Med Pregl 2025; LXXVIII (5-8): 167-172. Novi Sad: maj-avgust.

QUALITY OF LIFE OF PATIENTS WITH PACEMAKERS

KVALITET ŽIVOTA PACIJENATA SA PEJSMEJKEROM

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Original study
Originalni naučni rad
UDK 616.12-008.314:615.87]-052:613
https://doi.org/10.2298/MPNS2508167R

Abstract

Introduction. Single-chamber and dual-chamber pacemakers are used for the treatment of bradycardia. Dual-chamber pacemakers more closely replicate physiological cardiac function by preserving atrioventricular synchrony, whereas single-chamber pacemakers are less complex, more cost-effective, and easier to implant. Clinical trials comparing these two pacing modalities have reported inconsistent results, largely depending on the studied population and study design. The AQUAREL questionnaire is a disease-specific instrument designed to assess life quality of life in patients with pacemakers. The aim of this study was to compare the quality of life of patients with single-chamber and dual-chamber pacemakers using the AQUAREL questionnaire. **Material and Methods.** After providing informed consent, 80 patients treated at the Institute for Cardiovascular Diseases of Vojvodina completed the AQUAREL questionnaire. Inclusion criteria were age ≥60 years and implantation of either a single or dual-chamber pacemaker. These criteria were met by 69 patients, including 33 with single-chamber and 36 with dual-chamber pacemakers. Data were obtained from the Institute's digital medical record. Statistical analysis was performed using standard methods. **Results.** The mean age of the patients was 76 years; 42 participants (63.77%) were male, and 92.75% had at least one comorbidity. Analysis of AQUAREL questionnaire scores revealed no statistically significant differences in overall quality of life between patients with single-chamber and dual-chamber pacemakers. **Conclusion.** Although patients with dual-chamber pacemakers reported fewer severe symptoms compared with those with single-chamber pacemakers, the difference was not statistically significant. Overall, no significant difference in quality of life was observed between patients according to pacemaker type.

Key words: Pacemaker, Artificial; Quality of Life; Surveys and Questionnaires; Signs and Symptoms

Sažetak

Uvod. Jednokomorski i dvokomorski pejsmejkeri se koriste za lečenje bradikardija. Dvokomorski pejsmejkeri teorijski nude više fiziološki pejsing zbog omogućavanja atrioventrikularne sinhronije, dok su jednokomorski jeftiniji i ugrađuju se brže. Brojna istraživanja koja su poredila navedene pejsmejkere su došla do različitih rezultata, u odnosu na ispitivanu populaciju i koncepciju istraživanja. AQUAREL je specifični upitnik za kvalitet života pacijenata sa pejsmejkerom, validiran je i preveden na više jezika. Cilj rada bio je poređenje kvaliteta života pacijenata sa jednokomorskim i dvokomorskim pejsmejkerom korišćenjem AQUAREL upitnika. **Materijal i metode.** AQUAREL upitnik je preveden na srpski jezik. Nakon potpisivanja saglasnosti, anketirano je 80 pacijenata koji su došli zbog redovne kontrole pejsmejkera u Institut za kardiovaskularne bolesti Vojvodine. Kriterijume za uključenje u studiju, koji podrazumevaju starost preko 60 godina i implantiran jednokomorski ili dvokomorski pejsmejker, ispunilo je 69, 33 sa jednokomorskim i 36 sa dvokomorskim pejsmejkerom. Iz baze podataka Instituta za kardiovaskularne bolesti Vojvodine prikupljeni su podaci o godištu pacijenta, vrsti pejsmejkera, kao i komorbiditetima. Podaci su obrađeni uobičajenim statističkim metodama. **Rezultati.** Prosečna starost ispitanika je 76 godina, 42 su muškog pola (63,77%), a 92,75% ima bar jedno pridruženo oboljenje. Rezultati dobijeni ispitivanjem putem AQUAREL upitnika pokazuju da ne postoji statistički značajna razlika (p = 0,493) u kvalitetu života ispitanika u odnosu na vrstu pejsmejkera. **Zaključak.** Bolesnici sa dvokomorskim pejsmejkerom prijavljuju manje izražene simptome u odnosu na bolesnike sa jednokomorskim pejsmejkerom, ali ta razlika ne dostiže nivo statističkog značaja, čime zaključujemo da nema razlike u kvalitetu života ispitanika u odnosu na tip pejsmejkera.

Ključne reči: pejsmejker; kvalitet života; upitnici i ankete; znaci i simptomi

Introduction

Pacemakers are implantable electronic devices used in the treatment of sinoatrial node dysfunction, atrioventricular (AV) block, reflex syncope, and hypertrophic obstructive cardiomyopathy. They are also indicated in selected cases following acute myocardial infarction and cardiac surgical procedures [1]. Single-chamber pacemakers sense and stimulate either the atrium or the ventricle, whereas dual-chamber pacemakers provide sensing and pacing in both chambers, thereby more closely replicating physiological cardiac activation. Rate-adaptive pacing refers to sensor-mediated adjustment of heart rate in re-

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Abbreviations

AV	– atrioventricular
VVIR	– ventricular pacing, ventricular sensing, inhibition response, rate-adaptive
DDDR	– dual pacing, dual sensing, dual response, rate-adaptive
ICVDV	– Institute for Cardiovascular Diseases of Vojvodina
ICD	– Implantable Cardioverter-Defibrillator

sponse to physical activity. Accordingly, pacing modes are designated as VVIR (ventricular pacing, ventricular sensing, inhibition response, rate-adaptive) for single-chamber pacemakers and DDDR (dual pacing, dual sensing, dual response, rate-adaptive) for dual-chamber pacemakers [2]. The expansion of indications for pacemaker implantation, along with population aging and increased life expectancy, has led to a steady rise in the number of pacemaker implantation procedures worldwide [3].

Epidemiological data from the United States indicate a pacemaker prevalence of 2.6 per 1,000 individuals, increasing markedly with age – from 0.4 per 1,000 among individuals aged 18–64 years to 26 per 1,000 in those older than 75 years. Pacemaker implantation is approximately 1.5 times more frequent in men [4]. In several European countries, the reported implantation rates during 2018-2019 ranged from 60 to more than 1,000 devices per million inhabitants [3].

Following pacemaker implantation, some patients may develop pacemaker syndrome, a clinical entity characterized by symptoms such as syncope, dyspnea, chest discomfort and pain, palpitations, and lethargy primarily resulting from AV dyssynchrony. The reported incidence of pacemaker syndrome in patients with VVIR pacing varies widely in literature, ranging from 7–10% as high as 83%. This variability is largely attributable to the absence of a universally accepted definition of pacemaker syndrome and nonspecific nature of its symptoms, which are common in cardiology patients regardless of pacemaker implantation. In addition to reducing the incidence of pacemaker syndrome, DDDR pacemakers are believed to lower the risk of atrial fibrillation, stroke, and mortality, while improving exercise tolerance and overall quality of life compared with VVIR pacemakers [2]. Notably, atrial fibrillation is associated with a more severe clinical course of hypertrophic obstructive cardiomyopathy [5].

The selection of pacemaker type is influenced not only by clinical evidence but also by practical and economic considerations. Single-chamber pacemakers are less expensive and simpler to implant and follow up, whereas dual-chamber devices preserve AV synchrony and more closely mimic physiological cardiac conduction [2]. British guidelines published in 1991 recommend atrial pacing in patients with preserved AV conduction and ventricular pacing in those with established or impending AV block.

Quality of life represents a critical clinical outcome encompassing physical, psychological, cognitive, and social dimensions. Although several generic quality-of-life questionnaires have been validated, they lack sufficient sensitivity for patients with pacemakers. To address this limitation, the AQUAREL questionnaire was developed as a disease-specific instrument for assessing quality of life in pacemaker recipients, with well-established psychometric properties and validated reliability [6].

Despite the theoretical advantages of DDDR pacing over VVIR pacing, the clinical benefits remain incompletely defined, particularly in the light of the substantially higher costs associated with dual-chamber systems [7]. Consequently, quality of life may represent an important additional parameter in the selection of pacemaker type [6].

The aim of this study was to compare the quality of life of patients with VVIR and DDDR pacemakers using the AQUAREL questionnaire.

Material and Methods

This prospective study was conducted at the Institute for Cardiovascular Diseases of Vojvodina (ICVDV), Novi Sad, Serbia, between December 2022 and January 2023. The study protocol was approved by the Ethics Committee of the Institute for Cardiovascular Diseases of Vojvodina in Sremska Kamenica, and all participants provided written informed consent prior to enrollment.

The AQUAREL questionnaire was translated into Serbian for the purposes of this study. The questionnaire consists of 24 items evaluating the frequency of symptoms commonly associated with pacemaker syndrome. A total of 80 patients presenting for routine pacemaker follow-up at ICVDV were screened. Inclusion criteria were age ≥60 years and implantation of either a single-chamber (VVIR) or dual-chamber pacemaker (DDDR) pacemakers. These criteria were met by 69 patients, of whom 33 had VVIR and 36 had DDDR pacemakers. Exclusion criteria included age <60 and implantation of an implantable cardioverter-defibrillator (ICD). Demographic and clinical data, including year of birth, pacemaker type, and comorbidities, were obtained from the ICVDV database. Data were analyzed using SPSS software, employing the Mann–Whitney U test.

Within the AQUAREL questionnaire, questions 1–6 assess chest discomfort; questions 7–12 evaluate dyspnea; question 13 assesses lower extremity edema; questions 14–16 assess palpitations; question 17 evaluates dizziness; question 18 explores difficulties in decision-making; question 19 examines memory impairment; question 20 assesses concentration; questions

Table 1. Patient comorbidities

Comorbidity	Group 1 (N=33)	Group 2 (N=36)	p-value
Arterial Hypertension	31 (93.93%)	31 (86.1%)	0.102
Atrial Fibrillation	23 (69.7%)	4 (11.11%)	<0.001
Type 2 Diabetes Mellitus	14 (42.42%)	5 (13.89%)	0.009
Valvular Heart Disease	20 (60.6%)	12 (30.56%)	0.024
Chronic Kidney Disease	5 (15%)	0 (0%)	0.016
Mean Age (years)	79	72.25	0.004
Mean Patient Response Score	1.11	1.007	0.493

Table 2. Comparison of symptom scores between patients with VVIR and DDDR pacemakers

Symptom	Group 1	Group 2	p-value
Dyspnea	0.35	0.4	0.839
Dizziness	0.51	0.7	0.622
Chest Discomfort	0.85	0.78	0.869
Palpitations	0.67	0.8	0.427
Insomnia	0.45	0.6	0.332
Reduced Sleep Quality	1.06	1.114	0.511
Decision-Making Difficulties	0.69	0.64	0.458
Memory	1.09	1.26	0.463
Concentration	1.06	1.083	0.626
Edema of Lower Extremities	1.21	1.22	0.92
Physical Activity	1.82	1.28	0.079
Fatigue	2.21	1.83	0.24
Overall Score	1.11	1.007	0.493

VVIR – ventricular pacing, ventricular sensing, inhibition response, rate-adaptive; DDDR – dual pacing, dual sensing, dual response, rate-adaptive.

21–22 evaluate insomnia and sleep quality; and question 24 addresses fatigue during daily activities. Physical activity tolerance is specifically assessed through questions 2-5, 8-10, and 23.

Results

The study population consisted of 69 participants, including 42 (60.9%) males, with a mean age of 76 years. Group 1 (VVIR pacemaker) included 33 patients, of whom 20 (60.6%) were male, with a mean age of 79 years. All patients in this group (n=33, 100%) had at least one comorbidity. Hypertension was present in 31 patients (93.93%), atrial fibrillation in 23 (69.7%), type 2 diabetes mellitus in 14 (42.42%), valvular heart disease in 20 (60.6%), and chronic kidney disease in 5 (15%) patients **(Table 1)**.

Group 2 (DDDR pacemaker) consisted of 36 participants, including 22 (61.1%) males, with a mean age of 72.75 years. Comorbidities were present in 31 patients (86.1%). Hypertension was observed in 29 patients (80.5%), atrial fibrillation in 4 (11.11%), type 2 diabetes mellitus in 5 (13.89%), and valvular heart disease in 12 (30.56%). None of the patients in this group had chronic kidney disease.

As shown in **Table 1**, statistically significant differences ($p<0.05$) were observed between the two groups regarding the prevalence of atrial fibrillation, type 2 diabetes mellitus, valvular heart disease, and chronic kidney disease. A statistically significant difference in mean age was also identified ($p=0.004$). These findings are consistent with current European Society of Cardiology (ESC) guidelines, which recommend VVIR pacemaker implantation in patients with atrial fibrillation and/or significant comorbidities.

Analysis of AQUAREL questionnaire responses revealed no statistically significant difference in overall quality of life between VVIR and DDDR pacemaker ($p=0.493$).

Mean symptom scores obtained from the questionnaire are presented in **Table 2**. Although patients with DDDR pacemakers demonstrated slightly better physical activity tolerance, this difference did not reach statistical significance.

Discussion

This study evaluated the quality of life of patients with single-chamber and dual-chamber pacemakers and demonstrated no statistically significant difference between the two groups based on pacemaker type.

Previous research by Nguyen et al. [8] showed that more than 70% of pacemakers are implanted in patients older than 70 years, suggesting that preservation of atrioventricular (AV) synchrony – achieved with dual-chamber (DDDR) pacemakers – may be particularly

beneficial in elderly patients [9,10]. A long-term Japanese observational study spanning 1979-2019 reported a 12.1-year increase in the mean age at first pacemaker implantation, especially among individuals aged over 80 and 90 years [11]. In line with these data, the mean age of patients in this present study was 76 years.

Dual-chamber pacemakers are associated with higher costs, greater implantation complexity, and an increased risk of complications compared with single-chamber devices [12]. Despite these differences, our analysis did not reveal statistically significant difference in overall quality of life between the two pacemaker types. Some subgroup analyses reported in the literature – notably in patients with sinus node dysfunction and AV block – suggest improved quality of life with DDDR pacemakers, particularly in terms of physical capacity and symptom burden [2]. Several retrospective studies have also reported improved clinical outcomes associated with dual-chamber pacing [13–15]; however, these findings are limited by selection bias, as DDDR devices are more frequently implanted in younger patients with fewer comorbidities. To minimize heterogeneity, this study included only patients older than 60 years. Nonetheless, statistically significant differences noted in **Table 1** must be considered.

Patients with DDDR pacemakers demonstrated a trend toward greater physical exertion capacity, although this did not reach statistical significance. This finding may be partially explained by the younger mean age and a lower prevalence of comorbidities – particularly atrial fibrillation – in this group. A meta-analysis of 14 studies comparing physical capacity in patients with single- and dual-chamber pacemakers reported inconsistent results: six studies showed significantly greater exertion capacity in DDDR patients, while eight found no difference between pacing modes [16]. Importantly, none of the included studies demonstrated inferior exertion capacity in patients with VVIR pacemakers. Variability in findings had been attributed to examiner bias and heterogeneous patient populations. Hemodynamic studies suggest that primary benefit of DDDR pacing during maximal exertion is mediated by rate responsiveness rather than AV synchrony alone [17].

Symptom analysis in the present study revealed no statistically significant differences between groups. Similar investigations have reported lower rates of dyspnea and reduced physical activity in VVIR recipients. This study evaluated 17 parameters, of which 11 showed a trend favoring DDDR pacemakers without reaching statistical significance, whereas 2 parameters – related to memory and concentration – demonstrated non-significant trends in favor of VVIR pacemakers [18]. Another comparable study reported left atrial enlargement and impaired left ventricular diastolic function associated with VVIR pacing [19]. Furthermore, Ouali et al. demonstrated significant increases in left atrial size (p=0.007) and pulmonary arterial pressure (p=0.0001) in patients with VVIR pacemakers, accompanied by worsening mitral regurgitation, which may contribute to a higher incidence of atrial fibrillation in this population [20].

This study did not assess perioperative complication rates. Data from the CTOPP trial (2000) showed a higher complication rate with dual-chamber pacemakers (9%) compared with single-chamber devices (3.8%) ($p < 0.01$) [21]. Large trials such as MOST [22] and UKPACE [23] found no superiority of DDDR pacing over VVIR in reducing stroke or mortality. The UKPACE trial evaluated the clinical benefits of single- versus dual-chamber pacemakers in elderly patients with AV block. The pacemaker type did not influence overall mortality over five years post-cardiac event or three years post-implantation, supporting the rationale for implanting DDDR devices in older patients [23]. Conversely, hemodynamic evidence suggests that atrial contribution to ventricular systolic function becomes increasingly important with advancing age [9,24] .

Patient perception of VVIR pacing may be influenced by prior exposure to DDDR pacing. Since pacemaker implantation – regardless of type – results in substantial improvement in quality of life compared with untreated AV block or sinus node disease, both groups experience marked benefit, making it difficult to determine which group perceives greater improvement [20].

Conclusion

No statistically significant difference in quality of life was identified between patients with dual-chamber and single-chamber pacemakers as assessed by the AQUAREL questionnaire **(Appendix 1)**. The cost of implantation should be taken into account when deciding between single-chamber and dual-chamber pacemakers.

Appendix 1. AQUAREL questionnaire

1. Have you felt discomfort in the chest? • no discomfort at all • very mild discomfort • mild discomfort • moderate discomfort • great discomfort	13. Did you have swollen ankles? • never • seldom • once in awhile • often • continuously

2. Do you get chest discomfort while walking upstairs or uphill? • no discomfort • very mild discomfort • mild discomfort • moderate discomfort • severe discomfort	14. Have you suffered from an irregular heartbeat? • never • seldom • once in awhile • often • continuously
3. Do you get chest discomfort while walking quickly on • • • level ground? • no discomfort • very mild discomfort • mild discomfort • moderate discomfort • severe discomfort	15. Have you suffered from heart pounding? • never • seldom • once in awhile • often • continuously
4. Do you get chest discomfort while walking on level ground at the same pace as people usually do at your age? • no discomfort • very mild discomfort • mild discomfort • moderate discomfort • severe discomfort	16. Have you suffered from pounding in the neck or abdomen? • never • seldom • once in awhile • often • continuously
5. Have you been restricted by chest discomfort during physical exercise? • Not restricted at all • Slightly restricted • Moderately restricted • Very restricted • Extremely restricted	17. Have you felt close to fainting? • never • seldom • once in awhile • often • continuously
6. Have you experienced chest discomfort at rest? • no discomfort • very mild discomfort • mild discomfort • moderate discomfort • severe discomfort	18. Have you noticed decision-making difficulties? • never • seldom • once in awhile • often • continuously
7. Do you get short of breath while walking upstairs or uphill? • not short of breath • very mildly short of breath • mild short of breath • moderate short of breath • extreme short of breath	19. Have you noticed memory fog? • never • seldom • once in awhile • often • continuously
8. Do you get short of breath while walking quickly on level ground? • not short of breath • very mildly short of breath • mild short of breath • moderate short of breath • extreme short of breath	20. Do you have difficulty to maintain focus? • never • seldom • once in awhile • often • continuously
9. Do you get short of breath while walking on level ground at the same pace as people usually do at your age? • not short of breath • very mildly short of breath • mild short of breath • moderate short of breath • extreme short of breath	21. Do you have trouble falling asleep? • never • seldom • once in awhile • often • continuously
10. Have you been restricted by breathlessness during physical exercise? • not restricted at all • slightly restricted • moderately restricted • very restricted • extremely restricted	22. Do you feel tired and exhausted after a night's sleep? • never • seldom • once in awhile • often • continuously
11. Have you been out of breath at rest? • not out of breath • slightly out of breath • moderately out of breath • very out of breath • extremely out of breath	23. Have you been restricted in your daily activities due to tiredness or lack of energy? • extremely restricted • very restricted • moderately restricted • slightly restricted • not restricted at all

12. Do you awake when sleeping due to shortness of breath? • never • seldom • once in awhile • often • continuously	24. Did you have to sit or lie down during the day to rest? • never • seldom • once in awhile • often • continuously

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Rad je primljen 26. XI 2025.
Recenziran 7. XII 2025.
Prihvaćen za štampu 7. XII 2025.
BIBLID.0025-8105:(2025):LXXVIII:5-8:167-172.