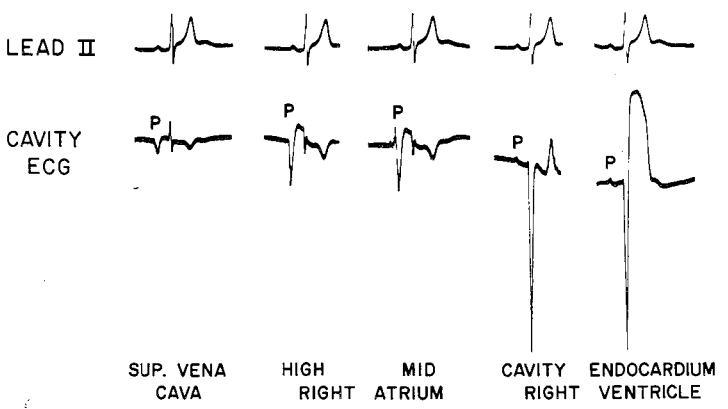

Fig 2. Simultaneous recording of surface lead II and intracavitary electrogram recorded from the distal electrode of the flotation pacing catheter. Note the different configuration of the P, QRS, and ST-T segment as the catheter is advanced from the superior vena cava through the right atrial and right ventricular cavities to the endocardium of the right ventricle.

QRS. As soon as such a change was noted, the advancement was stopped and the balloon deflated to prevent the catheter from floating toward the outflow tract. The catheter with the balloon deflated was then advanced until contact with the endocardium was reached, as indicated by ST segment elevation. Reliable contact with the endocardium was indicated by a stable S-wave amplitude and ST-segment elevation.

The pacing threshold (the minimum current sufficient to produce consistant capture) was determined. If the capture and/or sensing were inconsistent, the

catheter position was changed by slightly advancing the catheter under ECG control, or, if unsuccessful, by readvancing the catheter from the right atrium. The position of the catheter was confirmed by roentgenogram.

PATIENTS

The pacing catheter was applied to 18 patients. The indication for pacing was: 1) Arrhythmias associated with slow ventricular rate; 2) The likelihood of a high degree of atrioventricular block.

RESULTS

Effective catheter placement and pacing was accomplished in all 18 patients, in 16 of them within three minutes and in two patients within six and nine minutes. The pacing threshold was less than one mamp in all patients. The catheter was left in place from two to 360 hours, and averaged 109 hours.

In 15 patients the threshold remained one mAmp or less. In two patients the threshold increased from 0.5 to 1.8, and from 0.5 to 1.3, respectively. One catheter got displaced and had to be repositioned after 12 hours.

According to the roentgenogram, the catheter tip was located in the apex in 11 patients and in the inflow tract of the right ventricle in seven patients.

There was no difference in the threshold or stability of pacing between the two locations. In a number of patients the stability of position was confirmed by additional chest roentgenograms obtained 24 hours after insertion, and/or at a later stage. The only complications were occasional premature ventricular beats during insertion and local thromobophlebitis, especially in patients with long-term pacing.

DISCUSSION

The insertion technique described here utilizes the inflated balloon only for entering the right ventricular cavity. It is crucial that the balloon be deflated as soon as the intracavitary electrogram indicates entrance to the right ventricular cavity. The tip of the catheter, pointing leftward and slightly inferior, would respond to a simple advancement and would anchor at the apex or right ventricular inflow tract. Our experience indicates that the inflow tract is not less effective than the apex as a pacing site.

The advantage of this technique is its simplicity, since the catheter is advanced directly towards its final position and does not require pulling back from the right ventricular outflow tract or the pulmonary artery.

Our catheters were inserted from the antecubital area. However, it can be assumed that insertion from the internal jugular or subclavian veins can be performed with equal reliability.

Our experience is similar to that of Schnitzler et al [1], showing that the balloon-flotation pacing catheter can be reliably inserted at the bedside without fluoroscopic guidance.

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Transfemoral Pacing With Balloon-Tipped Catheters

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A method for rapid, bedside institution of temporary pacing has been developed utilizing floating, balloon-tipped, bipolar pacing catheters inserted percutaneously via a femoral vein. Successful pacing was accomplished without fluoroscopy in 30 of 31 patients. Ease and rapidity of insertion have been remarkable. The preformed "J" configuration of the catheter plus the transfemoral route of insertion aid in the attainment of a stable pacing position at the apex of the right ventricle.

PROMPT institution of temporary transvenous pacing often becomes necessary in clinical situations where fluoroscopic guidance for catheter placement is unavailable. "Blind" insertion (ie, without fluoroscopy) of pacing catheters is often a difficult and time-consuming procedure, even in experienced hands. This report describes a new technique for rapid and reliable institution of temporary transvenous pacing utilizing a "flow directed" balloon-tipped bipolar electrode catheter inserted percutaneously via a femoral vein.

Methods

Catheter Design.—The pacemaker catheters are constructed of soft, polyvinyl chloride. They are 100 cm in length, No. 5 in diameter, and are banded at 10-cm intervals. The two stainless steel pacing electrodes are mounted at the catheter tip and 1 cm distal to it. A thin-walled latex balloon, inflatable with 1.5 ml of air is mounted between the two electrodes (Fig 1, left). The distal 10 cm of the catheter is preformed into a "J" configuration with a 3.5-cm radius of curvature. The proximal end of the catheter carries terminals for the pacing electrodes and Luer-type connector with a two-way stopcock for the lumen to the balloon (Fig 1, right).

Method of Insertion.—Either femoral vein may be used. However, the right is preferred since it provides a somewhat straighter course to the inferior vena cava. The catheter is passed percutaneously into either femoral vein via a sheath of suitable diameter. Either direct puncture, utilizing a 13-T Escher-longdwell venous catheter needle, or the Seldinger technique with a No. 7 Desilets sheath is satisfactory. Once the sheath has been positioned in the femoral vein, the cather is inserted to a depth of 15 cm. The balloon is then inflated and the terminal for the tip electrode is connected to the V lead of the electrocardiograph. The catheter is "floated" to the right ventricle under continuous electrocardiographic monitoring. Passage across the tricuspid valve is signaled by the abrupt appearance of a characteristic, large negative intraventricular complex.[1] The balloon is then deflated and the catheter advanced for an additional 3 to 5 cm until premature beats or S-T elevations (in the intracardiac lead) indicate that the tip electrode is in firm contact with the right ventricular endocardium). Pacing is begun. If capture is complete, the pacing threshold is determined in the usual manner. The patient is asked to take deep breaths, cough, and shift his position in bed while stability of pacing is assessed. If pacing is not continuous during these maneuvers, or if the pacing threshold is greater than 1.5 ma, the catheter is advanced or withdrawn slightly until stable pacing is independent of these maneuvers and a satisfactory threshold is obtained. A chest x-ray film is taken to examine catheter position. Typically, the intracardiac portion of the catheter resembles an inverted J with its tip in or near the right ventricular apex (Fig 2).

Results

To date this technique has been used successfully for temporary pacemaker insertion in 30 of 31 attempts. Time for catheter passage from the femoral vein to the right ventricle has been less than 30 seconds in the great majority of cases, with institution of stable pacing in one to three minutes. The one unsuccessful attempt was due to inability to negotiate the inferior vena cava in an 84-year-old patient with evidence of severe generalized atherosclerosis. In four subsequent patients, the catheter initially failed to progress through the femoral or iliac veins. In

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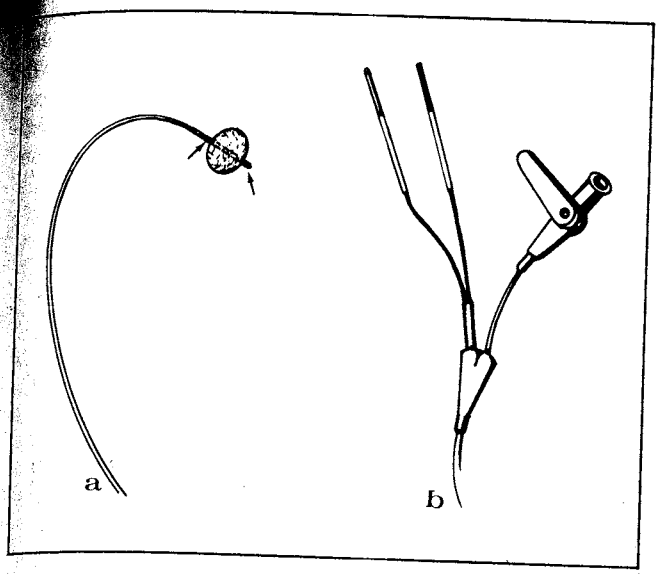

Fig 1.—Left, inverted J curve of the catheter tip, two electrodes (arrows), and balloon located between them. Right, two pacer terminals and two-way valve for balloon lumen.

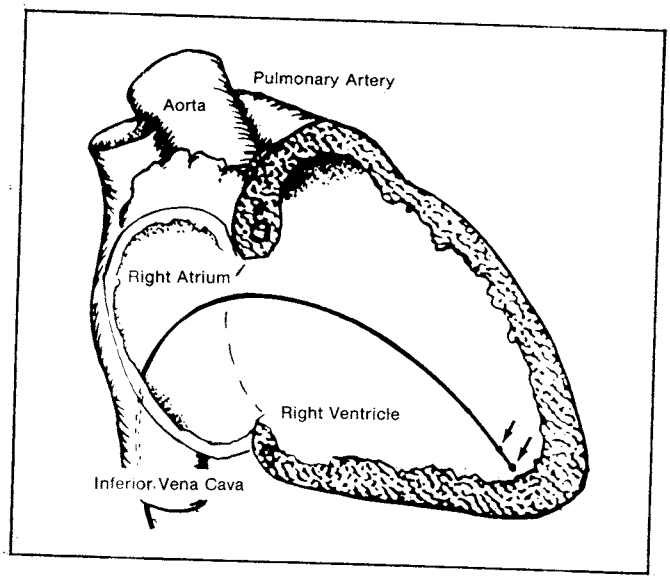

Fig 2.—A balloon-tipped catheter in optimal position for stable pacing with its tip wedged near the right ventricular apex.

each instance, this was easily remedied by readvancing the catheter past the obstruction with the balloon temporarily deflated. In two patients the catheter initially passed through the right ventricle and out into the pulmonary artery. This was evident from an abrupt drop in the amplitude of the negative QRS complex while the catheter was being advanced with the balloon inflated. This was easily corrected by withdrawing the catheter into the right ventricle, deflating the balloon and readvancing it, and was subsequently avoided by deflating the balloon as soon as the tricuspid valve was crossed.

In our earlier experience, four instances of interrupted pacing due to catheter-tip displacement occurred. In each instance chest x-ray film taken prior to displacement revealed suboptimal catheter position, ie, the catheter tip was near the tricuspid valve. In three instances the catheter remained within the right ventricular cavity and required only minimal manipulation (advancement) to reestablish pacing. In one patient, displacement into the right atrium occurred, and reinflation of the balloon was necessary for repositioning. No interruptions of pacing occurred when initial catheter position was adequate. Stable pacing has been maintained for up to eight days.

No complications referable to this system of pacing have been encountered to date.

Comment

Floating, balloon-tipped catheters, when introduced into the right portion of the heart via the superior vena cava, have a strong tendency to pass to the right ventricular outflow tract and out to the pulmonary artery.[2] This propensity is ideal when the intent is to catheterize the pulmonary artery but is a liability for pacing purposes, since the right ventricular outflow tract is often an unstable site for pacing.[3] Light, floating-type catheters would seem particularly likely to be displaced to the pulmonary artery by the rapid blood flow in this area.

On the other hand, standard cardiac catheters entering the right side of the heart via the inferior vena cava are typically deflected toward the right ventricular apex,[4] which is an ideal pacing site. These considerations as well as the relative immobility and easy accessibility of the femoral vein at the pelvic rim led to choice of this site for insertion. However, the approach through the superior vena cava has not been used in our institution, and we are unaware of any published data on stability of balloon-tipped pacing catheters inserted via this route.

With our technique, passage of the catheter to the right ventricle and initial institution of pacing has been extremely rapid and technically very simple. The 97% incidence of successful insertion that we have encountered so far represents a definite improvement over the 80% success rate reported for the subclavian technique[5] which is currently favored for blind insertion of conventional, nonballoon-tipped catheters by many authorities. Of equal importance is the great rapidity and technical ease of insertion that we have experienced in nearly all instances. Because of this, we would anticipate that this technique would be particularly suitable for use by house officers and other physicians who have not had prior training in catheter manipulation.

Initially, stability was less than we have customarily experienced with conventional catheters positioned with fluoroscopy from the subclavian or femoral veins, although substantially better than that generally encountered with entry from the median basilic vein.[6] However, as experience accumulated, it became evident that excellent stability could be obtained if careful attention was given to ensuring good endocardial contact and optimal catheter position. The latter was found to be importantly influenced by the degree of curvature of the catheter tip. A 3.5-cm radius of curvature was found to

be optimal and consistently placed the catheter tip in or near the right ventricular apex. Greater and lesser degrees of curvature usually resulted in suboptimal positioning.

While we have as yet experienced no complications related to this technique, it is unrealistic to assume that none would occur with widespread usage. Certain types of complications may be anticipated and should be carefully guarded against. Certainly the potential for ileofemoral thrombophlebitis and consequent pulmonary embolism exists. Thus, although these catheters are extremely soft and flexible, some potential for trauma to the tunica intima must be assumed, and forward passage should never be forced if resistance is encountered. Furthermore, the leg that is used for catheter insertion should be examined carefully at frequent intervals for signs of thrombophlebitis. (If any appear, the catheter should be withdrawn and anticoagulation therapy instituted.) It is reassuring to note, however, that only one instance of thrombophlebitis and no instances of pulmonary embolism have been reported in 292 patients paced with conventional bipolar catheters inserted via the femoral vein.[5,6] Similarly, Cheng[7] has reported no thromboembolic complications in 100 cases paced for as long as 310 days by this route. Anticoagulants were not used in either series. Nevertheless, we have used low-dosage heparin sodium prophylactically in a few patients with concurrent conditions known to predispose to thromboembolism.

In some individuals, the femoral artery partially overlaps the femoral vein anteriorly in the femoral triangle. Thus, it is possible to transfix the femoral artery with the sheath and catheter while entering the vein. If this occurred and were unrecognized, serious damage to the artery might ensue. This possibility should be entirely avoidable if proper technique is used for femoral vein puncture. Specifically, when either the Cournand or Escher-longdwell needle is advanced toward the vein, its innermost occluding stylet (which is necessary only for puncturing the skin) should be removed. Inadvertent arterial puncture is then heralded by forceful back bleeding through the open lumen.

Conversely, certain complications seen with other pacing systems seem likely not to be encountered with this approach. In particular, cardiac perforation would seem far less likely with this type of soft, flexible catheter than with standard pacing catheters. Serious complications referable to subclavian puncture are not uncommon,[7,8] particularly in inexperienced hands, and are of course avoided entirely when the femoral vein is used. Entry into the coronary sinus occasionally occurs with conventional catheters and may lead to confusion and delay in establishing pacing. This possibility is precluded with balloon-tipped catheters, provided that the balloon is inflated during passage through the right atrium.

Finally, it is axiomatic that the flow-directed principle on which this system is based ceases to operate when cardiac output approaches zero. Thus, in complete asystole, or bradyarrhythmias where ventricular activation fails to generate detectable arterial pressure pulses, other methods for pacer insertion offer better potential for success.

With these reservations in mind, transfemoral pacing with balloon-tipped floating catheters appears to be a method that offers significant advantages over conventional techniques for institution of temporary transvenous pacing when fluoroscopy is unavailable.

Catheter prototypes used in this study were provided by Edwards Laboratories, Santa Anna, Calif.

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dispense the diluent for the glucagon whenever intravenous doses over 10 mg are ordered. The dispensing label would contain instructions for reconstitution of the drug with physiologic saline or water for injection.

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INTRACARDIAC KNOTTING OF A FLOW-DIRECTED BALLOON CATHETER

To the Editor: With the introduction of the flow-directed balloon-tipped catheter,[1] hemodynamic investigation of the severely ill patient has become so greatly facilitated that the rapid and reliable determination of right ventricular, pulmonary arterial or wedge pressures is now feasible with or without fluoroscopy. Although complications have been infrequent, we wish to call attention to the following complication, which, to our knowledge, has not previously been described — namely, intracardiac knotting of the Swan–Ganz catheter.

A 48-year-old woman was admitted to the Myocardial Infarction Research Unit of the University of Chicago with a two-hour history of chest pain and T-wave inversion in Leads 3 and aVF of the electrocardiogram. Soon after admission a balloon-tipped flow-directed catheter was inserted into a right antecubital vein and advanced according to the technic of Swan et al.[1] Right ventricular pressure was recorded after the catheter was advanced from the right atrium with the balloon inflated, but the catheter could not be advanced into the pulmonary artery. The balloon was then deflated, and the catheter withdrawn until pressure in the right atrium was recorded, a short episode of ventricular tachycardia being noted even with the balloon tip registering the atrial pressure. The balloon was reinflated, and the catheter again advanced until the phasic pulmonary-artery pressure was recorded (20/6, mean 11 mm of mercury). Because it was not possible to obtain a satisfactory pulmonary-artery wedge pressure it was decided to replace the catheter with another. Resistance to withdrawal was encountered after all but 16 cm had been removed, but further gentle traction allowed complete removal of the catheter, which showed a firm knot 14 cm from the tip (Fig. 1).

In retrospect, it is probable that a loop formed in the right ventricle during its initial insertion, and although pressure in the right atrium was recorded when the catheter tip was pulled back, the loop remained in the right ventricle. Subsequent inflation of the balloon and readvancement caused a knot to form in the right ventricle.

Knotting is a known but uncommon hazard of cardiac catheterization,[2,3] being potentially more common when small-bore flotation catheters or electrodes are used without fluoroscopic control.[4] Ventricular dysrhythmias associated with records of pressure in the right atrium are highly suggestive of this complication, and if ready access to

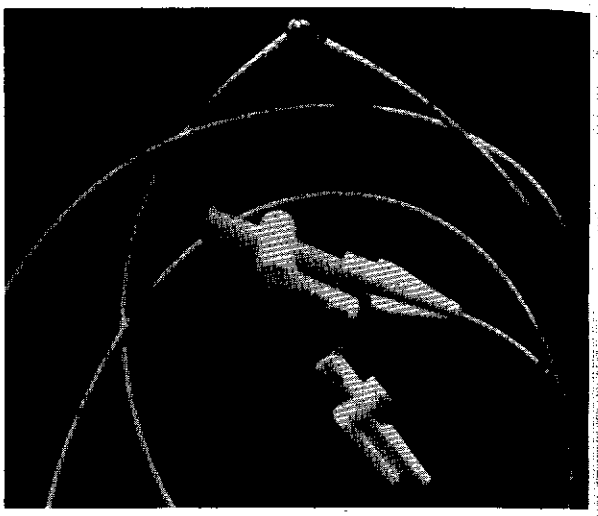

Figure 1. Firm Knot Situated 14 Cm from the Tip of the Flow-Directed Balloon-Tipped Cather.

fluoroscopy is unavailable, the catheter should be gently withdrawn. The dimensions of the balloon-tipped catheter are such that minimal difficulty should be experienced in extraction transvenously through the original venotomy even if the catheter is knotted, provided the balloon is not inflated.

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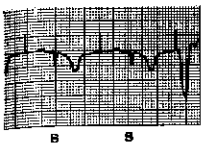
PACEMAKER REFRACTORY PERIODS

To the Editor: The key to the understanding of demand pacemaker function and complex pacemaker arrhythmias depends heavily on accurate knowledge of pacemaker specifications, which may be evaluated by chest-wall stimulation, a simple technic providing a model for the study of arrhythmias specifically related to the sensing mechanism.

We have measured the refractory periods of over 50 *implanted* demand (R-wave inhibited) pacemakers by chest-wall stimulation[1] and found that the 25 Medtronic 5841 pacemakers we have evaluated exhibit a refractory period at variance with the value listed in Table 2 in the third part of the article by Lown and Kosowsky on "Artificial Cardiac Pacemakers" (New Eng J Med 283:1023, 1970). Other workers have quoted the refractory period of this particular pacemaker to be 0, 80 and 200 msec.[2-4] However, we have found, as pointed out by Castellanos and Spence,[5] the effective refractory period after the delivery of a pacemaker stimulus to measure 380 to 440 msec in vivo.[1]

Figure 1 shows the electrocardiogram of a patient with



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Boston, Mass.

BIPOLAR BALLOON PACING CATHETER

For transmitting a pacing electrical stimulus from a pluse generator to the heart.

For transmitting the electrical signal of the heart to a recording device.

STERILE AND NON-PYROGENIC:

Only if package is not open or damaged.

FOR SINGLE USE ONLY

STORAGE INSTRUCTIONS:

Store at normal room temperatures and avoid prolonged exposure to direct light in order to protect the integrity of the latex balloon.

READ ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS CAREFULLY PRIOR TO USE.

CAUTION:

Federal law (U.A.S.) restricts this device to sale by or on the order of a physician.

CAUTION:

This product utilizes a natural latex balloon and should be used with caution in patients with known sensitivity to latex proteins.

<u>WARNINGS:</u>

Maximum Balloon inflation: 1.0 cc maximum.

Pulmonary complications may result from improper inflation technique.

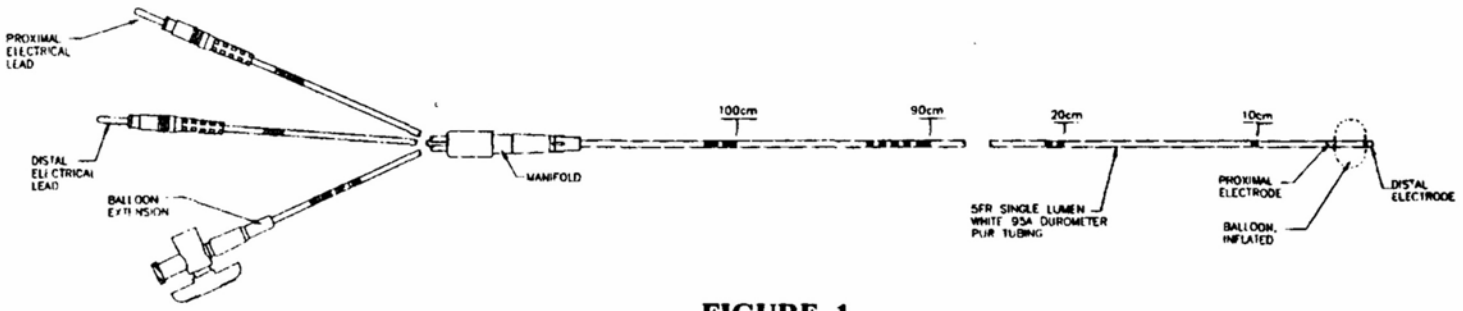

FIGURE 1

Catheter Size	Useable Length	Inflated Balloon Diameter	Electrode Spacing	Maximum Balloon Inflation
5F	90 cm	8 mm	1.0 cm	1.0 cc
5F	90 cm	8 mm	2.5 cm	1.0 cc
5F	110 cm	8 mm	1.0 cm	1.0 cc
5F	110 cm	8 mm	2.5 cm	1.0 cc

When using Pacing Catheters for temporary pacing and/or intracardiac ECG refer to the Pluse Generator and/or ECG operation manual for specific use instructions.
The catheter has 10 cm increments marked along its length. The length marks in the code illustrated in Figure 2 allow the physician to determine how much of the catheter has been inserted in the patient.

I	II	III	IIII	=	=I	=II	=III	=IIII	= =
10	20	30	40	50	60	70	80	90	100

FIGURE 2

DESCRIPTION:
Bipolar Balloon Pacing Catheters are designed for temporary transvenous cardiac pacing. They do not require the use of fluoroscopy. However, they are radiopaque polyurthane so that fluoroscopy can be used to guide insertion or to verify position if desired. The catheter is shipped in a sterile and non-pyrogenic package designed to prevent catheter kinking. Sterility will be lost if the package is opened or damaged prior to use. Bipolar balloon pacing catheters cannot be repaired if damaged.
The bipolar balloon pacing catheters contain two lumens for the following purposes:
1. Inflation lumen: provides a means of inflating and deflating the latex balloon near the distal tip of the catheter to facilitate catheter advancement to desired location.
2. Electrode Lumen: provides electrial conductor isolation from electrodes to the connector pins.

PRECAUTIONS
1. To avoid damage to the catheter or balloon when a cutdown is used, it is recommended that a vessel dilator or disposable vein guide be used. Never use forceps on the catheter.
2. Always deflate the balloon prior to withdrawing the catheter.
3. It is generally recommended that the catheter not be left in the patient for longer than three days.
4. Use filtered CO_2 for balloon inflation in any situation where balloon rupture may result in air embolus entering the arterial circulation, as in right-to-left.
5. Do not inflate the balloon with liquid or contrast media.

6. Perforations, arteriovenous fistula formation and other vascular trauma have been reported with the use of vascular catheters and complications may develop during any catheterization procedure.
7. Do not exceed the recommended balloon inflation .
8. Excessive kinking or bending of the Bipolar Balloon Pacing Catheter may cause damage to the internal conductive wires.
9. To minimize ventricular irritability, inflate the balloon before the catheter reaches the right ventricle.
WARNINGS:
Carbon dioxide MUST be used to inflate the balloon if there is a possibility that balloon rupture would result in air embolism in the left heart or systemic circulation.
Do not inflate the balloon on the catheter beyond the stated maximum inflation capacity(see Warning, Page 1). Exceeding this volume will not appreciably increase the diameter of the balloon and will increase the possibility of balloon rupture.

Although temporary pacing procedures have proven to be safe, the physician should be aware that certain complications can occur with the use of the cardiac catheter.

Bipolar Balloon Pacing Catheters should be used only by or under the supervision of physicians thoroughly trained in the techniques of transvenous temporary pacing.

When using ECG monitoring equipment for catheter placement, the equipment must be "Front End Isolated," or must have an isolated cable.

Due to arm movement, malposition and perforation occur more frequently when a transbrachial approach is used.

CATHETER INSPECTIONS AND TESTING

Bipolar Balloon Pacing Catheters are supplied in sterile packages. Inspect the package and do not use the catheter if there is any evidence that the package has been punctured or that the catheter has been damaged.

1. Remove the catheter from the package using sterile techniques.
2. Test each electrode and appropriate connector for continuity with an ohmmeter.

CAUTION: Do not use a standard continuity checker or ohmmeter when the catheter is in the vascular system. The relatively high current in the meter can cause electrical shock to the patient in the event of insulation breakdown.

3. Inflate the balloon to the recommended capacity of air and immerse the balloon in sterile water. If there is any evidence of air bubbles escaping around the balloon or if the balloon will not remain inflated, do not use the catheter.

CAUTION: Never use liquid for balloon inflation. Never inflate the balloon in ice water for testing.

CATHETER INSERTION (Read PRECAUTIONS AND WARNINGS prior to insertion)
The following instructions are a general guide intended for informational purposes only; the physician should add to or alter procedural details with respect to his clinical experiences.

1. Introduce the catheter by cutdown or by percutaneous technique through a suitable needle or sheath.

2.The catheter should be passed to the desired intracardiac position with the aid of ECG or fluoroscopy.

3. For intracardiac ECG the distal electrode connector (negative) is connected to the V lead of the ECG. The proximal electrode connector (positive) is connected to the positive terminal of the external pacemaker.

4. For temporary pacing , the distal electrode connector (negative) must be connected to the negative terminal of the external pulse generator. The proximal electrode connector (positive) must be connected to the positive terminal of the external pulse generator.

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WARRANTY:

Seller warrants that reasonable care has been used in the manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness, since handling, storage, cleaning and sterilization of this product as well as factors relating to the patient, his/her diagnosis, treatment, surgical procedures, and other matters beyond seller's control directly affect this product and the results obtained from its use. Seller shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product other than replacement of it. Seller neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product.

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1. Merchandise cannot be returned without the prior approval of the Customer Service Manager.

2. Dated products (items with a shelf life) cannot be returned after 30 days from initial shipping date.