Pacemaker Generator Re-Implantation; 25 Years Experience in Over 2000 Patients?

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**Background:** Permanent pacemakers were first developed in the late 50s to prevent mortality from complete heart block. The information on complications related to modern pacemaker therapy is sparse and with a few exceptions limited to experience in single dedicated centers. Such information is important and has been used for quality improvement in the individual center. The quality assessment of therapeutic procedures is essential to evaluate and monitor the practice of permanent pacemaker implantation, which is needed for continuous quality improvement of the patient's life. The present study addresses the issue of pacemaker re-implantation at the Critical Care Department - Cairo University, which is a referral center over a quarter of a century in terms of incidence, etiology and long term outcome.

**Patients and Methods:** The study protocol included all the implantations whether first time or re-implantations of permanent pacemakers that took place from 1982 till the end of 2006. For some more analyses two separate periods were studied, in order to assess the impact of the pacemaker technology improvement and learning curve of the operators on the pacemaker implantation and re-implantation. Patients with pacemaker problem were subjected to the following techniques for assessing pacemaker functions: Twelve lead ECG, magnet test, telemetry, plain X-ray chest and/or fluoroscopy, ambulatory ECG monitoring, echocardiography, venous duplex, provocative maneuvers, and invasive pacemaker testing in patients with suspected pacemaker malfunction with inconclusive noninvasive testing.

**Results:** 2699 permanent pacemakers were implanted in 2088 patients (pts) and pacemaker generator re-implantation was done in 611 pts (29.3%). Normal battery end of life: Occurred in 352 patients (57.6%) of 611 patients had their pacemaker replaced. Pocket infection and extrusion: Were diagnosed in 89 patients (14.6%). Requirement of new mode of pacing or programmability: Occurred in 78 patients (12.8%) of the replaced pacemaker generators. Battery replacement due to technical failure of lead placement: Diagnosed in 30 patients (8.2%). Electronic battery component failure: In 37 patients (6%). Premature battery end of life (EOL): only in five patients (0.8%) of the replaced pacemaker generators. Compared to the group I of patients, the second group exhibited a significantly lower rate of pocket infection and extrusion (12% in group II versus 33.8% in group I, \( p=0.0003 \)), and lower need for battery replacement due to technical failure of lead placement (6.9% in group II versus 18.3% in group I, \( p=0.002 \)), also there was a decline in the incidence of premature battery end of life due to insulation defect in group II (0.56%) versus (2.8%) in group I (\( p\)-value=0.02). But there was a higher rate of normal battery end of life in group II as compared to group I (61.5% versus 28.2% respectively, \( p=0.002 \)), whereas in both groups there was comparable prevalence of redo-implantation due to the need for a new pacing mode or programmability (11.3% in group I versus 13.0% in group II, \( p\geq0.05 \) and electronic component failure (5.6% in group I versus 6.1% in group II, \( p\geq0.05 \)).

**Conclusions:** An organized follow-up program, strictly adhering to the international scientific guidelines for pacemaker follow-up, is necessary in order to improve the healthcare services we provide to the pacemaker patients. The pacing practice in Critical Care Department - Cairo University revealed that, the rate of total battery re-implantation agrees with the reported literature, but with higher incidence of pocket infection and extrusion, technical failure of lead placement which necessitates battery replacement, and the need of a new mode of pacing or programmability.

**Key Words:** Pacemaker – Battery life termination – Complication.
Background

Permanent pacemakers were first developed in the late 50s to prevent mortality from complete heart block [1]. Over the subsequent decades, there was impressive progress in pacing technology and permanent pacing became the standard treatment for symptomatic bradycardia. The early primitive pacing devices which allowed only fixed rate asynchronous pacing in the right ventricle, soon evolved into more complicated systems capable of responding to the patient’s heart rate, as well as pacing right atrium, right ventricle and left ventricle. These advances allowed pacemaker therapy to progress from simply preventing mortality to restoring normal atrioventricular activation, improving haemodynamic function and thus improving quality of life [2]. The information on complications related to modern pacemaker therapy is sparse and with a few exceptions limited to experience in single dedicated centers [3-9]. Such information is important and has been used for quality improvement in the individual center [10,11]. The quality assessment of therapeutic procedures is essential to evaluate and monitor the practice of permanent pacemaker implantation, which is needed for continuous quality improvement of the patient’s life. Twenty five years have passed since the first implanted permanent pacemaker (PM) in 1982 at the Critical Care Department of Cairo University; during this lengthy follow up several pacemakers implanted had to be replaced for a variety of reasons. So the present study addresses the issue of pacemaker re-implantation in a large referral center over a quarter of a century in terms of incidence, etiology and long term outcome.

Patients and Methods

The study protocol included all the implantations whether first time or re-implantations of permanent pacemakers that took place in the Critical Care Department, Cairo University from 1982 till the end of 2006. For some more analyses two separate periods were studied, in order to assess the impact of the pacemaker technology improvement and learning curve of the operators on the pacemaker implantation and re-implantation. Period I from 1982 to the end of 1993 and period II from 1994 to the end of 2006. Implantations with many missing data were excluded from the study.

The following data were obtained for each patient: Personal history (age & sex....etc), clinical examination, indication for permanent pacemaker implantation, pacemaker data (e.g. mode of pacing, programmed rate, programmed sensitivity ....etc), pacemaker malfunction, side effects and management by subjecting the patients with pacemaker problem to the following techniques for assessing pacemaker functions:

1- Twelve lead ECG to assess the pulse repetition rate, presence or absence of stimulus artifacts, adequacy of capturing and sensing.

2- Magnet test done by applying the magnet over the battery of the pacemaker to determine the capturing function in patients with dominant intrinsic rhythm and battery life assessment.

3- Telemetry; which is the transmission of data from the implanted pulse generator to an extracorporeal receiver which serves in:
   - Hardware identification including battery status (cell voltage and impedance), in addition to lead impedance, pacing and sensing thresholds.
   - Event markers which report the real time behavior of the implanted pacemaker with respect to paced and sensed events; it indicates the relationship between atrial and ventricular sensing and stimulus emission, it can also indicate a stimulus emission from either ventricular or atrial channel, which may be not reflected on the surface ECG.
   - Intracardiac electrocardiogram (EGM) which represent the intracardiac signals.
   - Memory contents which include the data placed into memory by the physician and the event counter which allows the pacemaker to store information that will give a detailed report of what the pacemaker did over a given period of time.

4- Plain X-ray chest and/or Fluoroscopy.

5- Ambulatory ECG monitoring which is used in intermittently symptomatic patients in order to correlate the symptoms with the underlying rhythm disturbance.

6- Echocardiography used to determine post implantation complications as haemopericardium, masses or vegetations involving pacemaker leads.

7- Venous duplex used to detect deep venous thrombosis (DVT) related to pacemaker implantation; if the patient’s clinical examination suspects a diagnosis of DVT.
8- Provocative maneuvers to detect the evoking skeletal muscle myopotential which may cause pacemaker inhibition due to over sensing, and this was done by interlocking the fingers and pulling the arms vigorously or abducting both arms while hands are placed palm to palm and pushed together. Also movement of the pulse generator beneath the skin may demonstrate a break in the electrical circuit. In addition to deep breathing or vigorous coughing, which may enhance lead tip instability.

9- Invasive pacemaker testing in patients with suspected pacemaker malfunction with inconclusive noninvasive testing; surgical exploration is done in the catheter laboratory, where facilities for invasive testing and emergency pacing are available.

Statistical analysis:

For continuous variables mean value, median value, variance and standard deviation were computed. Dichotomous variables were expressed as rates and percentages. Continuous variables were tested for normal distribution and appropriate statistical tests were applied. Means were compared using Student’s t-test for the normally distributed variables, or the Mann-Whitney test otherwise. A p-value <0.05 was considered statistically significant.

Results

Over the above mentioned period, 2699 permanent pacemakers were implanted in 2088 patients (pts). The patients were consisted of 1036 male (49.6%) and 1052 female (50.4%) with age range from 3-95 years (mean 63±15.4 years). The rate of new implantation increased from 9/year in 1982 to 192/year in 2006 and pacemaker generator re-implantation was done in 611 pts. (29.3%) (Fig. 1 & Table 1).

1- Normal battery end of life (EOL): Which occurred in 352 patients which represent 16.9% out of total 2088 patients included in this study and 57.6% of 611 patients had their pacemaker replaced. Patients who presented with this problem were subjected to new pacemaker battery re-implantation.

2- Pocket infection and extrusion: Occurred in 89 patients out of total 2088 patients implanted with pacemaker (4.3%), which represent 14.6% out of 611 who had pacemaker re-implantation. Patients presented to our pacemaker clinic by pocket infection, infective endocarditis or extrusion. Explanation of the pacemaker and re-implantation on the other side or at a deeper sub pectoral plane on the same side after complete healing of the wound or epicardial lead implantation after removal of the infected leads via median sternotomy and cardiotomy with implantation of the battery under the muscles of the anterior abdominal wall were performed (Fig. 2).

3- Requirement of new mode of pacing or programmability: Occurred in 78pts. (3.7%) out of study population, which represent (12.8%) of the replaced pacemaker generators. Generator re-implantation was carried out due following reasons e.g. myopotential inhibition in VVIO that was replaced by a VVIM generator pacemaker, VVI replaced by VVIR to add rate-response characteristic in patients with chronotropic incompetence or DDD in patients with pacemaker syndrome (Fig. 3), AAI replaced by a DDD pacemaker in sick sinus syndrome progressed to bi-nodal disease or DDD replaced by a biventricular pacing (CRT-P or CRT-D) in heart failure patients.

4- Battery replacement due to technical failure of lead placement: Occurred in 50 patients (2.4%) out of study population, which represent (8.2%) of the replaced pacemaker generators for the following indications e.g. under sensing malfunctions in VVIO pacemaker, so the battery was replaced by a VVIM generator, displacement of floating atrial lead in VDD pacemaker replaced by a VVI or DDD pacemaker, and failed reposition of atrial lead in DDD pacemaker, so the pacemaker was replaced by VVI pacemaker generator.

5- Electronic battery component failure: Occurred in 37 patients (6%), all the batteries were replaced, except one case which was not recalled by the manufacturer (Biotec pacemaker), and unfortunately the patient died before the generator could be replaced.

6- Premature battery end of life (EOL): Occurred in five patients (0.8%) of the replaced pacemaker generators, where the insulation failure led to battery premature end of life due to high current drain from the battery. All of the five patients were subjected to generator and leads replacement (Fig. 4).
The studied patients were divided into two groups, group I covered the period from 1982 to the end of 1993 (including 648 implants in 578 patients), and group II covered the period from 1994 to the end of 2006 (including 2051 implants in 1510 patients). The patients were consisted of 294 male (50.9%) and 284 female (49.1%) with age range from 3-85 years (mean 58±15.8 years) in the group I, while in group II there were 742 male (49.1%) and 768 female (50.9%) with age range from 3-95 years (mean 61.09±17.2 years) (p-value >0.05). The mean rate of new implantation increased from 54/year in group I to 160/year in group II, also PM re-implantation showed progressive increase with time from 71 cases in group I to 540 cases in group II (mean rate of re-implantation of 6/year in group I as compared to 42/year in group II) (Fig. 5).

Compared to the group I of patients, the second group exhibited a significantly lower rate of pocket infection and extrusion (12% in group II versus 33.8% in group I, p=0.00003), and lesser need for battery replacement due to technical failure of lead placement (6.9% in group II versus 18.3% in group I, p<0.002), also there was a decline in the incidence of premature battery end of life due to insulation defect in group II (0.5%) versus (2.8%) in group I (p-value=0.02). But there was a higher rate of normal battery end of life in group II as compared to group I (61.5% versus 28.2% respectively, p=0.002), whereas in both groups there was comparable prevalence of redo-implantation due to the need for a new pacing mode or programmability (11.3% in group I versus 13.0% in group II, p>0.05) and electronic component failure (5.6% in group I versus 6.1% in group II, p>0.05). (Table 1 & Fig. 6).

### Table 1: Indications of re-implantation in both groups.

<table>
<thead>
<tr>
<th>Indications of pacemaker generator re-implantation</th>
<th>Total</th>
<th>Group I</th>
<th>Group II</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal battery end of life (EOL)</td>
<td>352 (57.6%)</td>
<td>20 (28.2%)</td>
<td>332 (61.5%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Pocket infection and extrusion</td>
<td>89 (14.6%)</td>
<td>24 (33.8%)</td>
<td>65 (12%)</td>
<td>0.00003</td>
</tr>
<tr>
<td>Newer mode or programmability required</td>
<td>78 (12.8%)</td>
<td>8 (11.3%)</td>
<td>70 (13.0%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Battery replacement due to technical failure of lead placement</td>
<td>50 (8.2%)</td>
<td>13 (18.3%)</td>
<td>37 (6.9%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Electronic component failure</td>
<td>37 (6%)</td>
<td>4 (5.6%)</td>
<td>33 (6.1%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Premature battery EOL due to lead insulation defect</td>
<td>5 (0.8%)</td>
<td>2 (2.8%)</td>
<td>3 (0.56%)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

N = Total number of re-implants. p<0.05: Means statistically significant.

![Figure 1: Yearly implanted rate of permanent pacemakers over 25 years.](image-url)
Discussion

This work presents the data on cardiac pacing with focusing on pacemakers re-implantation in one of the referral departments in Egypt, it describes the most salient characteristics and the changes in recent years, discusses how closely the pacing practice adhere to current clinical guidelines, and facilitates hospital comparisons of their pacing activity.

The total pacemaker re-implantation occurred in 29.3% in our department and this coincides with the other pacemaker registries as stated by Danish pacemaker registry 2006, which was 25.8% [12]. The incidence of pacemaker re-implantation was 25.1%, 25.4% and 26% in Spanish pacemaker registries 2005, 2007 and 2008 respectively [13-15].

Figure 5: Mean rate of implantation and re-implantation per year in the two groups.

Figure 6: Indications of re-implantation in both groups.

Figure 2: Patient with pacemaker extrusion, in which pacemaker was explanted and a new pacing system was implanted on opposite side.

Figure 3: Patient with VVI pacemaker presented with pacemaker syndrome due to retrograde conduction (black arrows), so the VVI pacemaker was replaced by DDD pacemaker and the above rhythm strip ECG and the event channel of the pacemaker document the presence of retrograde conduction which is responsible for pacemaker syndrome in this patient.

Figure 4: Patient with premature battery end of life due to lead insulation defect, which seen under the Lt. clavicle (black arrow).
The main indication for re-implantation was normal battery end of life (57.6%) in our study, but the battery running out at the end of its useful life is expected as a normal course of pacemaker implantation not as a battery failure. The incidence of the normal end of life as reported by Danish pacemaker registry 2006 was 46.7% of the total re-implantation procedures [12] and by a single academic centre in northern Greece was 85% [16] and by Swedish pacemaker registry 2008 was 88.5% [15], and by Swedish ICD and pacemaker registries were 81.2% and 79.9% in 2007 & 2009 respectively [17,18]. Normal battery end of life constitutes the second indication for battery replacement in group I of our study (28.2%), while in group II it presented as first indication for battery replacement which occurred in 61.5% of the patients (p=0.002), and this represents normal endpoint of the normal batteries which implanted in the first group. Gadler F and Fredenson A. Reported in the same manner; that the pacemaker re-implantation due to normal battery end of life was 47% in 2003, while in 2007 increased to be 81.2% [17].

Pocket infection and extrusion was the second cause of re-implantation in our study population (14.6%), but still this incidence is high in comparison to the Danish pacemaker registry which was 4.9% of the total re-implantation procedures [12]. The academic centre in northern Greece reported the incidence of pocket infection and extrusion to be 5.7% [16], the incidence was 7.3% by Spanish pacemaker registry 2008 [15], and Gadler F and Fredenson A. Reported that; the pacemaker re-implantation due to pocket infection and extrusion was 5%, 4.1% and 4.9% in 2003, 2007 and 2009 respectively [17,18].

We have to state that we still have higher incidence of pocket infection and extrusion in comparison to international records. But pocket infection and extrusion was the main cause of re-implantation in group I (33.8%), and it showed a progressive decline to (12%) in group II (p=0.00003), this can be attributed to the continuously giving attention to the experience of the pacemaker implantation team and application of antiseptic techniques at our catheter laboratory. Another issue in the pocket infection and extrusion in our center is that; the apparently large percentage of infection-erosion (14.6%) does not coincide with the percentage of infection-erosion as a complication following pacemaker implantation in our center, which is estimated to be less than this figure. But it refers to the incidence of infection-erosion among the patients who came for re-operation in our centre, which is a reference centre in Egypt and attracts the complicated cases.

The total incidence of pacemaker re-implantation due to requirement of new mode of pacing or programmability was 12.8%, which still high in comparison to the Danish pacemaker registry (5.9%) [12]. The academic centre in northern Greece reported the incidence of new mode of pacing or programmability was required in 3.3% of the total re-implantation procedures [16]. It was 1.1% by Spanish pacemaker registry 2008 [15], and by Swedish ICD and pacemaker registries were 6.6% and 8.1% in 2007 & 2009 respectively [17,18].

The need of a new mode of pacing or programmability was (11.3%) in group I and (13.0%) in group II (p≥0.05). The nearly fixed rate of re-implantation due to this indication, despite the marked increase in the implantation rate in the group II, illustrates the shift to more physiologic pacing modes, which reflect the global trend in pacing for mimicking the physiological activity of the heart and for addressing problems other than symptomatic bradycardia. Changes in pacing modes from 1982 to 2006 in our centre reflect a global attempt at approaching normal myocardial excitation. Ventricular pacing was followed by dual-chamber pacing in order to maintain atrioventricular synchrony, while at the same time, rate-responsive systems were used in order to offer an adjunctive benefit to chronotropically incompetent patients. Finally, since 2002 cardiac resynchronization therapy has been used, following the discussion about inter and intraventricular synchrony that began in the mid 90s. Gadler F and Fredenson A. reported in the same manner; that the pacemaker re-implantation due to requirement of a new mode of pacing or programmability was 7.4% in 2003, 6.6% in 2007 and 8.1% in 2009, which is more or less the same rate of re-implantation in different periods [17,18].

Battery replacement due to technical failure of lead placement as an indication for pacemaker re-implantation showed a significant decrease in the second group 6.9% in comparison to 18.3% in group I (p=0.002). Bayata S, et al, stated that; his retrospective data revealed temporal changes in pacemaker implantation practice during second period (First period: 1986-1996, second period: 1997-2007) of the study in his department of a teaching hospital [19]. But still the total incidence
in our study (8.2%) is higher in comparison to the Danish pacemaker registry which is 1.3% [12] and than the Swedish pacemaker and ICD registries, which were 0.3% and 0.6% in 2007 & 2009 respectively [17,18].

Electronic component failure as an indication for re-implantation showed comparable incidence in both groups (5.6% in first group Vs. 6.1% in the second group; p≥0.05). However the total incidence of this problem (6%) is still high as compared to the Danish pacemaker registry where the incidence of this problem was reported to be 2.6% of the total re-implantation procedures [12] & by Spanish pacemaker registry 2008 is 1.1% [15], and by Swedish ICD and pacemaker registries to be 0.3%, 0.1%, and 0.5% in 2003, 2007 and 2009 respectively [17,18]. But the academic centre in northern Greece reported the incidence of re-implantation due to electronic component failure was 5.5% [16].

Premature EOL due to lead insulation defect occurred in 2.8% in the first group, while in the second group occurred in 0.56% (p-value = 0.02), and the total incidence in our study was 0.8%. It is comparable with the other reported registries such as Danish pacemaker registry which was 0.1% [12] and Spanish pacemaker registry 2008 which was 1.1% [15], and Swedish ICD and pacemaker registries which were 2%, 2.4% and 1.8% in 2003, 2007 and 2009 respectively [17,18].

Conclusion

An organized follow-up program, strictly adhering to the international scientific guidelines for pacemaker follow-up, is necessary in order to improve the healthcare services we provide to the pacemaker patients [20]. The annual report of the different centers implanting the pacemaker is representing a corner stone in assessment of the quality of the therapeutic procedures of the permanent pacemaker implantation, which will be reflected on the quality improvement of the patient’s life, and this report should extent to the all pacemaker implanting centers in Egypt, like some countries which have established a pacemaker annual report in order to obtain detailed information on national practice as well as from individual centers. As regard the Critical Care Department - Cairo University which is considered as one of the centers which has average rate of pacemaker implantation per year with a trend to increase the implantation of physiologic and biventricular pacing, our pacing practice revealed that, the rate of total battery re-implantation agrees with the reported literature, but with higher incidence of pocket infection and extrusion, technical failure of lead placement which necessitate battery replacement, and the need of a new mode of pacing or programmability, as their incidence in our study still high compared with the other international standard quality for permanent pacemakers re-implantation. So we have to work and push forward to improve the standardization in these points.

References


Pacemaker Generator Re-Implantation


