THE EFFECT OF RIGHT VENTRICULAR PACEMAKER LEAD POSITION ON FUNCTIONAL STATUS IN PATIENTS WITH PRESERVED LEFT VENTRICULAR EJECTION FRACTION

EFERAT POLOŽAJA PEJSMEJKER ELEKTRODE U DESNOJ KOMORI NA FUNKCIONALNI STATUS PACIJENATA SA OČUVANOM EJEKCIONOM FRACIJOJ LEVE KOMORE

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Summary

Introduction. The study was aimed at assessing the difference between the right ventricle apex versus the right ventricular outflow tract lead position in functional capacity in the patients with the preserved left ventricular ejection fraction after 12 months of pacemaker stimulation. Material and Methods. This was a prospective, randomized, follow-up study, which lasted for 12 months. The study sample included 132 consecutive patients who were implanted with permanent anti-bradycardic pacemaker. Regarding the right ventricular lead position the patients were divided into two groups: the right ventricle apex group consisting of 61 patients with right ventricular apex lead position. The right ventricular outflow tract group included 71 patients with right ventricular outflow tract lead position. Functional capacity was assessed by Minnesota Living With Heart Failure score, New York Heart Association class and Six Minute Walk Test. Left ventricular ejection fraction was assessed by echocardiography. Results. The study was aimed at assessing the difference between the right ventricular apex versus the right ventricular outflow tract lead position in functional capacity in the patients with the preserved left ventricular ejection fraction after 12 months of pacemaker stimulation. The patients from right ventricular apex group walked 20.95% (p = 0.03) more in comparison to starting values. The patients from right ventricular outflow tract group walked only 13.63% (p = 0.09) longer distance than the starting one. Conclusion. Analysis of tests of functional status New York Heart Association class and Minnesota Living With Heart Failure questionnaire showed an even improvement in the right ventricle apex and right ventricular outflow tract groups. Analysis of 6 minute walk test showed that only the patients with the preserved left ventricular ejection fraction from the right ventricle apex group had a significant improvement after 12 months of pacemaker stimulation.

Key words: Pacemaker; Artificial; Electrodes; Implanted; Heart Ventricles; Ventricular Function; Left; Stroke Volume; Questionnaires; Walking; Bradycardia; Treatment Outcome

Sažetak

Uvod. Cilj istraživanja je procena uticaja stimulacije pejsmejkerom iz vrha desne komore (Right Ventricle Apex) i izlaznog trakta (Right Ventricle Outflow Tract) desne komore, nakon 12 meseci stimulacije pejsmejkerom, na funkcionalni status pacijenata sa očuvanom ejekcijom frakcijom leve komore. Materiał i metode. Sprovedena je prospektivna, randomizovana studija praćenja u trajanju od 12 meseci. Istraživanjem su obuhvaćena 132 pacijenta kod kojih je implantiran permanentni antibradikardijski pejsmejer. U odnosu na položaj komorske elektrode, pacijenti su podeljeni u dve grupe: prva grupa – 61 pacijent sa elektrodom pozicioniranim u vrhu desne komore; druga grupa – 71 pacijent sa elektrodom pozicioniranim u izlaznom traktu desne komore. Funkcionalni status pacijenata procenjen je preko upitnika Minnesota Living With Heart Failure i određivanjem vrednosti skora, određivanjem pripadnosti New York Heart Association klasi, kao i šestominutnim testom hodanja. Ejekcijna frakcija leve komore procenjivana je echokardiografskim pregledom. Rezultati. Vrednosti Minnesota Living With Heart Failure skora i New York Heart Association klase imali su statistički značajno poboljšanje u obe praćene grupe pacijenata. U prvoj grupi pacijenti su pelazili 20.95% (p = 0.03) duže distance u odnosu na početne vrednosti. U drugoj grupi pacijenti su pelazili samo 13.63% (p = 0.09) duže distance u odnosu na početne vrednosti. Zaključak. Testovi za procenu funkcionalnog statusa, New York Heart Association klasa i Minnesota Living With Heart Failure upitnik, pokazali su podjednako poboljšanje u obe grupe. Analizom rezultata šestominutnog testa hodanja dobijeno je da je statistički značajno funkcionalno poboljšanje imali samo pacijenti iz prve grupe, nakon 12 meseci stimulacije pejsmejkerom, kod pacijenata sa očuvanom ejekcijom frakcijom leve komore.

Ključne reči: pejsmejer; implantacija elektroda; srčane komore; funkcija leve komore srca; udarni volumen; upitnici; štatanje; bradikardija; ishod lečenja

Introduction

Standard pacemaker lead position and thus stimulation from right ventricle apex (RVA) is characterized by prolonging transseptal and intraventricular impulse conduction with QRS at least twice longer than the normal duration [1]. The pacemaker stimulation from right ventricular outflow tract (RVOT) provides stim-
ulcus conduction that enables the chamber activation from the septum to the rest of the myocardium which in turn gives less dyssynchrony and shorter QRS duration [2–4]. Twenty years of experience and the results of multi centre randomized trials showed a benefit of alternative pacemaker stimulation site in the patients with a decreased left ventricular ejection fraction (LVEF), while the benefit is absent in the patients with preserved LVEF. However, the influence of lead position on the functional class, exercise capacity and quality of life in patients with preserved LVEF is still unclear [5]. Bacior et al. reviewed a number of studies involving patients with low LVEF, and concluded that almost all of the studies showed an improvement in the quality of life after pacemaker stimulation [6]. However, in the patients without a structural heart disease, Cano et al. found no difference in the quality of life, New York Heart Association (NYHA) class or physical endurance in RVOT versus RVA [7].

This study was aimed at assessing the difference between right ventricle apex versus right ventricular outflow tract lead position in functional capacity in patients with preserved left ventricular ejection fraction after 12 months of pacemaker stimulation.

**Material and Methods**

This was a prospective, randomized study, which lasted for 12 months and included 132 consecutive patients who were implanted with permanent anti-bradycardiac pacemaker in the Pacemaker Center Medical Center Zaječar, Serbia in the period from 2010 to 2011. This study was approved by the Ethical Committee of Zaječar Health Center and by Faculty of Medicine of the University of Niš. All patients gave their informed consent to participate in this study. The equipment applied was VVID 3 GE Medical Systems. LVEF was calculated by Teicholtz formula:

$$EF = \frac{EDV - ESV}{EDV} \times 100\%$$

(a similar formula to the above mentioned, but without the background activity). Reference values of LVEF were 62±8%, with lower limit set at 54%.

All statistical analyses were performed in SPSS 12.0 (SPSS Inc, Chicago, Illinois) statistical package. The results were presented as frequency, percentage and mean±SD. The X², Mann-Whitney U test and T test were used to compare the two groups. T test and Wilcoxon Signed Ranks test were used to test differences of paired samples. All p values less than 0.05 were considered significant.

**Results**

According to the tests performed, there was no difference between the groups at the beginning of the study regarding their sex, age, BMI (body mass index), VVI to DDD pacemaker implantation ratio, or functional capacity. The only difference between groups was in the QRS duration in pacemaker stimulation. QRS was statistically significantly shorter in the RVOT group compared to the RVA group (Table 1).

The average LVEF was within the normal range, and did not show any statistically significant difference between groups at the beginning of the study. After 12 months of pacemaker stimulation, LVEF remained the same regardless of lead position, 60.96±10.56% (p=0.31) in RVA group, and 57.77±10.86% (p=0.27) in RVOT group (Table 2).
After 12 months of pacemaker stimulation, both groups had the same rate of improvement in MLWHF score. In the RVA group, MLWHF score improved from 44.65±20.72 to 32.76±21.02 (p<0.0001). The patients from the RVOT group achieved smaller, but still statistically significant improvement, from 39.98±18.11 to 32.37±23.56 (p<0.006) (Table 2).

NYHA Class
After 12 months of pacemaker stimulation, both groups made the same statistically significant improvement of NYHA class. The majority of patients from the RVA group had a statistically significant improvement, and thus fell into NYHA class I, meaning that 36 patients (67.92%) were in NYHA class I, and 9 (16.98%) in class II (p<0.001). The same tendency of statistically significant NYHA class improvement was also observed in the RVOT group, where 32 patients (54.23%) were in class I, and 19 (32.22%) were in class II (p<0.001) (Table 2).

6 MWT
After 12 months of pacemaker stimulation, the patients from the RVA group walked 531.59±272.30 m or 20.95% (p=0.03) more in comparison to the
starting values, whereas the patients from the RVOT group walked 550.04±254.73 m, but that was only 13.63% (p=0.09) longer distance than the starting values (Table 2).

Discussion

Our research focused on comparing different pacemaker lead positions in the right ventricle, regarding its influence on the functional status in the patients who had the preserved left ventricular function at the beginning of the study and also after 12 months in real life circumstances.

The authors have concluded on the basis of the literature data published so far that the QRS duration in RVOT stimulation is shorter than in RVA stimulation [8–21]. Other authors also showed that QRS duration in the patients from the RVOT group was statistically significantly shorter than in the patients from the RVA group, but it had no protective effect on the left ventricular systolic function. LVEF was the same in the RVA group, and it even deteriorated slightly in the RVOT group after 12 months of pacemaker stimulation. Our results even showed a negative effect on diastolic function in the RVOT group compared to the RVA group [21]. Protect-Pace study also showed that lead position in the right ventricle had no protective effect on the left ventricular function regardless of the QRS duration [22]. Although RVOT position yielded a shorter QRS, it has not led to an improvement in LVEF or the patient’s functional capacity in any of the studies performed. The majority of performed studies analyzing the influence of pacemaker stimulation from RVA vs. RVOT on the functional status were done in the patients with decreased LVEF. ROVA study, with 103 patients with heart failure, found no difference in the life quality [9]. Some CRT studies found an improvement in functional capacity [23], while in others there was no difference in NYHA class between the patients with RVA and the patients with RVOT stimulation [24]. A review article analyzed data from three studies which had followed up 800 patients with ventricle pacemaker lead in RVA or RVOT, regardless of the LVEF for 3 years. This analysis confirmed the influence of pacemaker lead positioning in the right ventricle on the distance in 6 MWT [25]. Tse et al. performed a study involving patients with the preserved LVEF, which had their lead position changed from RVA to RVOT on pulse generator change, and they found that after 18 months of follow-up, the distance they were able to cover was significantly longer [18].

In contrast to the above mentioned studies, our results suggested 6 MWT to be an “objective” measure of functional status. By measuring the distance covered by the patient it showed a statistically significant improvement only in the RVA group who had walked a distance longer for 20.95% (p=0.03), whereas the RVOT group patients covered a distance longer only by 13.63% (p=0.09), which was not statistically significant. Our earlier results also showed an advantage of RVA stimulation over RVOT [26].

In our research we also found an equal improvement in “subjective” functional tests MLWHF score and NYHA class in both RVA and RVOT groups, after 12 months of pacemaker stimulation.

Conclusion

Analysis of tests of functional status, such as New York Heart Association class and Minnesota Living With Heart Failure questionnaire, showed an even improvement in the patients from the right ventricle apex and right ventricular outflow tract group. Analysis of 6 Minute Walk Test showed that only the patients with the preserved left ventricular ejection fraction from the right ventricle apex group had a significant improvement after 12 months of pacemaker stimulation.

References


