

International Journal of Current Research in Chemistry and Pharmaceutical Sciences

www.ijcrcps.com

Volume 1 Issue: 4 2014 Pages: 08-14

(p-ISSN: 2348-5213; e-ISSN: 2348-5221)

RESEARCH ARTICLE



PSYCHOLOGICAL IMPACTS OF PATIENTS AFTER PACEMAKER IMPLANTATION

MRINMOYEE KANJILAL¹, SOUMITA GOSWAMI², DILIP KUMAR³ AND TAPAN KUMAR CHATTERJEE^{1*}

¹Student of Pharmacovigilance course, Clinical Research Center, Department of Pharmaceutical Technology, Jadavpur University, Kolkata - 700032, India.

²Student of Clinical Pharmacy, Department of Pharmaceutical Technology, Jadavpur University, Kolkata - 700032, India.

³Interventional Cardiologist & Electrophysiologist Chief Academic Co-ordinator, Medica Superspeciality Hospital, 127, Mukundopur, E.M.Bypass, Kolkata-700099.

^{1*}Director, Clinical Research Center, Jadavpur University, Kolkata-700032, India *Corresponding author e-mail: tkchatterjee_81@rediffmail.com

Abstract

A pacemaker is a small device that's placed in the chest or abdomen to help control abnormal heart rhythms. This device uses electrical pulses to prompt the heart to beat at a normal rate. Pacemakers are used to treat arrhythmias. Arrhythmias are problems with the rate or rhythm of the heartbeat. During an arrhythmia, the heart can beat too fast, too slow, or with an irregular rhythm, as the heart may not be able to pump enough blood to the body. This can cause symptoms such as fatigue (tiredness), shortness of breath, or fainting. Severe arrhythmias can damage the body's vital organs and may even cause loss of consciousness or death. A pacemaker can relieve some arrhythmia symptoms, such as fatigue and fainting. A pacemaker also can help a person who has abnormal heart rhythms resume a more active lifestyle. In this study 20 patients with single or dual chamber pacemaker implantation will be recruited and each patient will be asked 12 questions. Each question consists of a specific score and that score will be given with respect to time. This study will be conducted in 3 month interval. The score below or equal to 25 will be considered to be impaired cognitive function. The entire data will be analysed which will further helps in the understanding for the doctors in management of cognitive function of patients after pacemaker implantation. This study is conducted to determine Psychological Function after pacemaker implantation in a patient having Cardiovascular Disease .It has been documented in a study, previously done in the Western population which include patient with symptomatic Bradycardia, that, single chamber ventricular (VVI(R)) pacing is detrimental to cognitive function when compared with atrial based pacing. This study is further extension of the above said previous study to prove whether pacemaker is really detrimental to psychological function.

Keywords: Pacemaker, Arrhythmias, Single-chamber pacemaker, Dual-chamber pacemaker, mini-mental state examination.

Introduction

A pacemaker is a small device that's placed in the chest or abdomen to help control abnormal heart rhythms. This device uses electrical pulses to prompt the heart to beat at a normal rate. Pacemakers are used to treat arrhythmias. Arrhythmias are problems with the rate or rhythm of

the heartbeat. During an arrhythmia, the heart can beat too fast, too slow, or with an irregular rhythm. A heartbeat that's too fast is called tachycardia. A heartbeat that's too slow is called bradycardia. During an arrhythmia, the heart may not be able to pump enough blood to the body. This can cause

symptoms such as fatigue (tiredness), shortness of breath, or fainting. Severe arrhythmias can damage the body's vital organs and may even cause loss of consciousness or death. A pacemaker can relieve some arrhythmia symptoms, such as fatigue and fainting. A pacemaker also can help a person who has abnormal heart rhythms resume a more active lifestyle. Since the introduction of permanent pacemakers for the treatment of bradyarrhythmias 1958, many investigators have studied psychological wellbeing in this patient group, and it has been found that, in general, the implantation of a permanent pacemaker improves health related quality of life (Oto et al., 1991; Linde-Edelstam et al., 1992; Lukl et al., 1994; Lamas et al., 1998; Deharo et al., 1996). Pacemaker system includes the pacemaker itself and wires that connect this to the heart. It is slightly larger than a man's wristwatch and contains a battery and computer circuits.

At present, 3 approaches to permanent cardiac pacing are in common use:

Single-chamber pacemaker – With this device, 1 pacing lead is implanted in the right atrium or ventricle.

Dual-chamber pacemaker – With this device, 2 pacing leads are implanted (1 in the right ventricle and 1 in the right atrium); this is the most common type of implanted pacemaker.

Biventricular pacing (cardiac resynchronization therapy [CRT]) – With this approach, in addition to single- or dual-chamber right heart pacing leads, a lead is advanced to the coronary sinus for left ventricular epicardial pacing. Remarkable advances have been made in pacemaker technology, including reduced size, increased battery longevity, and remote monitoring capability, as well as the addition of magnetic resonance imaging (MRI)-safe pacemakers.

There are about 3 million people worldwide with pacemaker and each year 600,000 pacemakers are implanted . At this moment everyday 18,000 patients get pacemakers in India. With rare exception, implantation of a pacemaker does not change the recipients activities and life styles. Although most people who receive pacemakers are aged 60 years or older but from a child to an old man, anyone may need pacemaker.

Study Objective

- To investigate if there is any cognitive impairment in the patient with pacemaker implantation
- 2. Whether dual-chambered pacemaker is superior than single-chambered one's
- 3. To understand whether a patient is suffering from mild, moderate or severe dementia
- 4. To investigate whether VVIR pacing has detrimental effect on cognitive function.

Study Methodology

Description of study design

This study is a type of psychological study which will help to understand effect of pacemaker implantation in East Indian population .In this 40 patients i.e. 20 with single and 20 with dual chamber pacemaker are recruited and each patient is asked 12 questions. Each question consists of a specific score and that score will be given with respect to time if the answer is correct. This study will be conducted in 3 month interval. The score below or equal to 25 is considered to be impaired cognitive function. The entire data will be analyzed which will further helps in the understanding for the doctors in management of cognitive function of patients and superiority of dual chambered pacemaker with single chambered after pacemaker implantation.

The mini-mental state examination (MMSE) is a brief 30-point questionnaire test that is used to screen for cognitive impairment. It is commonly used in medicine to screen for dementia. It is also used to estimate the severity of cognitive impairment and to follow the course of cognitive changes in an individual over time, thus making it an effective way to document an individual's response to treatment.

Any score greater than or equal to 25 points (out of 30) indicates a normal cognition. Below this, scores can indicate severe (9 points), moderate (10-20 points) or mild (21-24 points) cognitive impairment. The raw score may also need to be corrected for educational attainment and age. That is, a maximal score of 30 points can never rule out dementia. Low to very low scores correlate closely with the presence of dementia, although other mental disorders can also lead to abnormal findings on MMSE testing. The presence of purely physical problems can also interfere with interpretation if not

properly noted; for example, a patient may be physically unable to hear or read instructions properly, or may have a motor deficit that affects writing and drawing skills.

Inclusion criteria

- 1. Male or Female above 35 years of age
- 2. Having sick sinus syndrome (Bradycardia or Tachycardia)
- 3. Having pacemaker (single/dual chambered)
- 4. Having loss of consciousness, loss breathing, fainting, chest pain and need a pacemaker

Exclusion criteria

- 1. Child
- 2. Pregnant woman
- 3. Person unable to speak read and write (Physically incapable)
- 4. Fully psychic person
- 5. Do not have any pacemaker or pacemaker not necessary

Statistical Analysis

In older patients cognitive functioning is especially likely to decline during illness or injury or a patient with Cardiovascular Disease or patient with pacemaker implantation (Gribbin et al., 2005). Cognitive impairment can be assessed by a number process viz. MMSE (Mini-mental state Examination), **CANTAB** (Cambridge neuropsychological test automated battery) CAMCOG(the cognitive section of the Cambridge examination for mental disorders of the elderly) etc.. The MMSE is one of the effective screening tool for cognitive impairment (William et al., 1997). The mini-mental state examination (MMSE) is a brief 30-point questionnaire test that is used to screen for cognitive impairment. It is commonly used in medicine to screen for dementia. It is also used to estimate the severity of cognitive impairment and to follow the course of cognitive changes in an individual over time, thus making it an effective way to document an individual's response to treatment. So, in this study MMSE questionnaire tool will be used for screening cognitive function.

Scoring and Assessment of cognitive Function

Any score greater than or equal to 25 points (out of 30) indicates a normal cognition. Below this, scores © 2014. IJCRCPS. All Rights Reserved

can indicate severe (9 points), moderate (10-20 points) or mild (21-24)points) cognitive impairment. The raw score may also need to be corrected for educational attainment and age. That is, a maximal score of 30 points can never rule out dementia. Low to very low scores correlate closely with the presence of dementia, although other mental disorders can also lead to abnormal findings on MMSE testing. The presence of purely physical problems can also interfere with interpretation if not properly noted; for example, a patient may be physically unable to hear or read instructions properly, or may have a motor deficit that affects writing and drawing skills (B.C. Home, Ministry of Health, BC Guideline & Protocols, 2008).

Description Of Statistical Method Employed

For this study a Questionnaire i.e. Mini-Mental State Examination is used (William et al., 1997). It has 12 questions in it and each question has a specific score to form a total score of 30. On the basis of score out of 30 the dementia level of the patient can be analyzed.

Any score greater than or equal to 25 points (out of 30) indicates a normal cognition. Below this, scores can indicate severe (9 points), moderate (10-20 points) mild (21-24)points) coanitive impairment. The raw score may also need to be corrected for educational attainment and age. That is, a maximal score of 30 points can never rule out dementia. Low to very low scores correlate closely with the presence of dementia, although other mental disorders can also lead to abnormal findings on MMSE testing. The presence of purely physical problems can also interfere with interpretation if not properly noted; for example, a patient may be physically unable to hear or read instructions properly, or may have a motor deficit that affects writing and drawing skills.

Results

Twenty-four patients completed the two stages of cognitive assessment;17 were male, mean age 60(age range 45-90 years), patients were paced for sick sinus syndrome and/or syncope and/or hypertension and/or low blood pressure and/or chest pain and/or loss of breath. 12 patients were paced with DDD(R) and the remaining 12 with VVI(R) i.e. 50% of each group was paced with VVI(R) or DDD(R).

Baseline scores obtnd

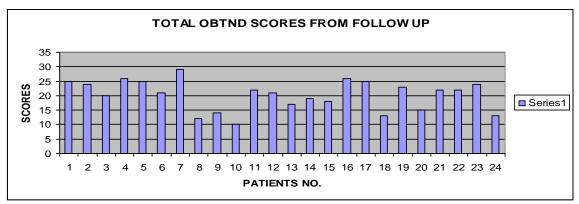
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25

Patient enrolled

Figure 1. Shows baseline scores obtained by enrolled patient

From the above figure 1 it is found that only two out of twenty four are in normal cognitive level. The following figure shows obtained scores at follow up.

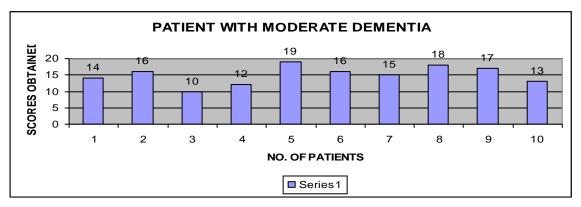
Figure 2. This shows final MMSE scores during follow up after three months where there is no significant change in the trend of the score.



Three patients amongst twenty four are in normal cognitive function level.

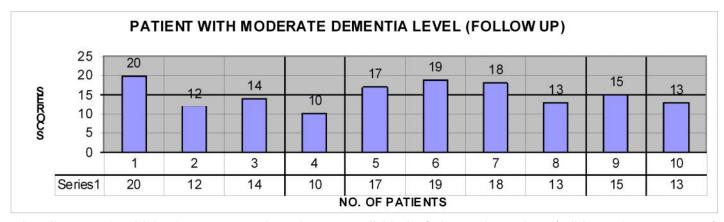
Another representation for the score below 20 can be plotted in a column graph from which the patient with moderate dementia level can be identified.

Figure 3. This chart shows 10 patients out of 24 are with moderate dementia level On the basis of baseline data.



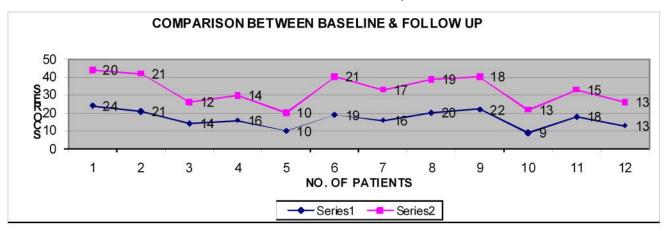
It has been seen from the study that, the patients with moderate dementia level often suffering from syncope which is the main effect of cardiovascular disease regardless of single or dual chamber pacing.

Figure 4. This figure shows during follow up again 10 out of 24 patients are under moderate dementia level This above graph proves that this study has got no significant changes in the scores obtained during baseline and follow up.



Another line graph which shows comparison between all kind of dementia patient (mild, moderate, severe) related to cardiovascular disease.

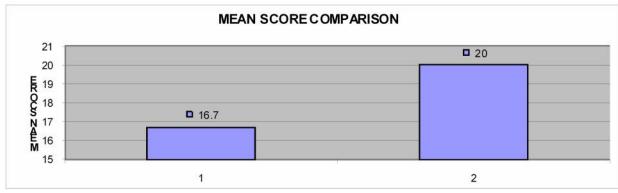
Figure 5. This explains the comparison of the scores of patients with mild, moderate and severe dementia which is related to cardiovascular disease at baseline and follow up



Series 1: baseline data line graph

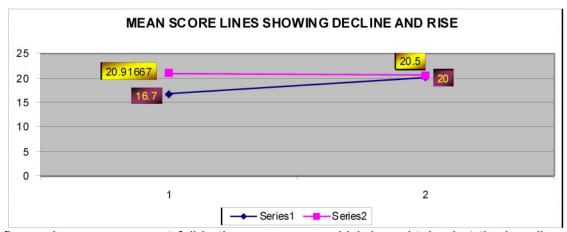
Series 2: follow up data line graph. This shows that there is a relationship between cardiovascular disease and cognitive function. But there is no significant effect on the scores in this study which can prove that VVIR pacing has detrimental effects on the cognitive function. Below are the graphs which shows mean values for VVIR and DDDR both in the baseline and follow up.

Figure 6. This shows the comparison of the mean score obtained at baseline and follow up data (VVIR)



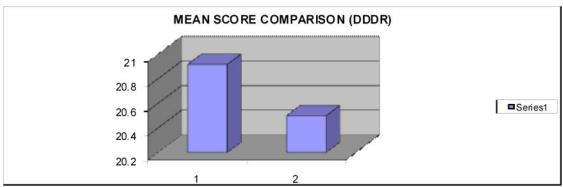
From the above figure it is clear that the VVIR pacing mode improves the cognitive function in average i.e. after implantation of single chambered pacemaker blood supply increased towards brain leading to improvement of the cognitive function.

Figure 7. This shows there is an apparent fall in the mean score obtained during baseline and follow up



The above figure shows an apparent fall in the mean score which has obtained at the baseline and follow up that may be due to the level of education. It has been found from previous study DDDR pacing is effective for cardiovascular disease. But the decline in the score may be due to illiteracy and/or unusual circumstances as human body is a biological system.

Figure 8. shows line graph representation of the mean score which declines and rises



The VVIR mean has improved from 16.7 to 20 on the contrary the the DDDR shows decline from 20.91667 to 20.5 within baseline and followup.

MMSE (Mini-mental State Examination) scores at three months interval were taken for each patient. Pacing mode had no significant effect on MMSE scores. Mean score raised from 16.7 to 20 in the VVIR and in case of DDDR it fell from 20.91667 to 20.5.

The MMSE scores at baseline data are shown in figure 1.

Discussion

These data comprise the evaluation of pacing mode on cognitive function. From this study, no significant effect was seen in the cognitive functioning of the patients and the predominant factor proved to be cognitive performance at 3 months. It is important to note that a person's MMSE score can be affected by their level of education. This is because for

highly educated people the questions may be too easy and for poorly educated people some may be too difficult. This means that a highly educated person with mild dementia may score in the normal range, whereas a poorly educated person with no problems in cognition may score in the dementia range (Koide et al., 1994).

From this study it can be found that the mean scores for VVIR pacing mode has been improved from 16.7 to 20.0 and for DDDR pacing mode mean score declines from 20.91667 to 20.5 which may not be related to cardiovascular disease. Another consideration for this study is that, this project has been completed with twenty four patients only where it has mentioned previously that it would be completed with 40 patients but due to inadequate time schedule this study has been done with 24 patients (12 VVIR, 12 DDDR).

So, this study will continue for rest of the patients that it needs. Since it has been mentioned above that the score depends on the level of education . Most of the patients are aged and especially the poorly educated patients are the reason for the decline in the DDDR scores.

Previous one study has provided that AAIR pacing is associated with a higher incidence of paroxysmal atrial fibrillation and a two-fold increased risk of pacemaker reoperation. These findings support the routine use of DDDR pacing in these patients (Nielsen et al., 2011). Another study shows that between VVI(R) i.e. single chambered ventricle-based pacing and atrial-based pacing that, VVI(R) pacing shows reduced function in the area of visuospatial memory and for that reason patients getting single chambered pacemaker may sometimes be with impaired cognitive function (Gribbin et al., 2005).

But this study does not show any kind of significant effects on the visuo-spatial memory for VVIR pacing and the decline in the DDDR score is due to insufficient patient number and also depends on educational level of the patients.

Conclusion

This study has provided no evidence for a detrimental effect of VVIR pacing on cognitive function. There were no trends towards reduced cognitive function in the area of visuo-spatial memory in this study. Further examinations required to focus within this special cognitive domain. So, this study currently does not provide any evidence to prove VVIR pacing is detrimental to cognitive function over DDDR. However, this study will continue to estimate more data which could be useful for further investigation.

References

- B.C. Home, Ministry of Health, BC Guideline & Protocols. Cognitive Impairment In The Elderly Recognition, Diagnosis And Management. British Columbia, Revised January 30, 2008.
- Deharo, J.C., Badier, M.and Thirion, X. 1996. A randomized, single-blind crossover comparison of the effects of chronic DDD and dual sensor VVIR pacing mode on quality-of-life and cardiopulmonary performance in complete heart block. *Pacing. Clin. Electrophysiol.* 19:1320-6.

- Gribbin, G.M., Gallagher, P., Young, A.H., McComb, J.M., McCue, P., Toff, W.D., Bexton, R.S., Bland, J.M., and Kenny, R.A. 2005. The effect of pacemaker mode on cognitive function. *Heart*, 91(9): 1209-10.
- Gribbin, G.M., Gallagher, P., Young, A.H., McComb, J.M., McCue, P., Toff, W.D., Bexton, R.S., Bland, J.M., and Kenny, R.A. 2005. The effect of pacemaker mode on cognitive function. *Heart*, 91(9): 1209-10.
- Koide, H., Kobayashi, S., Kitani, M., Tsunematsu, T. and Nakazawa, Y. 1994. Improvement of Cerebral Blood Flow and Cognitive Function following Pacemaker Implantation in Patients with Bradycardia. *Gerontology*. 40:279-85.
- Lamas, G.A., Orav, E.J. and Stambler, B.S. 1998. Quality of life and clinical outcomes in elderly patients treated with ventricular pacing as compared with dual-chamber pacing Pacemaker Selection in the Elderly Investigators. *N. Engl. J. Med.* 338: 1097-104.
- Linde-Edelstam, C., Nordlander, R. and Unden, A.L. 1992. Quality-of-life in patients treated with atrioventricular synchronous pacing compared to rate modulated ventricular pacing: a long-term, double-blind, crossover study. *Pacing. Clin. Electrophysiol.* 15: 1467–76.
- Lukl, J., Doupal, V. and Heinc, P. 1994. Quality-of-life during DDD and dual sensor VVIR pacing. *Pacing .Clin. Electrophysiol.* 17:1844-8.
- Nielsen, J.C.A., Thomsen, P.E.B., Højberg, S., Møller, M., Vesterlund, T., Dalsgaard, D., Mortensen, L.S., Nielsen, T., Asklund, M., William, D., and Andersen, H.R. 2011. Comparison of single-lead atrial pacing with dual-chamber pacing in sick sinus syndrome. *Eur. Heart. J.* 32(6): 686-96.
- Oto, M.A., Muderrisoglu, H. and Ozin, M.B. 1991. Quality of life in patients with rate responsive pacemakers: a randomized, cross-over study. *Pacing. Clin. Electrophysiol.* 14: 800-6.
- William, Moloy, D., and Timothy and Standish, I.M. 1997. Mental Status and Neuropsycho1ogica1 Assessment A Guide to the Standardized Mini-Mental State Examination. *International Psychogeriatric Association*, 9(1): 87-94.

•