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Research Article

Possible Pitfalls of Autocapture and Automatic Capture Management Algorithms or Trust but Verify- Post Marketing Study

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Abstract

Background: Automatic pacing output management has been used for more than 20 years and it has been generally accepted as safe and device longevity prolonging mode of pacing. Despite that, accuracy of these algorithms in traditional VVI(R) and DDD(R) pacemakers on long term basis has not, to our knowledge, been defined. There is evidence that in patients with atrial fibrillation (AF) and low percentage of ventricular pacing (VP) this function might be less suitable.

Methods: We have followed up a population of 559 patients with permanent pacemakers for 3 years and 8 months. 274 of them had the automatic output management (AOM) function activated. We have prospectively searched for inappropriately set pacing output in both subgroups. That is, either too high or too low. We have compared this subgroup to that with fixed output pacing (FOP). Patients with any mechanical complication and those having pacemaker implanted for less than three months were excluded from the study.

Results: We have found 11 patients out of 274 in whom the value of pacing output was inappropriate.

Conclusions: In our study, 99.6% of patients with AOM functions activated always had effective pacing and the percentage of ideal performance of this function was 96%. These numbers confirm safety of AOM functions with only a few caveats.

Keywords

Auto capture; Cardiac pacing; Evoked response; Polarization signal; Threshold management algorithm

Abbreviations: A: Atrial; AC: Autocapture; AOM: Automatic Output Management; AF: Atrial Fibrillation; AP: Atrial Pacing; ER: Evoked Response; ERI: Elective Replacement Indication; FOP: Fixed Output Pacing; HR: Heart Rate; PS: Polarization Signal; PSA: Pacing System Analyser; SJM: St. Jude Medical; SR: Sinus Rhythm; V: Ventricular; VCM: Ventricular Capture Management; VP: Ventricular Pacing

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Introduction and Review of Literature

The idea of threshold tracking pacemaker was introduced by Funke, Preston, Bowers and Mugica in the 1970s [1-5]. Research, which was initiated by these authors, led to the first clinically successful automatic algorithm of a pacemaker capable of detecting capture, i.e. evoked response to electric stimulation and adapting pacing output according to measured pacing threshold in a singlechamber pacemaker (Pacesetter Microny, Solna, Sweden in 1994 - Pacesetter - a subsidiary of St. Jude Medical since 1994). In 1999 a dual-chamber pacemaker with this technology (Affinity DR) was presented. Algorithms for automatic management of pacing energy have also been developed by other manufacturers.

Thereafter, there were studies leading to a common sense that AOM algorithms offer, besides other advantages [6-16] enhanced patient's safety [17,18].

However, other authors [19] conclude that: benefit in some patients with ventricular pacing $\leq 25\%$, low stimulation threshold, and/or AF could be questionable, special attention should be paid to the long-term AOM functioning reports, activation of the algorithm should be individualized in each patient and long-term AOM pattern must be checked routinely during follow-up. Authors of this work also point out, that a long-term evaluation of the efficiency of AOM in the real world is lacking.

The aim of our study is to report inadequately set values of pacing output by automatic algorithms with a concise explanation of possible causes and this way contribute to generally better awareness of potential problems and their solutions.

Materials and Methods

We have analysed a population of 559 patients, coming to our hospital for routine pacemaker controls in the period since February 2013 to October 2016 (3 years and 8 months). Out of these, 274 patients (49%) had the AOM function activated. In this AOM subgroup, there are 130 Medtronic, 133 St. Jude Medical, 6 Biotronik and 5 Vitatron devices. In all automatic algorithms we have left the default (nominal) setting unchanged (once daily measurement in Medtronic and three times in 24 hours in St. Jude Medical devices). The control group with FOP consisted of 285 patients: 184 with Medtronic and 101 with Saint Jude Medical devices. We have included all patients coming for pacemaker controls into our hospital, even those whose pacemaker was implanted in another hospital and those who already underwent generator replacement(s). So, the time from implantation was random, but we have excluded those with pacemaker implanted less than three months ago. Only patients without any mechanical complication (like lead dislodgement, lead damage or perforation) were included into the study.

In both groups, we have prospectively searched for inappropriately set pacing output. In pacemakers without automatic output algorithms it has been common practice to set the output on twice the value of the threshold. Therefore, in our study, we have defined the inappropriate pacing output as either lower than pacing threshold or more than 3 times the value of the pacing threshold but not less than 2.5 V/0.4 ms. In all patients with the automatic capture management activated, we have measured the pacing threshold manually and compared

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it to that determined automatically and with the pacing output. These measurements were performed within one minute interval. The threshold was considered accurate if it corresponded with the manually measured one. In the following text, the term "pacing threshold" will refer to the manually measured pacing threshold unless stated otherwise. Data collected by authors were verified by the expert analysis of the hospital information system (Akord Stapro s.r.o.). We have compared two groups of patients with regard to the difference between the pacing threshold and pacing output. We have not compared the relative amount of energy depletion, because there are multiple factors influencing the energy consumption and thus it is too complicated to quantify it accurately enough.

Results

In the AOM group, the mean pacing threshold and output were 0.91 V/0.40 ms and 1.67 V/0.40 ms respectively (average difference 0.76 V). We have found 9 patients (3.2%) in whom the pacing output was set too high and 2 patients (0.7%), in whom it was too low. Characteristics of these patients are summarized in Table 1.

In the control group with FOP we have not recorded any case of ineffective pacing. We have seen very few of such cases, but these were due to some mechanical complication, like lead dislodgement or perforation (mainly in the first 3 months after implantation) and these patients were excluded from the study as mentioned above. Mean pacing threshold in the control group was 0.94 V/0.40 ms and average pacing output in this group was 2.23 V/0.40 ms. Average difference between threshold and output in this group was 1.29 V/0.4 ms. Statistical analysis (ANOVA) have confirmed, that in the AOM group the difference between the output and threshold was significantly lower than in the FOP group (P<0.001).

In the control group, we have found 19 patients meeting our criteria of too high output with maximum difference between threshold and output of 2.8 V.

Prevalence of AF in both groups (559 patients), is 47.9%. In 15 % the AF was only subclinical and device detected AF - with low AF burden. Distribution of the particular types of AF is displayed in Graph 1.

In the AOM group with inappropriate output, there are only three patients (27%) with significant proportion of AF or permanent AF and only two patients (18%) with VP<30%. The rest of them had long standing sinus rhythm and high percentage of ventricular pacing.

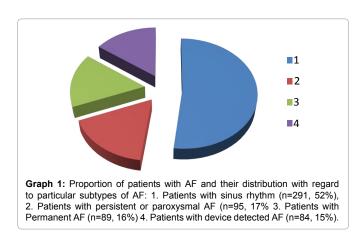
As shown in Table 1, in 10 of these patients the pacing output was set inappropriately high and, in 2 cases inappropriately low with output set below the pacing threshold. Because this is a feared malfunction of a pacemaker - when it fails to pace - we give detailed information on these two cases.

First one was 87 years old, but mentally and physically capable (self-contained) female patient, with Verity TM ADx XL device with VP (ventricular pacing) of 30% and permanent atrial fibrillation. This patient had suffered multiple episodes of dizziness with falling (it was uncertain, if these were accompanied by losses of consciousness), but bradycardia or loss of capture was not documented. In this patient AC was functioning well for several years before this episode. We have checked the evoked response/polarization signal ratio and it was excellent and stable (evoked response 12-17 mV, polarization 0.39 mV) just like other electrical parameters. Despite that, the automatically measured pacing threshold was falsely stated 0.125 V while in reality it was 1V. The value of automatically set output was 0,375 V. Hence, we have set the device on FOP 2V/0.4 ms but, when

Pt. No.	Age	Pacemaker model, year of first implantation, year of generator replacement(s)	Lead (V/A, type)	Manually determined pacing threshold (V/ms)	Pacing output set by AOM (V/ ms)	Sensing (mV)	VP (%)	AP (%)	Pacing mode	Rhythm	Intrinsic HR	Paced AV delay (ms), in SR intrinsic PR interval (if not high degree AV block), (ms)
1.	83	SJM Sustain 2006, 2014	V/ SJM 1688T	0.75/0.4	5/0.4	10.7-12	50-55	NA	VVIR	Permanent AF	83	NA
2.	77	SJM Zephyr DR 2005, 2010	A/unknown	0.75 /0.4	3.25/0.4	3.3-3.7	100	1	DDD	3 rd degree AV block	<30	160, NA
3.	87	SJM VerityADx XL, 2008	V/SJM, 1788TC/58	1.25 /0.4	4.5/0.4	12.3-16.3	98	7	DDD	SR, 2 nd degree AV block	30-60	160, 180
4.	78	SJM Sustain 2003, 2014	A/ Medtronic 5076	0.5/0.4	3/0.4	0.6-0.8	> 99	99	DDDR	SR, 3 rd degree AV block	35-40	200, NA
5.	85	SJM Zephyr DR, 2011	V/SJM, 1788TC/58	1/0.4	5/0.75	3.5-4	11	98	DDD	SR	54	Adaptive,190-200
6.	94	Medtronic Sensia DR, 2012	A/Unknown	0.75 /0.4	4.5/0.4	0	100	100	DDDR	3 rd degree AV block	30-60	160, NA
7.	86	SJM Accent DR, 2013	A/SJM, 1888TC -	0.75/0.4	3.25/0.4	2.6	4-8	25	DDDR	SR	69-80	Adaptive, 200
8.	75	SJM Zephyr DR, 2010	V/SJM, 1788TC/58	0.75 /0.4	5/0.4	12	100	98	DDDR	SR, parox. AF	30	Adaptive, 220
9.	94	SJM VerityADx XL, 2008	V/ SJM, 1788TC/58	0.75 /0.4	4.5/0.4	8.3-9.1	42	NA	VVI	Permanent AF	50-100	NA
10.	87	SJM VerityADx XL 2007	V/ SJM,1788TC/58	1.0/0.4	0.375/0.4	11.4-16.6	30	NA	VVIR	Permanent AF	60-70	NA
11.	91	SJM Sustain, 2009, 2014	V, SJM,1788TC/58	1-4/1	1.8/1	2-2.6	98	41	DDDR	SR, complete AV block	<30-32	220, NA

Table 1: Characteristics of patients with automatic output management and inappropriately set pacing output.

A - Atrial, AOM- Automatic Output Management, AF - Atrial Fibrillation, AP - Atrial Pacing, FOP - Fixed Output Pacing, SJM - St. Jude Medical, V - Ventricular, VP-Ventricular Pacing, NA - Not Applicable



writing this article, the patient still reported episodes of dizziness with falling.

The second case of pacing output set below the pacing threshold was a 91- year old man, with SJM SustainTM XL DR and an unstable pacing threshold ranging, according to the records of the device for several months, from 1 to 4 V/1 ms. This patient, who was dependent on the pacemaker, with AC function activated, experienced repeated episodes of ineffective pacing with symptomatic bradycardia and also with syncopes. Since the last (emergent) pacemaker control, it was not even possible to just switch the AC on, because this immediately led to a loss of capture and severe symptomatic bradycardia, resolving only after manual reprogramming it to fixed output. We have interrogated the pacemaker and displayed the leads by chest fluoroscopy, CT scan and transthoracic echocardiography. The only abnormities we have found were unstable pacing threshold - on long term basis - and lower sensing (2.6-2.8 mV) on the ventricular lead. The impedance was stable, around 380 Ohms. This patient's intrinsic heart rate was under 30 bpm for the most of the time and the sensing was only measurable during the last session, thus it did not prompt any physician or technician to switch the AC off. The device has been put on high FOP - 7V/1ms (with regard to the patients age and comorbidities we have decided to wait with new lead implantation until ERI) and the patient had no syncope since then (when writing this article - for two months).

Discussion

In the literature, we have found only one case report [8] of pacing output set by AOM algorithm lower than threshold. Despite the fact, that the cause of this was identified and resolved, this case report has illustrated the need for close post-marketing surveillance of this technology. We have found two patients with pacing output lower than pacing threshold. In one of these ineffective pacing was documented. 2 patients in the group of 274 patients is so low and insignificant number, that it is actually not suitable for any statistical analysis. But these cases have taught us an important lesson on how to manage patients with these algorithms activated. In the first case, the intrinsic rhythm of the patient on follow up was 60-70 bpm, so the algorithm most probably interpreted patient's own beats as an evoked response. It was a SJM device with beat to beat verification of ER and we have not documented ineffective pacing in this case. So it is very unlikely, that the syncopes or falls were caused by bradycardia.

In the second reported patient usage of AC function was inconvenient because of too low value of sensing. There is evidence, that auto capture should not be used if the ER amplitude is small

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(<2.5 mV), the polarization signal amplitude is large (>4 mV), the ER sensitivity/ polarization ratio is <1.7, or the ER amplitude/ER sensitivity ratio is <1.8 (20-21). This also must have been the case of our patient, although Sustain model does not enable manual numeric measurement of polarization and ER/polarization ratio. It seems clear, that this case was an example of a poor cardiac substrate or a suboptimal lead placement. This case demonstrates that in patients with intrinsic heart rate lower than 30 bpm - with unmeasurable i.e. unknown sensing and in whom the value of evoked response is also unknown, auto capture should probably not be activated.

Changes in pacing threshold are described in literature [21-24]. In the study of Burri et al. [25] on Medtronic Concerto CRT-D devices it has been shown, that LV Capture Management algorithm was actually beneficial in patients with threshold fluctuations of more than 1 V, which were those with higher pacing threshold.

It would be unrealistic to expect from any method or algorithm to have 100% reliability. In the real world, the most exact and most reliable methods have over 90% reliability. In our opinion, 99.6% likelihood that the pacemaker will effectively pace with the AOM function on, and only 3.3% probability, that the energy output is higher, than it could be, would be, from that point of view, excellent numbers. Of note, our results are not very different from those, recorded by other authors [16,26,27]. Although the latter two studies were performed on totally different devices and leads: First of them [26] evaluated the performance of automated pacing threshold algorithm on RV ICD leads, working with RV-coil to can sensing of ER. The second study [27] was performed on LV-leads (Boston Scientific CRT-D/P devices) with automatic threshold detection algorithm using four pacing vectors and it demonstrated significantly higher accuracy than we have found in our group of patients.

Our data show that under certain circumstances automatic output algorithms may fail to set optimal value of output and this is the fact which, in our opinion, still prevents routine pacemaker controls to be performed without supervision of an experienced specialist, with good knowledge of all of these algorithms. One of the important limitations of our study is, that it included devices practically only of two manufacturers, thus its conclusions cannot be applied to all AOM algorithms. It is convenient to add, that algorithms are undergoing continuous development and improvements like fusion detection algorithms, e.g. that by Biotronik [28] are expected to further decrease the number of inaccurately working algorithms.

We are not trying to question reliability of automatic algorithms. Our data actually suggest high reliability and it has been reported in PACE [11] that automated output management is safer than a fixed output, which may result in exit block. We would rather like to provide clues on how to interpret and manage output, which is inadequate to a measured threshold. We offer these recommendations: Unstable pacing thresholds with significant circadian fluctuation can be unmasked by setting automatic threshold tests at least 3 times daily. Fusion or pseudo fusion can be revealed by running automatic threshold tests at pacing rate similar to the intrinsic rate. If the automatically set output is too high in chronically inhibited pacemakers and the device does barely have a chance to measure the threshold, the algorithm does not necessarily have to be switched off because in this case the battery longevity is not significantly affected due to very low pacing percentage.

Our first case report indicates, that in patient with atrial fibrillation, predominant intrinsic rhythm, who would have pacemaker without

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beat to beat verification of capture, ineffective pacing might occur in theory, but these devices, as a rule, operate with higher safety margin and thus the likelihood of such an event is extremely low and will probably be even lower with further extension of fusion detection algorithms.

As indicated in the text, values of ER and PS are crucial for optimal AOM functioning. Yet, these measurements cannot be made with the standard pacing system analysers (PSA) during implantation. As a consequence, approximately 5-7% of patients were found to have inadequate ER signals and AC could not be activated [15,29]. The correlation between the spontaneous R wave as measured with the standard PSA and the ER signal has been reported to be weak to moderate: In the studies of Clarke [6] and Schubert [15] the correlation coefficients were r=0.29 and r=0.44 respectively. Therefore, it should probably be a topic of consideration to develop and implement analysers with such capabilities. And for the same reason, it would be also, in our opinion, probably worth considering to enable direct numeric measurement of these values in all pacemaker models during follow up controls.

We did not compare the influence of both methods of pacing (FOP and AOM) on battery depletion, but it is logical and there is also evidence in the literature [10-14] that the AOM functions are less energy consuming than fixed output pacing.

According to Benezet-Mazuecos et al. [19], suboptimal performance of AOM is most likely in patients with AF and those with VP<25%. Despite that, as logical as it may seem, finding of these authors, is not supported by our investigation.

Conclusion

According to our analysis, the percentage of an ideal performance or accuracy of the AOM function is 96%. Potentially very harmful situation is setting the pacing output under the pacing threshold. This situation did not occur in any patient in the control group and only twice (0.7%) in the "AOM" group. In the first case, low value of pacing output had no clinical significance because the PM was inhibited by patient's intrinsic heart rate and ineffective pacing did not occur. In the second case, AOM function should not have been activated at all, in accordance with the manufacturer's recommendation, because of low sensing and very unstable pacing threshold.

Over 20 years, the AOM functions have proved its advantages. However, since the first rule in medicine is "safety first" or "primum non nocere", on the basis of our findings, we would suggest that the AOM functions be checked during every pacemaker control: Automatically measured pacing threshold should be compared to the manual measurement and the record of pacing thresholds measured by the device between the patient's visits (or remote controls) should be read. Similarly, the measurements of evoked response and polarization should also be performed on regular basis, if the device enables it. Despite the on-going developments of algorithms and leads, even in the year 2017, the supervision of an educated specialist during pacemaker controls is still necessary.

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Conflict of interest

The authors declare that they have no competing interest.

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