

## IS A ROUTINE POST PACE MAKER IMPLANTATION CHEST X RAY MANDATORY? DATA FROM A TERTIARY CARE HOSPITAL IN A DEVELOPING COUNTRY

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### **Contribution**

All the authors contributed significantly to the research that resulted in the submitted manuscript.

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### **ABSTRACT**

**Objective:** To determine the yield of routine chest X-Ray for ruling out major complications after implantation of permanent pacemaker.

**Methodology:** We conducted an observational cross sectional study of patients undergoing permanent pacemaker insertion at The Aga Khan University Hospital Karachi, from October 2009 till December 2012 with average age of 70.1 and 68.8 years respectively. Population was divided into two groups including dual chamber pacemaker and single chamber pacemaker.

**Results:** This study included 317 patients who undergone permanent pace maker. Pneumothorax and lead displacement occurred in 0.63% and 1.57%, respectively. The pneumothoraxes were large and clinically significant and picked up clinically, which could have been predicted using the lung/chest pathology in the pre implant CXR. The lead displacements were picked by symptoms and pacemaker interrogation.

**Conclusion:** We have shown that in a tertiary care center and in the hands of experienced operators, with a good pre-implant and post implant examination and a routine device interrogation, the routine CXR can be skipped after implantation of permanent pacemaker.

**Key Words:** Chest X Ray, Permanent Pacemaker, Complications, Pneumothorax, Lead Displacement

## INTRODUCTION

Chest X- rays (CXR) are performed as protocol after the placement of cardiac implantable electrical devices (CIED).<sup>1</sup> Whereas, the implantation of most complex CIEDs may cause more complications, the implant of permanent pacemakers carries a relative low complication risk that is less than 1-2% for both single and dual chamber pacemakers. The CXR is done to document the position of the leads and also to look for any residual pneumothorax after the subclavian puncture.<sup>2</sup> Now a day, there is a lot of patient exposure to iatrogenic radiation and as the effect of radiation is cumulative, it is prudent to minimize this life time exposure. Medical X-rays are a significant source of man-made radiation exposure. In 2006, medical exposure constituted nearly half of the total radiation exposure of the U.S population from all sources. The increase is traceable to the growth in the use of medical imaging procedures, in particular computed tomography (CT), and to the growth in the use of nuclear medicine.<sup>3</sup>

To place the increased risk in perspective, a plain chest X-ray will expose a person to the same amount from background radiation that we are exposed to (depending upon location) every day over 10 days that is about 0.1 mSv.<sup>4,5</sup> If the routine CXR does not have a high yield for picking up post implant complications then it can be done away with. This would save the patient undue exposure to radiation. We report observations from our study that looks at the yield of routine post implant CXR for picking up complications.

## METHODOLOGY

This observational cross sectional study was done at the Aga Khan University Hospital to assess the need for a post permanent pacemaker implantation CXR. All patients undergoing permanent pacemaker implantation between October of 2009 and December of 2012 were included. Data was collected from the catheterization laboratory log. The files were reviewed for the procedural details as well as the complications arising in the index admission. Patients who came for a generator change only and patients coming for other CIEDs like implantable cardioverter defibrillators (ICD) were excluded. The center had three implanting physicians but the major load was shared by two cardiologists both were trained cardiac electrophysiologists.

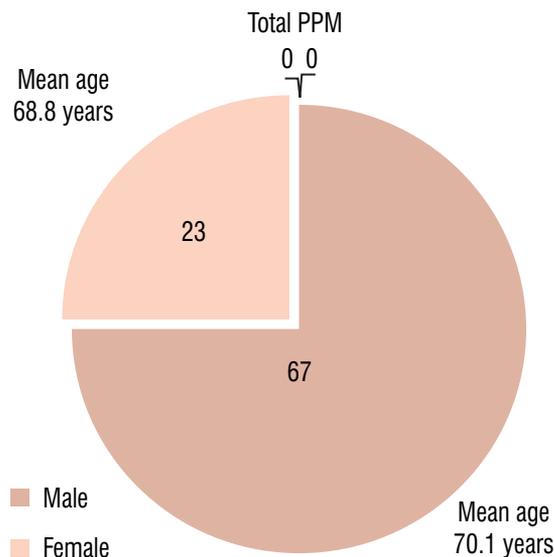
The approach for all pacemakers except one patient was subclavian and predominantly left subclavian. The right subclavian was only done if the left subclavian was inaccessible or if there was a contraindication to the use of the left subclavian due to another medical condition like cancer surgery, AV fistula for hemodialysis on the left arm or skin damage over the left infraclavicular space etc. We used the extrathoracic subclavian vein approach where the puncture was performed over the first rib. With this technique the needle was advanced (gently aspirating on an

attached syringe as with any other indirect puncture), aiming for the space below the clavicle and over the first rib until either the vein was cannulated or the rib was struck. If the rib was struck the needle was gently withdrawn 1–2 cm while still aspirating and, if there was still no flashback of blood, the caudo-cephalad angle of the needle was changed to aim for either a slightly more cephalic or caudal position on the first rib and the same process repeated.<sup>6</sup> Leaving it to the operator's discretion, if the extra thoracic fluoroscopic puncture was unsuccessful, radiocontrast was used to visualize the axillary vein. To do this, a small amount of radiocontrast (typically, 5 - 10 mL) was injected into the ipsilateral arm and following immediately with a vigorous flush. At times access was gained in real time while the contrast was still visible via fluoroscopy within the lumen, or a fluoroscopic image of the contrast-filled vein was stored and used as a roadmap. Both these techniques address the axillary vein or the extrathoracic subclavian veins and if the medial border of the first rib is not crossed the incidence of pneumothorax is said to be close to zero.<sup>6,7</sup>

## RESULTS

A total of 317 cases were included in total, 67 % were male (Figure 1). The study population was divided into two groups (Table 1), the single and dual chamber. The mean age of the dual chamber group was 68.2 years (age range 22-91 years) while for the single chamber pacemaker mean was 70 years (age range 24-93 years). Only one patient (0.315%) had a cephalic cut down approach, while the remaining patients underwent a subclavian vein approach. The subclavian approach was carried under fluoroscopic view.

**Figure 1: Gender Distribution in the Study Population**



Pneumothorax occurred in 2 cases (0.63%), both had DC pacemaker implants. Both had moderate pneumothoraxes, which required insertion of chest tube. Acute lead displacement occurred in 5 cases (1.57%) during the index admission. CXR was done in all cases as per protocol to look for lead displacement or development of pneumothorax. All of the lead displacement cases were by new onset clinical symptoms and was further confirmed by pacemaker interrogation, where there was failure to capture and under-sensing. All lead displacements occurred after the routine post implant CXR were done as per protocol. These lead displacements were all picked up by symptoms and routine pacemaker interrogation, where failure to capture and under-sensing was noted. Similarly, for both cases with pneumothorax there were structural abnormalities in the chest. One patient was small framed and had kyphoscoliosis, while the other presented with left apical lung fibrosis due to old healed pulmonary tuberculosis.

## DISCUSSION

In today's world where diagnostic modalities use radiation, with increasing cumulative radiation doses over a life time, subject humans to a significantly increased risk of adverse effects both acute and chronic.<sup>8</sup> Diagnostic and therapeutic radiological investigations are an essential part of the

workup of patients with a number of clinical problems across a variety of medical specialties. Based on global statistics and projections, radiation exposure of patients is increasing, in particular as a result of new indications and use in cross sectional imaging.<sup>9</sup> In addition, multiple investigations of patients with chronic disease can lead to substantial individual radiation exposure as surgical practice increasingly relies on the use of cross sectional imaging to aid diagnosis and treatment.<sup>10</sup> Different societies are now making specific recommendations to reduce radiation exposure.<sup>11</sup> The judicious use of radiological investigations and close liaison with radiologists in order to keep the radiation exposure of patients and staff as low as possible is being recommended.<sup>8</sup> Therefore, reducing the use of radiological investigations that have a low yield and where there is an alternative available is being suggested globally.

These days all pacemakers are being implanted under local anesthesia through either the cephalic vein approach or the subclavian approach. The subclavian approach, particularly with inexperienced operators is associated with a higher risk of procedural complications such as pneumothorax, arterial puncture and wound hematoma. However, in experienced hands the complication rate is low. As the subclavian approach is quicker, requires less surgical expertise and as it also allows the insertion of multiple leads it has become the

**Table 1: Results of the Two Groups Showing the Complications**

	<b>Group 1</b>		<b>Group 2</b>		<b>Percentage</b>	<b>Percentage</b>	<b>Percentage</b>
	<b>Dual chamber pacemaker</b>		<b>Single chamber pacemaker</b>				
	<b>n= 212</b>		<b>n= 105</b>				
	<i>male</i>	<i>female</i>	<i>male</i>	<i>female</i>	<i>Single chamber</i>	<i>Dual chamber</i>	<i>Total</i>
<b>Number</b>	97	115	43	62	33	67	100
<b>Age (years)</b>	69.7	67	70.1	68.8			
<b>Age range</b>	22 - 91	24 - 87	42 - 93	24 - 88			
<b>Pneumothorax</b>	02	00	00	00	00	0.94	0.63
<b>Lead displacement</b>	01	02	00	02	1.9	1.4	1.57
<b>Micro-displacement</b>	01	00	00	01	50	33	0.63

approach of choice.<sup>1</sup>

Traditionally, it has been standard protocol to assess lead position at the time of implantation using fluoroscopy, followed by postero-anterior (PA) and lateral chest radiographs immediately after pacemaker insertion.<sup>12</sup> The purpose of these radiographs is firstly to exclude pneumothorax in patients who have had direct subclavian puncture and secondly to record the position of the pacing leads and provide a comparison for future reference in case of pacing problems.<sup>13,14</sup>

In our study the incidence of pneumothorax was 0.63% (see table 1). Two cases were reported and both were in the dual chamber pacemaker group. Both patients had chest /lung pathology, while one had kyphoscoliosis; the other had apical fibrosis of the left lung apex secondary to healed tuberculosis. In a similar study by Edwards et al, a total, 192 post-procedural CXRs were performed, either postero-anterior (PA) and/or lateral views.<sup>15</sup> Iatrogenic pneumothorax occurred in one patient (incidence 0.8%) in the series. CXR confirmed the clinical diagnosis and allowed an assessment of size to guide treatment. The role of routine radiography after pacemaker insertion is not clearly defined.<sup>15</sup> The use of CXR post pacemaker implantation is one modality, the clinical utility of which is being questioned now. The only paper to support the use of chest radiography is from Grier et al.<sup>16</sup> In this study, two radiologists retrospectively reviewed chest X-rays of 600 patients who had undergone pacemaker implantation. They identified radiographic abnormalities on CXRs of 131 patients (21.8%). Individual radiographic complications ranged from lung atelectasis (0.3%) to unsatisfactory lead position (5.5%). Despite this high number of radiographic abnormalities, only a few were clinically significant abnormalities which required intervention at that time or later in the clinical course. A total of 60(10%) patients were considered to have either electrode tip malposition or loop abnormalities on their original chest X-rays. However, only three (0.5%) patients required lead repositioning because of pacing abnormalities. In our study (Table 1) there were 5 cases of lead displacement (1.57%) of which 2 were micro-displacements (no radiographic displacement but suboptimal pacing and sensing threshold). In the Edwards study, ventricular and/or atrial pacing lead contour and electrode position was considered radiographically appropriate in 86% CXRs.<sup>15</sup> Fourteen per cent of post-procedural radiographs were considered to have radiologically sub-optimal pacemaker lead positioning. None of the patients with these abnormal radiographs experienced subsequent pacemaker complications or had further radiographs recorded at a later date. Later repeat CXRs were performed in 16 patients (13%) but only 3 patients (2%) had pacing abnormalities as the primary indication. All three had satisfactory pacing lead position on initial post-implantation and later radiographs, but required

further procedures for lead re-positioning. It was concluded that routine CXR after permanent pacemaker insertion is not necessary in uncomplicated cases with adequate pacing characteristics. Expert comments on the topic by Hunter in a letter published in the same issue, stated anecdotal experience of seeing 2-4 pneumothoraxes in a busy cardiac specialty center in the US.<sup>17</sup> He also opined that a delayed CXR may carry a better yield. However, he commented that high risk pneumothorax was noted in less than 1% of patients. In another letter Karthikeyan and Bhargava referred to a group of patients where a note of caution was to be taken, as these clinical scenarios were not addressed in the study population.<sup>18</sup> The high risk patients would be with extremes of BMI (<20 and >30), number of needle passes, surgery in the region, previous subclavian catheterization and experience of the implant physician.<sup>19</sup> They state that there are some conditions where the utility of the CXR remains like in the pediatric population where serial CXR would help study the atrial loop and its change with growth and in single pass VDD leads where the atrial pole position may change with posture and cause atrial under-sensing.<sup>20</sup> It has also been suggested in another study of 250 patients over 3 years that when the subclavian puncture is extrathoracic, a CXR may be skipped.<sup>21</sup> It has been noted in the literature that pacing parameters are the best predictor of pacing failure, while the CXR position does not have a significant bearing in this regard.<sup>18</sup> This is consistent with our study where 2 leads had failed to pace despite no change in the radiologic position (micro-displacement).

The results of our study provide evidence that in a tertiary care set-up in a developing country, pacemaker insertion in the hands of trained and experienced implant physicians can be carried out with a low risk of adverse outcome. We have shown that pneumothorax and lead displacement post PPM was rare, and the complication occurred in patients with known abnormalities and could have been pre-empted by using other clinical parameters, thus CXR did not improve the diagnostic yield.

## CONCLUSION

Pneumothorax and lead displacement were rare in our study and occurred in 0.63% and 1.57% of the cases. The yield of CXR for picking up pneumothorax was 100% but this complication could have been predicted on the basis of history, examination and critical perusal of the old CXR. In the normal LSCV puncture, provided the pre-implantation CXR was normal, post implantation normal physical examination and optimal pacemaker interrogation parameters, a CXR did not add to the management and could be done without thus limiting undue radiation exposure.

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