In the light of discussions about limiting the number of certain procedures

Critical appraisal of pacemaker implantations in a tertiary Swiss hospital

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Summary

In the light of possible restrictions to the number of pacemaker implantations in Switzerland and missing local data on this topic, we aimed to evaluate if the pacemaker indications in a tertiary Swiss hospital are in accordance with current guidelines of the European Society of Cardiology.

We included all 309 pacemakers implanted between the 1 January 2018 and the 15 March 2019. Cardiac resynchronisation pacemakers were excluded. Mean age of the patients was 78.3 years (standard deviation 10.2). Class I indication was present in 90.6%, class IIa in 3.6%, class IIb in 3.6%, and class III in 2.2%.

Based on these results, it is unlikely that a prespecified restriction of annual pacemaker implantations will prevent volume expansion. On the contrary, these measures may even result in withholding indicated therapy for symptomatic patients.

Introduction

"Too many operations/procedures are performed", a sentence often referred to in the lay press as well as in journals of medical societies [1, 2]. A survey by Comparis, a commercial online provider of healthcare counselling, showed a 145% increase in knee replacement and a 50% increase of hip replacement between 2003 and 2014 [3]. Orthopaedic procedures such as hip replacements, meniscus operations and intervertebral disc surgery are especially under scrutiny [1, 4]. The rise in caesarean sections, even though only a minority of cases might have a profound medial indication [5–8], is also of concern.

In cardiology, continuously rising numbers of coronary angiographies are in focus [4]. De novo pacemaker implants have also increased, from 3948 in 2008 to 5556 in 2018 [9]. Certain Swiss cantons, therefore, mandate hospitals and medical societies such as the FMH to survey indications. In Basel Stadt, for example, authorities are discussing limiting the number of certain procedures and might ask physicians to justify indications if a predefined number of interventions is exceeded.

To the best of our knowledge, no data exist about the quality of pacemaker indications in Switzerland.

The aim of the present study was therefore to evaluate how many pacemaker implantations in a tertiary Swiss hospital were in accordance with European Society of Cardiology (ESC) guidelines valid in 2019 [10] and whether there was a difference between patients diagnosed at our hospital or referred for implantation.

Methods

Consecutive single or dual chamber pacemaker implantations performed between the 1 January 2018 and the 15 of March 2019 at the University of Basel Hospital were included, independently of whether they were scheduled or emergency procedures. Lead implants in the setting of revision procedures and generator replacements were not included. Also not considered were cardiac resynchronisation therapy (CRT) pacemakers. The first author primarily verified the indication. In the case of doubt, she discussed the patient with an electrophysiologist not involved in pacemaker implantation at our hospital in the study period. Seven cases were finally re-classified by the last author during the revision process. Indications were compared regarding referral (indication made by a University of Basel Hospital 0.(USB) cardiologist or by a referring cardiologist). We also determined whether the arrhythmia was permanent or paroxysmal, even though this makes usually no difference for indication.

Quality of data documentation available to the authors to verify the type of arrhythmia was categorised as:

Level A: the authors could identify the arrhythmia in the source data of the hospital (12-lead ECG, Holter, telemetry) or in the documents sent by the referring cardiologist.

Level B: the arrhythmia was mentioned in the referral letter of the cardiologist, but could not be reviewed by the authors.

Level C: the implanting electrophysiologist referred in his operation letter to the arrhythmia, but no source

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data were available (e.g. "patient after valve replacement had AV block III" or "on the monitor a sinus arrest of 13 seconds was seen").
Level D: patients scheduled for a "pace and ablate" procedure due to drug refractory permanent atrial fibrillation.
A chi-square test was used to compare indications according to referral.
The study was approved as a quality control study by the local ethics committee (EKNZ; AO_2022-00016).

Results

We included 309 pacemaker implantations; the mean age of the patients was 78.3 years (standard deviation 10.2 years). A total of 135 patients were female (44%). Hypertension was present in 65%, and diabetes in 17% of patients.
The most common symptoms reported were syncope in 36% and dizziness in 23%. The most common cardiomyopathy was coronary artery disease in 38%. No further evaluation was performed in only 12% of the patients. In 36 patients (12%), implantation was performed during the hospital stay for aortic valve replacement (transcatheter approach in 26 patients, surgical in 10). Twenty-seven patients (9%) were scheduled for the "pace and ablate" procedure. Devices used were dual chamber pacemakers in 84% (DDD 72% [one epicardial system], VDD 12%) and single chamber pacemakers in 16% (VVI 15%, of which 10 were leadless pacemakers, AAI 1%).
The level of documentation was A in 161 patients (51%), B in 62 (20%), C in 59 (20%) and D in 27 (9%).
A class I indication was present in 90.6%, class III in 2.2%. Table 1 gives more details. There was no difference according to referral status. Table 2 shows type of bradycardia, paroxysmal or persistent, as well as all indication classes. Table 3 describes the seven patients in whom a pacemaker was implanted even though they had a class III indication.

Discussion

Main results

Firstly, a very high percentage of pacemaker implantations had either a class I (90.6%) or a class IIA (3.6%) indication, commonly appraised as a very good indication for a procedure; and secondly, there was a low rate of 2.2% of procedures with a class III indication.
Based on these results, it does not seem justified to restrict pacemaker implantations to a prespecified annual number in order to prevent volume expansion. These measures would lead to the withholding of indicated pacemaker therapy in symptomatic patients

Table 1: Overview of patients according to indication level, split between in house and referral indication.

Indication class	Overall	USB indication (n = 231)	Referral indication (n = 78)
I	280 (90.6%)	209 (90.5%)	71 (91.0%)
IIa	11 (3.6%)	8 (3.5%)	3 (3.8%)
I and II a	291 (94.2%)	217 (94.0%)	74 (94.8%)
IIb	11 (3.6%)	10 (4.3%)	1 (1.4%)
III	7 (2.2%)	4 (1.7%)	3 (3.8%)

Table 3: Details of the seven patients with a Class III indication.

Situation not mentioned in guidelines		
87 y old male	Paroxysmal AV block II type I, before TAVI	No symptoms
82 y old female	Asymptomatic sick sinus syndrome	Symptomatic hypertrophic obstructive cardiomyopathy in need of beta-blocker therapy
Evidence level B		
84 y old male	Left bundle branch and AV block I after TAVI, HV interval unknown	No symptoms
Evidence level C		
86 y old female	Sinus rhythm, no bundle branch block, no documented bradycardia	Syncopes, resuscitation with "use" of AED, no print outs
90 y old female	Atrial fibrillation, no bundle branch block, 24-h Holter normal	Recurrent syncopes with injury
78 y old female	Sinus rhythm, left anterior fascicle block	Two syncopes with injury

AED: automated external defibrillator; AV: atrioventricular; HV interval: His bundle–ventricular interval; TAVI: transcatheter aortic valve implantation

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Table 2: Details of bradyarrhythmia as the main indication for pacemaker implantation.

Class I	
AV Block III	128 (56 permanent, 72 paroxysmal) (41.4%)
Symptomatic sick sinus syndrome	70 (17 poor chronotropic response, 53 symptomatic sinus arrest) (22.6%)
AV block It Type II	44 (11 permanent, 33 paroxysmal) (14.2%)
Atrial fibrillation, with the aim of pace and ablate	27 (8.7%)
High degree AV block, not further specified	5 (1.6%)
Atrial fibrillation, slow ventricular response	4 (1.3%)
Bundle branch block, syncope, pathological electrophysiological study	2 (0.6%)
Class IIa	
Syncope, sinus arrest of > 6s	10 (3.2%)
Symptomatic AV Block II Type I	1 (0.3%)
Class IIb	
Sick sinus syndrome with presumed symptomatic bradycardia	2 (0.6%)
Bundle branch block, unexplained syncope	9 (2.9%)
Class III	7 (2.3%) (details see Table 3)

AV: atrioventricular

simply because the annual number of implants attributed to a hospital is exhausted. However, it might be wise to ask implanters to justify their procedure in cases of class IIb or even class III indication in their discharge letter.

The seven patients with a class III indication deserve special consideration. Two asymptomatic patients with paroxysmal AV block II type I or left bundle branch block and AV block I after transcatheter aortic valve replacement (TAVI) have to be considered in hindsight as clearly not indicated. Four patients with a history of one or several syncopes without evidence of bradyarrhythmias could have been managed differently, i.e. with implantation of a loop recorder. With this approach, a symptom-rhythm correlation can be established, but with the risk of further injury. After careful discussion with the patient and their next of kin, pacemaker implantation, even though not indicated according to guidelines, can be an option in this situation. The last patient, with a strong indication for beta-blocker therapy and asymptomatic bradycardia, has to be considered a very rare case that cannot find its way into guidelines.

General considerations

Pacemaker implantations in Switzerland have increased from 3949 in 2008 to 5556 in 2018. Some reasons for this increase are obvious: (a) the number of CRT pacemaker implantations increased from 133 to 340 owing to more awareness of this specific heart failure therapy without a pure bradyarrhythmic indication; (b) the advent of TAVI for the treatment of patients who were considered inoperable in 2008, but are not anymore in 2018 (8% of our implants); (c) an ageing population with bradyarrhythmias – in 2008 40.3% of patients were older than 80 years, compared with 45.4% in 2018; (d) six additional implant centres. Guidelines, on the other hand, have not relevantly changed in the past ten years.

In the surrounding countries Italy, France, Austria and Germany between 1152 and 1006 pacemaker implantations per million inhabitants were performed in 2014 [11], compared with only 812 per million in Switzerland. It thus can be speculated that it is usual practice in our country not to implant "unnecessary" devices. However, this cannot be proven by our results.

Comparison with other studies

Adherence to the ESC guidelines was investigated by a centre in Galway, Ireland ([12], only abstract available). In this series, 96.2 % of patients had a class I or IIa indication, similar to our population. However, direct comparison is difficult, as implantable cardioverter defibrillators (ICD) implantations and generator replacements were also included and it is not possible to exclude them from the analysis. Regarding ICDs, data are also very limited. One study [13] evaluated the indication of primary prevention ICD implantation based on the four major randomised controlled trials. Later on, these formed the basis for the guidelines, but are not exactly congruent with them. In this report, 86% of ICD were implanted correctly. The main factors for not complying were a high degree AV block and a non-cardiologist as first implanter. The paneuropean CRT survey [14], published by Normand et al., showed in 93% of cases a class I or IIa indication, again similar to our

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results. However, indication classes were not independently reviewed. Men and, surprisingly, elderly patients were more likely to undergo CRT implantation with lower indication class.

Limitations

Results stem from a single centre and might therefore be prone to a certain bias. However, our hospital was second in the 2018 ranking of numbers of pacemaker implantations in Switzerland. In sick sinus syndrome, indication is based on symptoms, especially in poor chronotropic response. Due to the retrospective character of the study, we were not able to determine a definite correlation in all patients. The same holds true for some patients with syncope, where we had to rely on the charts that a cardiological syncope was present.

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Conflicts of interest (last 3 years)
HB: none.
CS: consulting fees by Medtronic, Biotronik, Microport, Abbott and Boston Scientific, Safety monitoring and advisory boards for Medtronic and Boston Scientific.
BS: speaker's bureau for Medtronic

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