Positive Results with a New Screw-in Electrode with Isolated Screw and Fractal Coating of the Ring: the RETROX Electrode in the Atrial Position

M. BOKERN
Waterland Ziekenhuis, Purmerend, Netherlands

J. RES, K. VAN ENGELEN, G. KROON
Ziekenhuis De Heel, Zaandam, Netherlands

Summary

The clinical evaluation presented here gives the data of the implantation of the RETROX-electrode in the atrium and the pacing parameters measured from implantation till 6 month follow-up. In 14 patients, a DDD-pacemaker was indicated and in this 14 patients, a preshaped J-form electrode was used (Biotronik RX 53-JBP). A long term evaluation is planned, up to 12 months and this report is the preliminary experience with RETROX. Special care was taken to position the tip in a proper place for pacing and sensing by using the unfiltered intra-atrial electrogram before and after screwing. Atrial threshold was at implant and at 3 month follow-up 0.8 ± 0.4 V at 0.5 ms pulsewidth and 1.7 ± 0.55 V at 0.4 ms pulsewidth respectively, P-wave amplitudes were 2.1 ± 1.0 mV (range 0.7 - 4.0 mV) and 2.3 ± 0.9 mV (range 1.0 - 3.7 mV) respectively. Handling characteristics of the electrode were good. Dislocation or other complications were not observed. RETROX is considered as a good alternative for atrial pacing electrodes, especially when active fixation is preferred or needed and the programming of low atrial output will enhance pacemaker longevity.

Keywords

Screw-in-electrode implantation, pacing parameters

Background

The ideal electrode has a combination of functions: easy to implant at any location in the atrium, stable position after implantation, permanent low or acceptable thresholds and good sensing properties. Among others, the new screw-in electrodes give a stable position in the atrium, especially in patients after open heart surgery or in patients with unstable position of tined electrodes. However, an unfavourable experience with not insulated screws showed that the threshold can increase to high levels [1,2]. In this case, the stimulation output has to be set at levels above a virtual maximum which the pacemaker cannot deliver. RETROX is a screw-in electrode with the screw isolated from the ring and a smooth running screw-mechanism, giving the advantage of easy insertion in the vessel and retraction when desired or needed. In this study, a long-term follow up of the RETROX electrode is planned and the results given here are a preliminary report of this prospective study.

Materials and Methods

The most important feature of RETROX is that the screw is insulated from the ring (surface of 5.3 cm², fractal coated, see Table 1). In 14 patients, a J-shaped RETROX electrode (RX 53JBP) was implanted in the right atrial appendage. However, any other place can be selected by preshaping the guide-wire as long as the required pacing and sensing conditions are fulfilled. Nine males and five females (age ranged from 53 till 80 years) were all symptomatic for dizziness or syncope due to a progressed AV block, either complete

Electrode material	tip	80% Pt/ 20% Ir
	ring	90% Pt/ 10% Ir
Surface	tip	fractal Ir coating
	ring	fractal Ir coating
Polarity		bipolar
Interelectrode distance		17 mm
Surface area	tip	5.3 mm²
	ring	25.4 mm²
Helix	material	70% Pt/ 30% Ir
	type	retractable
	length	1.8 mm
	insulation	yes
	soluble coating	no
Lead Body	construction	coaxial
	No. filaments	4
	conductor	PM35N
	insulation	Silicone rubber
	length	45 or 53 cm
	diameter	2.6 mm/ 7.8 F
Resistance	tip	± 60
	ring	± 20

Table 1. Technical data of RETROX 53-JBP & 45-JBP.

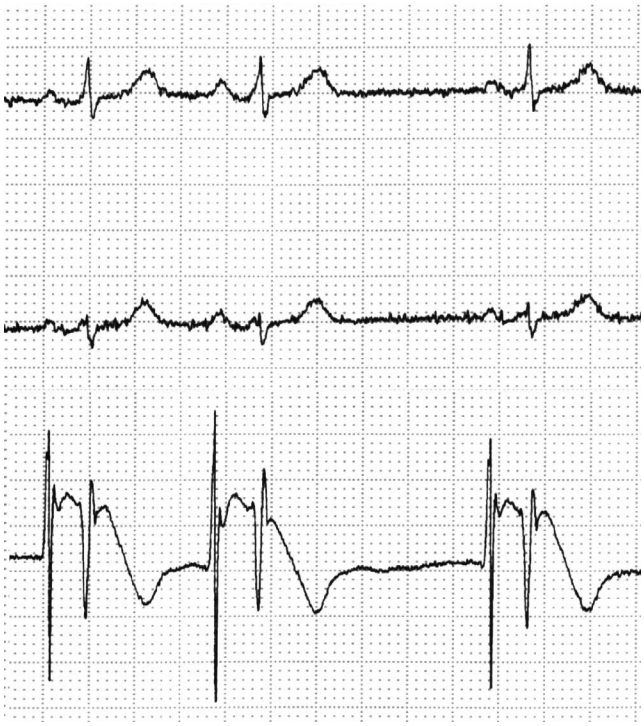

Figure 1. Unipolar intracardiac atrial electrogram from the tip of the electrode, which have to be recorded without filtering, either by hooking up to V1of an ECG-recorder or measured with the pacing system analyzer (note that the Biotronik ERA 300 will record a filtered electrogram if you press P/R). Note that the lesion-potential of the P-wave is present while the screw is still "in".

and permanent or on an intermittent base. All patients received a DDDR pacemaker. One patient had a previous coronary bypass surgery and one had paroxysmal atrial fibrillation in his medical history. Handling characteristics of the electrode, such as ease of introduction, flexibility, ease of manipulation, fixation, and röntgen-opacity, were scaled in a range from poor, difficult, moderate, good to very good.

During implantation, special care was taken for proper positioning of the tip which should be perpendicular to the atrial wall. Afterwards, the patient had bed rest for 24 hours. Dismissal followed usually the next day after checking and eventually reprogramming the pacemaker. A röntgen-thorax was performed in every patient. As a sign of good contact between the electrode-tip and the atrial wall the intracardiac atrial electrogram was observed, either on the pacing system analyzer without filtering, or on the ECG which could be observed by the implanting cardiologist on the monitor-screen in the catheterisation room (see Figure 1). If there is no lesion-potential present before or after turning the screw "out" than there is no proper contact between tip and atrial myocardium. In this case, the electrode will be repositioned or withdrawn and advanced to the atrial wall again. After turning the screw out, the lesion-potential should be increased compared to those before turning the screw "out" (see Figure 2). The stability of the position of the electrode is also confirmed by advancing and withdrawal the body of the electrode in and out of the vein. This can also be tested by turning the whole lead body; whereby the tip has to stay in its place. The third point of attention should be addressed to the "hole" in the distal part of the electrode. When the screw is in the "in" position, the tip is completely radio-opaque, otherwise, when the screw is "out", a hole may be visible in the

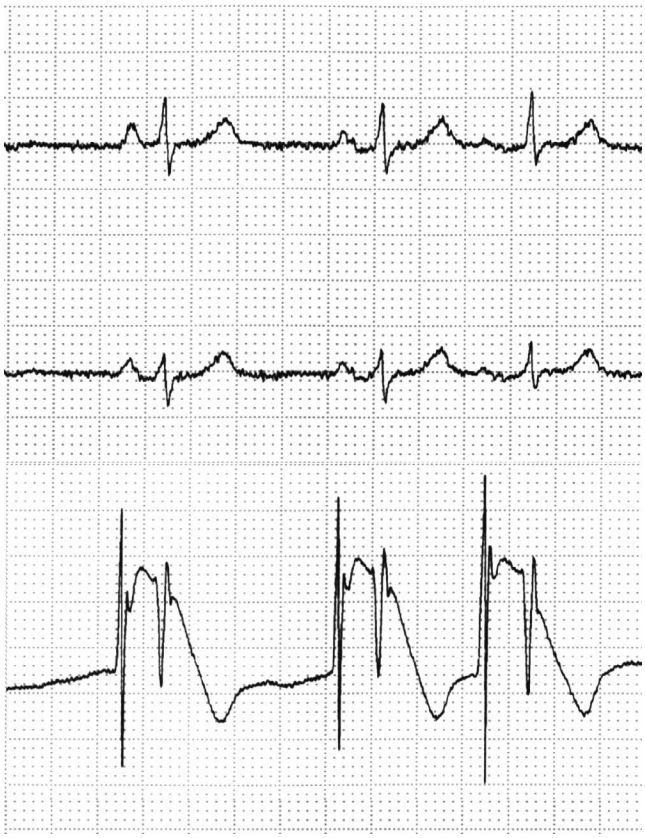

Figure 2. Unipolar intracardiac atrial electrogram from the tip of the electrode after the screw is turned "out". There is an increase of the lesion-potential. Note that in both recordings the remote signal of the ventricular activation is superimposed on the lesion-potential.

middle of the distal part of the tip of the lead (Figure 3). Atrial threshold, pacing impedance, and P-wave amplitude were measured with a standard pacing system analyzer (Biotronik ERA 300). For the observation of the lesion-potential, the intracardiac electrogram was recorded on the screen or in the print-out. When measuring the P-wave amplitude, the P/R button has to be activated, but, unfortunately, this changes the filtering characteristics which alters the morphology of the lesion potential. Therefore, special notice was undertaken to observe and record the lesion potential without filtering and measuring the P-wave amplitude with filtering. During follow up, all measurements were performed via the pacemaker (Biotronik INOS² CLS or ACTROS DR). The P-wave amplitude was defined as the lowest value during 10 seconds of recording, not as the average or highest value in the observation time.

Time point	Atrial voltage threshold (V)	
	mean	standard deviation
1	0.8	0.4
2	1.51	0.68
3	1.7	0.55
4	1.28	0.28

Table 2. Atrial threshold (mean and standard deviation) in 14 patients 1: at implantation, 2: before dismissal (usually day 2 or 3), 3: after 2 or 3 month, 4: after 6 months of follow-up.

Time point	Pacing impedance (Ω)	
	mean	standard deviation
1	442	140
2	342	66
3	400	111
4	364	103

Table 3. Pacing impedance (mean and standard deviation) in 14 patients 1: at implantation, 2: before dismissal (usually day 2 or 3), 3: after 2 or 3 month, 4: after 6 months of follow-up.

Results

In all patients, the subclavian vein was punctured; in 10 from the left side and 4 from the right side. For the atrial and the ventricular electrodes, separate punctures were done to avoid friction of the leads at the point of entrance in the vessel. Within 10 minutes, a good position in the right atrial appendage was found after 1 to 4 positions were tried. All handling characteristics of the electrode were scored as good, except for the radioopacity which was esteemed as very good in two occasions. Complications of any kind were not met, especially dislocation was not observed. The tip of the electrode was positioned in the right atrial appendage in all patients. The data of the atrial threshold is given in Table 2. The range at implantation was between 0.3 and 1.3 V (after three attempts to obtain a stable position). At day 2-3, the threshold was in the range between 0.4 and 2.8 V. The latter value was measured in a patient with proper atrial pacing. The value at implantation was 1.2 V and during follow up at 3 month the

Time point	P wave amplitude (mV)	
	mean	standard deviation
1	2.09	1.03
2	2.03	0.93
3	2.31	0.85
4	3.58	1.67

Table 4. P-wave amplitude (mean and standard deviation) in 14 patients 1.at implantation, 2: before dismissal (usually day 2 or 3), 3: after 2 or 3 month, 4: after 6 months of follow-up.

threshold was reduced to a very low level of 0.9 V.
The pacing impedance was in the normal range. In 6 patients, the atrial threshold was also determined at week 6: the data of the threshold are in the same range of those at 3 months. The pacing impedance varied widely, the overall results are given in Table 3. The individual impedance measurements show a wide range varying from 228 till 846 Ω during implant. One patient had a pacing impedance of 346 Ω shifting during follow up to 530 Ω. The patient with the lowest impedance stayed at that level, whereby no other pathology was present and other pacemaker data were excellent.
Table 4 reflects the data of the P-wave amplitudes during implantation and follow up. It has to be stressed that the lowest value during measurements was recorded. The range of values varied between 0.7 and 4.5 mV during implantation and at 3 month follow up measurements this range was 1.0 and 3.7 mV.

Discussion

Only during implantation, the position of the lead, its pacing and sensing characteristics and thus its future functions can be determined. Because functioning of the electrode cannot be programmed afterwards, this is of clinical importance for the pacemaker function in its continuous "cooperation" with the patient's heart. The implantation is a sterile operation which has to be elaborated in a rather short time under different and not always optimal conditions, i.e. dependent on individual physiological and pathological status of the patient, quality of paramedical assistance, availability of röntgen-equipment, etc. Therefore, the result of an implantation of a pacemaker electrode is always a trade-off

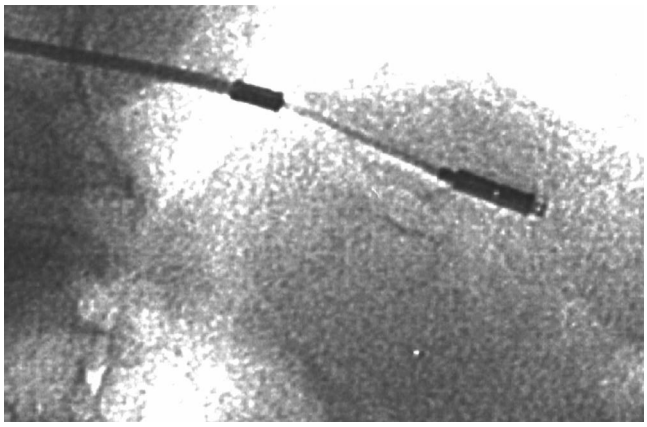

Figure 3. Röntgen or fluoroscopic recording of a straight (ventricular) electrode in antero-posterior view to check the fluoroscopic "hole"in the distal part of the electrode to confirm that the screw is turned completely in the final position: "out".

between the optimal and the practical. However, some practical tools can help during such procedures.
We have used the intracardiac electrogram deducted from the tip of the electrode which immediately gives information on the position of the tip with respect to a good contact with the myocardium. First, in case of the tip is only floating or adjacent to the myocardium, a P-wave can be seen and its amplitude can be measured. Second, the presence of lesion potential indicates a good contact which predicting in most cases a low threshold and a stable position even if the guide wire inside the electrode is withdrawn. In case of fixation by an insulted cork-screw, fixation of the tip may be ensured, but, moreover, a good contact between the ring of the electrode and the atrial myocardium is required for long-term pacing at low outputs. After turning the screw "out", the lesion potential has to increase (see the small but clear difference in Figure 1 and 2). The tip of the RETROX has also a special topic to determine that the screw in the "out" position: a radio-non-opaque hole in the distal part (see Figure 3). However, there might be some difficulties to observe this phenomenon, e.g. röntgen-equipment should be movable over a large range and not every pacemaker implanting centre has the disposal of a catheterization room for pacemaker implantations. Even if a large review in a single centre shows a rate of macro-dislodgement of 2.9% [3], the rate of dislodgement of atrial electrodes with active fixation can be very low

and the absence of dislocation is in coherence with this observation [4].

It may expected that the atrial pacing threshold will increase after implantation and the peak of the threshold will be achieved in about 6 till 8 weeks after implantation. This -more or less physiological- increase is also present in our data. It is already noticeable in the second measurement performed on 2. or 3. day after implantation. At 6 weeks or 3 months, the highest threshold value may be seen. It has to be stressed that the atrial threshold level increases after implantation, but, nevertheless, the increase was less then 3 times the initial value in all patients. Other leads show a higher peaking ratio (e.g. tenfold [5]) defined by the maximum threshold ever measured divided by the threshold at implantation. Also, special attention should be given to thresholds exceeding more than three times the initial value at the test before dismissal which may indicate (micro-) dislodgement. In general, the threshold levels found in this population are in agreement with other leads with active fixation, although a different technique of threshold determination is used [5].

Conclusion

Active fixation will enable to position the tip of the electrode at any location the physician has in mind. The right atrial free wall has been suggested as an alternative pacing and sensing site [6], but other sites as well can be considered such as bi-atrial site pacing in patients with paroxysmal atrial fibrillation and delayed intra-atrial conduction times [7]. In particular, RETROX electrodes with preshaped J-form and active fixation by an insulated screw have very good handling characteristics. Pacing threshold and sensing parameters were good, even if a higher pacing impedance shall increase the overall performance. Implanting electrodes, good results were achieved by taking special notice of the intracardiac atrial signal. Especially, the lesion potential played an important role to obtain the final position of the tip of the electrode, i.e., a proper contact with atrial myocardium.

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