Deactivation of implantable cardioverter-defibrillators: results of patient surveys

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Aims
The indications for implantable cardioverter-defibrillators (ICDs) have been expanding, especially for primary prevention of sudden cardiac death. Implantable cardioverter-defibrillator saves lives; however, in near end-of-life situations linked to incurable diseases, the question arises as to whether or not to turn off the ICD to avoid excessive numbers of shocks as the heart begins to fail. This study examined the wishes of a cohort of ICD recipients.

Methods and results
Consecutive recipients of ICDs for primary or secondary prevention of sudden cardiac death were examined during a routine out-patient follow-up visit. Subjects completed a written survey about expected ICD benefits, feelings and circumstances under which they would want to deactivate the device. One hundred and nine patients fully completed the survey. Mean age was 67.6 ± 8.7 years, 91 (83.5%) were male and the mean systolic ejection fraction was 31.5 ± 10.9%. The severity of symptoms of heart failure according to the New York Heart Association classification was 2.1 ± 0.59 at implantation. Ninety-nine (90.8%) patients felt more secure and safe following ICD implantation and 66 (60.6%) patients reported a sense of improved health status after implantation. Thirty-one (28.4%) patients had experienced an ICD shock. Fifty (45.9%) patients indicated that they had never considered ICD deactivation during near end-of-life situations. This topic had been discussed with only eight (7.3%) patients. Forty-four (40.1%) patients wanted more information about ICD deactivation. On the other hand, 10 (41.7%) patients from secondary prevention and 19 (22.4%) from primary prevention groups categorically refused more information or further discussion on this topic (P = 0.058).

Conclusion
Most ICD recipients felt safer following ICD implantation and most wanted more information regarding ICD deactivation. However, a significant number of patients (especially, secondary prevention patients) had no interest in receiving additional information about this topic.

Keywords
Heart failure • ICD • End-of-life

Introduction
Sudden cardiac death is the leading cause of death among heart failure patients following myocardial infarction with preserved New York Heart Association (NYHA) class (I–III).1 In addition, the mortality associated with sudden cardiac death of non-ischaemic origin, in heart failure patients, is also high. It has been shown through many large randomized clinical trials, that the treatment of high-risk patients with implantable cardioverter-defibrillator (ICD) therapy saves lives.2,3 The indications for ICDs have been expanding in recent years, especially for primary prevention of sudden cardiac death.4,5 Implantable cardioverter-defibrillators are highly effective in the treatment of sudden death caused by malignant arrhythmias. However, under special circumstances (such as near end-of-life), the question arises whether or not to turn off the ICD. In case of incurable diseases (such as untreatable cancer or end-stage heart failure), inappropriate and even appropriate shock deliveries can no longer prolong life and may simply lead to pain and reduced quality of life.

There are times, such as at the end-of-life, when patients and families may no longer desire treatment and wish to have their cardiac device turned off. During the last decade, several surveys have dealt with this issue.6 The European Heart Rhythm Association survey of physicians showed that ICD deactivation in
What’s new?

- The majority of patients (<90%) following implantable cardioverter-defibrillator (ICD) implantation feel more secure and safe following ICD implantation.
- Almost a half of ICD recipients had never thought about ICD deactivation during the near end-of-life period.
- Almost a half of ICD recipients want more information about ICD deactivation.
- However, a significant number of ICD recipients (41.7% from secondary prevention and 22.4% from primary prevention) categorically refuse more information or further discussion of this topic.

Methods

Study population

We conducted a study using ICD patients from October 2011 to May 2012 at the Charles University Hospital, in the ICD out-patient clinic, Prague, Czech Republic. All consecutive ICD recipients (with Czech as their native language) were asked to complete a special questionnaire administered by two cardiologists with the help of a psychologist. Only patients having uncertain mental status were not included. Patients’ clinical data were compared with electronic medical records to assess the association between the data obtained from the questionnaire and data contained in the medical records. These data included the indication for the ICD (i.e. primary vs. secondary prevention), type of ICD (single chamber, dual chamber, or biventricular), severity of heart failure symptoms (NYHA) at implantation and at the time of the questionnaire, the number of hospitalizations for heart failure decompensation within the last year, recent heart failure status, and previous ICD therapy.

The study was approved by the Ethics Committee of the University Hospital Kralovske Vinohrady and informed content was obtained from each participant before enrolment into the study. In order to link patient answers with medical data, the questionnaire could not be blinded. However, all obtained data were used only for the purpose of the study and the questionnaire did not become part of the patient records.

Survey instruments

A self-completion style was chosen. All patients were asked to participate in the study by a physician. Patients were instructed that all questions should be answered. Three experienced nurses were available to help patients if they did not fully understand the questions.

The questionnaire

The questionnaire included 13 questions as shown in Appendix 1. Most questions were qualitative and were answered ‘yes’ or ‘no’. In other, related, questions, three or more choices were offered and patients were instructed to pick the most applicable choice. For quantitative questions, a visual analogue scale (VAS) (a horizontal line 10 cm in length with 0 on left side and 10 on right side) was presented and patients were instructed to indicate a quantity by placing a mark on the line. During analysis, the distance from the left margin to the mark was measured.

The most important questions were question 10: Would you consider switching your ICD device off if ICD were in the terminal phase of a malignant illness, e.g. a non-treatable malignant tumor, taking into account that you could die of a sudden death due to a malignant arrhythmia, but not due to the tumor itself? And question 12: Would you like to discuss the possibility of switching your device off with your doctor? Or do you feel you have enough information on this subject? Or is this subject so unpleasant for you that you do not wish to discuss it with anyone at all? (a) Yes, I would like to receive more information regarding this; (b) No, my doctor has already informed me adequately (c) No, I do not want to discuss this subject at all]. The answers to these questions were tabulated separately—the answers were used as independent variables and logistic regressions and correlations were done with other clinical variables and other questions to assess, which variables and answers were independently associated with answers to these questions.

All questions were in the Czech language and only patients with Czech as native language were enrolled. For the purpose of the study, all questions were translated into English by a native bilingual (Czech and English) translator. Answers to question 5, regarding the number of delivered shocks was verified using ICD shock histories.

Depression was defined if it was mentioned in the patient’s history or if the patient was taking anti-depressive medication. Information regarding education (university degree or not) was obtained from patient medical histories. All patients were asked whether they lived alone or with family members (i.e. husband, wife, or children). Implantable cardioverter-defibrillator settings for single-chamber devices were VVI 40/min, for dual-chamber devices it was DDD 60/min with a long AV delay and in biventricular devices it was DDD-Biv. Implantable cardioverter-defibrillators were programmed using currently accepted standard algorithms [based on patient age, presence of atrial fibrillation (AF), and physical activity]. Ventricular tachycardia zone 1 was set between 167 and 190 b.p.m., and the ventricular fibrillation zone was set between 190 and 220 b.p.m.). Anti-tachycardia pacing was used in all patients.
Statistical analysis
A significant part of data analysis was done using descriptive statistics (Microsoft Excel). Categorical data are presented as absolute numbers and relative frequencies (percentages), while continuous data are presented as means and standard deviations (SD). Correlations were calculated using the Pearson correlation coefficient. Comparison of subgroups was based on the Student's two-sample t-test or Fisher' exact test, as appropriate.

For studying the association between the answer 'Yes' to question 10 with clinical variables and answers to other questions, a univariate logistic regression analysis was used, and selected variables were then entered into a multivariate logistic regression. For studying the association between the answers to question 12 (with three possible answers) with clinical variables and answers to other questions, polytomous logistic regression had to be done.

Clinical variables entered into the model were age, gender, the length of ICD therapy (i.e. the difference between the date of implantation and date of the survey), education (university degree or non-university degree), the total number of shocks, the number of appropriate and inappropriate shocks, type of ICD (single chamber, dual chamber, or biventricular), the indication for the ICD (i.e. primary or secondary prevention), ejection fraction of the left ventricle, NYHA class at the time they completed the questionnaire, living status (alone or with relatives), and pacemaker dependency. Variables that showed either a significant result (P < 0.05) or were near-statistical significance (P < 0.1) were included in a multivariate stepwise logistic regression model to determine which were independently associated with answers to questions 10 and 12. This part of the statistical analysis was performed using SPSS version 15.0 software (SPSS Inc.) or Sigma STAT (Systat Software Inc.). All statistical tests were treated as two sided and evaluated at a significance level of 0.05.

Results
Baseline characteristics
A total of 112 patients with ICDs were enrolled in the study. Three patients were excluded due to incomplete questionnaires; therefore, 109 patients were analysed (i.e. had fully completed questionnaires). The mean age of patients was 67.6 ± 10.9 years, 69 patients (63%) had sinus rhythm, 12 patients (11%) had paroxysmal AF, and 28 patients (26%) permanent AF. The length of ICD therapy was 662.4 ± 620.4 days. Twenty-nine patients (26.7%) had a university degree. Seventy-nine patients (72.5%) lived with family (i.e. husband, wife, or children), the remaining 30 (27.5%) lived alone. Thirty patients (28.4%) patients had experienced an ICD shock (question 5). The pain of the shock averaged 45.1 on 100% scale (question 6). Ten patients (32.2%) reported that the shock had negatively impacted on their psychological status (question 7).

Primary vs. secondary prevention
Eighty-five patients (78%) had ICDs for primary prevention and 24 (22%) patients for secondary prevention. Twenty-three (95.8%) patients in secondary prevention group and 76 (89.4%) patients in the primary prevention group reported feeling safer following ICD implantation (question 3). Thirty-two (37.7%) patients from the primary prevention group and 6 (25%) from the secondary prevention group indicated that they would consider deactivation of their ICD under the specific circumstances presented in question 10. This difference was also not statistically significant. Ten (41.7%) patients from the secondary prevention and 19 (22.4%) from the primary prevention group did not want ever to speak about ICD deactivation (question 12, Figure 1); the difference had borderline significance (P = 0.058).

Patients with and without ICD shocks after implantation
Thirty-one (28.4%) patients had received a shock after ICD implantation, and 78 (71.6%) had never been shocked. The shock was appropriate in 24 (22.0%) patients and inappropriate in 8 (7.3%) patients. Patients who received shocks were more often hospitalized (1.21 hospitalization/patients in the shocked group vs. 0.79 hospitalization/patients in the un-shocked group, P < 0.05). No other significant differences were found between these two groups of patients including answers to questions regarding ICD deactivation; no differences were found between appropriately and inappropriately shocked patients.

Answers to the questionnaire
Satisfaction with pre-implant awareness was 79.8 ± 27.6% (question 2). Ninety-nine (90.8%) patients felt safer following ICD implantation (question 3) and 66 (60.6%) patients felt that their health status had improved since implantation (question 4). Thirty-one (28.4%) patients had experienced an ICD shock (question 5). The pain of the shock averaged 45.1 on 100% scale (question 6). Ten patients (32.2%) reported that the shock had negatively impacted on their psychological status (question 7). Sixty-five (55.1%) patients had been hospitalized since implantation (question 9). Fifty (45.9%) patients indicated that they had never thought about ICD deactivation in near end-of-life situations (question 10). Only eight (7.3%) patients reported that they had discussed the topic with a doctor (question 11). Forty-four (40.1%) patients wanted more information regarding ICD deactivation (question 12). On the other hand, 28 (25.7%) categorically refused any additional information on the issue (question 12). If deactivation was considered, 55 (50.1%) said it would be a personal decision and they would not discuss it with their relatives (question 13).
Biventricular vs. single- and dual-chamber devices

Sixty patients (55%) had biventricular ICDs and the remaining 49 patients (45%) had either a single-chamber or dual-chamber device. Surprisingly, there was no difference in answers to question 3 (feeling of safety following implant) and question 4 (overall improvement of health following implant) between patients with biventricular devices and patients with other devices. In fact, there was no difference between the biventricular and non-biventricular patients regarding any of the questions.

Related answers—correlations between answers

Patients who answered that they felt safer after ICD implantation (question 3) were less likely to have considered switching off their ICD (question 10; $r = -0.245, P < 0.05$). In addition, more patients in this group (i.e. felt safer) reported that they had been sufficiently informed about ICD implantation prior to the procedure (question 2; $r = 0.2444, P < 0.05$) and that the topic of ICD deactivation had been discussed (question 11; $r = 0.3, P < 0.05$). Patients who indicated that the ICD shock had negatively influenced their psychological status (question 7) also indicated that they had not been sufficiently informed about ICD implantation ($r = -0.368, P < 0.05$). Patients who indicated that they had considered ICD deactivation, also indicated that they would make the decision alone, without discussion with their family (question 10 and 13; $r = 0.238, P < 0.05$).

Multivariate logistic regression

In the multivariate logistic regression, no variable was independently associated with the answer to question 10 (consideration of switching off ICD). However, although only a trend, patients living alone were more likely to have considered switching off their ICD in near end-of-life situations ($P = 0.10$).

In a multinominal logistic regression, no clinical or other variable was independently associated with the answer to question 12 (willing to speak about or get more information regarding ICD deactivation). While only trending, the secondary prevention group was associated with a complete lack of desire to receive more information about ICD deactivation ($P = 0.082$). In the subgroup of patients who had received shocks, the answer to question 6 (perception of shock pain) trended towards an association with question 12. Patients with higher shock pain perceptions were more likely to want more information regarding ICD deactivation ($P = 0.084$).

Discussion

The perception of health

This study shows that the majority of patients felt safer following ICD implantation and often perceived that their health had improved. There was no difference between patients who had been shocked and those who had not. Although, with borderline significance, more patients with ICDs for secondary prevention indicated that they had no interest in more information about ICD deactivation. No other differences between primary and secondary prevention patients were observed.

It was recently shown that heart failure patients anticipate long survivals and overestimate survival benefits conferred by ICDs. Despite the improvement in pharmacological and non-pharmacological treatment of heart failure patients, the prognosis for heart failure remains poor. After three hospitalizations for heart failure decompensation, patients older than age 70 have an estimated median survival of only 1.5 years. Implantable cardioverter-defibrillators were developed to treat malignant arrhythmias, and therefore to prolong the lifetimes of patients with a history or high risk for life-threatening arrhythmias. However, despite the significant benefits of ICDs, as shown in several randomized trials, the effect of ICDs on mortality is only moderate. For example, in the Sudden Cardiac Death in Heart Failure Trial, which included patients with left ventricular dysfunction, irrespective of ischaemic or non-ischaemic aetiology, the absolute benefit of ICD implantation on mortality was 7.2% at 5 years. In a recently published survey by Stewart et al., 54% of ICD patients thought that more than 50% of ICD recipients would still be alive at 5 years. Moreover, 65% of ICD patients thought they would live more than 10 years and 34% believed they would live more than 20 years. In fact, there was trend for patients with an ICD to be more optimistic than patients who lived alone reported more often that they would consider deactivation of their ICD in near end-of-life situations (question 10, $r = -0.21, P = 0.025$).
without an ICD.\textsuperscript{10} Thus, it seems that patients often overestimate the benefits and have unrealistically high expectations regarding ICD implantation. This is in agreement with the findings of our study, where a majority of patients felt safer and even healthier following their ICD implant.

ICD deactivation

In a study by Goldstein et al., no ICD patients were willing to engage in advance care planning discussions regarding ICD deactivation.\textsuperscript{11} Although patients in the study were invited to discuss the potential problems and pitfalls associated with ICDs in detail and in groups moderated by physicians and social workers, only 15 patients participated. Similarly in a study by Stewart et al., 39% of ICD patients said they would never turn their ICD off. This included during terminal diseases such as cancer or multiple daily shocks caused by constant dyspnoea due to end-stage heart failure. In our study, nearly half the patients had considered switching off their ICD as part of their near-end-of-life decisions. Whether this was due to specific characteristic associated with having received an ICD, or specific characteristic of the near-end-of-life period, is not known. If the first is true, then the population of heart failure patients with an ICD seems to be unique compared with other patients and dependent on other life-sustaining medical devices (dialysis, mechanical ventilation, etc.). Some authors have reported that patients dependent on dialysis were quite open to discussion and willing to address near the end-of-life treatment options.\textsuperscript{13,14}

In our study, and with only borderline significance, more patients from the secondary prevention group were intolerant of discussing or receiving more information about ICD deactivation. Past experience with sudden death could have deeply influenced the psychological status of these patients.

Surprisingly, we did not find any differences between patients with biventricular and other (single or dual chamber) devices, and between shocked and non-shocked patients. One would expect that patients with biventricular devices would feel safer and would perceive their general health as having improved. However, this result could be due to the small sample size of the subgroup. It is worth mentioning here that all sub-analyses must be viewed cautiously because of the sample sizes involved. For this reason, we did not divide the biventricular patients to responders and non-responder, because such division would have sample sizes so small as to make statistical analysis impossible. Although only a trend, ICD patients living alone more often reported that they would consider deactivation of their ICD in near-end-of-life situations. Loneliness in advanced age could also negatively affect a patient’s view of the future. However, we did not measure depression scores at the time of the questionnaire so we cannot comment on the role of depression in those living alone, although, it seems reasonable to expect depression to impact on attitudes towards ICD deactivation. Three patients had information about depression in their medical history and all had been or were being treated with antidepressive medication. It is also possible that responses to some of the questions on the questionnaire could have been influenced by latent depression.

Information regarding the option of ICD deactivation

Only a small portion of patients (7.3%) had discussed the issue of ICD deactivation with a doctor; however, a significant part (40.1% in our study) would like to be better informed regarding this issue. Previous reports have shown that clinicians and patients rarely engage in discussions about deactivating ICDs and most devices remain active until death.\textsuperscript{15} Whether this lack of discussion is due to patient’ reservations, embarrassment, and worries or similar issues on the side of the physician is not clear. Because of this, many patients may receive shocks in the final hours or minutes of life, an unpleasant situation that causes suffering to both patients and families.\textsuperscript{15} The discussion about ICD deactivation is not a pleasant one for the patient or the physician. However, both patient and physician need to be clear on this issue; therefore, this difficult topic has to be discussed before ICD implantation.

On the other hand, 28 (25.7%) categorically refused to discuss ICD deactivation in terminal stages of a disease. This percentage is in agreement with previous studies.\textsuperscript{11} This position must also be respected. Medical professional must always respect a patient’s wishes and take the necessary actions to give them a peaceful death by deactivating their ICD.\textsuperscript{16} The problem of turning off an ICD appears less problematic than turning off a pacemaker or cardiac resynchronization therapy device because an ICD is more preventive; additionally turning off an ICD, to comply the patient’s wishes, would likely produce less anxiety and apprehension in the medical professionals entrusted with the patient’s care.\textsuperscript{17}

The number of patients who wish to be better informed about ICD deactivation and the number of patients who have no wish to discuss this topic clearly demonstrates how difficult it is to meet the wishes and expectations of all patients.

Implications, improving the dialogue with patients

The first and most important step before ICD implantation is an open and complete discussion with the patient regarding the benefits and drawbacks of this treatment strategy.

Common practice today is that physicians discuss with patients the benefits of ICD implantation relative to survival and possible complications, which may occur during implantation, but there is almost no discussion regarding near-end-of-life issues associated with an implantable cardioverter defibrillator. This issue is pressing and requires our immediate attention. A study by Sherazi et al.\textsuperscript{18} demonstrated that primary care and medical specialists physicians lack important medical—legal information regarding ICD deactivation in terminally ill patients. As shown in our study, most patients wish to be better informed regarding ICD deactivation as part of their near-end-of-life decision-making process and the advice offered by physician must be medically and legally correct.

Study limitations

The survey data on ICDs have several limitations. The survey was only administered to the patient population of one academic centre and may not be representative of larger populations of heart failure patients. The survey instrument was novel and developed by investigators for the purposes of this study only. As such,
the ability to extrapolate patient answers on our questionnaire to all ICD patients or even all heart failure patients may be limited. As in all questionnaires, the formulation of questions is of great importance. Furthermore, although all of our patients had serious cardiac disease, which led to an ICD indication, all surveys were completed by outpatients and did not include hospitalized or hospice patients. It is possible that responses to the questionnaire could have been influenced by depression; however, a depression score was not calculated. Our patients sample also had a relatively good status (80% NYHA II), and results from a similar questionnaire that included patients in worse condition could give quiet different results. Finally, the reason why we conducted this study was to better understand the wishes, opinions, and attitudes of our ICD patients. Therefore, all statistical analyses of sub-groups must be viewed very cautiously because of the small sample sizes of the sub-groups.

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Appendix 1

Questionnaire
The complete questionnaire, as it was given to patients, is shown.

1. The date of primary implantation of ICD:
2. In your opinion, before the implantation of the ICD, were you given enough information about the device and why you were given this implant? On the horizontal line below please put a mark, which reflects how well-informed you were regarding the device and procedure:
   0 (left) = I was not informed at all, 100 (right) = I was given maximum information (VAS)
   0 ___________________________ 100
3. Do you believe that the ICD implant has made you feel safer?
   Yes – No
4. Do you think that your overall health (a) has improved, (b) has not changed at all or, (c) has gotten worse since you were given the implant?
   A—has improved, B—has not changed, C—has gotten worse
5. Have you received any ‘shocks’ from the ICD since implantation?
   Yes – No
6. If you answered (Yes) to question 5, please try to indicate on the horizontal line below the level of pain associated with the shock.
   (VAS: 0 (left) = no pain at all. …………………….100 (right) = very painful).
   0 _______________ 100
7. If you have received an ICD shock, did the ICD shock have an effect on your psychological status? (Skip this question if you have never received a shock from your ICD)
   Yes – No
8. If you have received an ICD shock, who helped you to manage your situation after the ICD shock? (Skip this question if you have never received a shock from your ICD)
   A—arrhythmologist
   B—general cardiologist
   C—general practitioner
   D—psychologist
   E—psychiatrist
   F—family member(s)
   G—nobody
9. How many times have you been hospitalized within last year (365 days)?
10. An ICD protects the patient from ‘malignant arrhythmias’.” These are very rapid arrhythmias, which cause the heart to experience very rapid and very chaotic electrical impulses, i.e. the heart fibrillates. In this case the ICD sends a shock, which ‘stuns’ all the cells for a short period of time. When the short ‘stun’ wears off, a normal, regular heart rhythm returns. However, an ICD is not able to improve heart failure (which can be caused by (i) a scar in the heart tissue after a heart attack or (ii) valve disease). Naturally, the ICD cannot treat other critical illnesses, such as malignant tumors. In light of this, the next question might seem a rather unpleasant topic, however, it is also part of one’s life.
   If you were to developed a serious disease and were in the late phases of that disease, for example a non-treatable malignant tumor, would you consider switching your ICD device off—taking into account that you could die of sudden death due to a malignant arrhythmia, but not due to the tumor itself?
   Yes – No – I do not know
11. Has anyone ever discussed with you the implications of switching the device off?
   Yes – No
12. Would you like to discuss the implications of switching the device off with your doctor? Or do you feel you have enough information on this topic? Or is this subject so unpleasant for you that you do not wish to discuss it with anyone at all?
   A. Yes, I would like to receive more information regarding this
   B. No, my doctor has informed me enough already
   C. No, I do not want to discuss this subject at all
13. If you considered switching the device off, would you make the decision on your own, without discussing this with your relatives?
   Yes – No

We thank you for filling in the questionnaire and for sharing your opinions.
A tachycardia with narrow-QRS morphology and prolonged RP intervals

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Differential diagnosis of a narrow-QRS tachycardia with prolonged RP intervals [AH = 172 ms, HA = 154 ms, VA = 136 ms, and tachycardia cycle length (TCL) = 324 ms] is presented. Interruption of tachycardia by ventricular extrastimulation and an atrio-ventricular (AV) response excluded an atrial tachycardia. Entrainment with ventricular pacing from the RV septum resulted in a correction of the TCL to 125 ms (Figure). These numbers argue against an accessory pathway. However, correcting the PPI–TCL by taking into account the pacing-induced incremental AV nodal conduction, resulted in a corrected cPPI–TCL = 125 ms. This suggests AVRT rather than AVNRT. Entrainment from the posterobasal RV wall produced a PPI–TCL was 85 ms, a StimA–VA interval 390 ms, and a cPPI–TCL 35 ms. The fact that both cPPI–TCL and StimA–VA intervals get shorter with entrainment at the RV base compared with RV apex, indicate a septal accessory pathway that was eventually mapped at the midseptal area near the His bundle. Slowly conducting accessory pathways that have VA intervals ≥ 40% of the TCL may demonstrate prolonged PPI–TCL and StimA–VA intervals that resemble atypical AVNRT. Consideration of corrected cPPI–TCL intervals, as well as entrainment from the posterobasal RV may be necessary for an accurate diagnosis.

The full-length version of this report can be viewed at: http://www.escardio.org/communities/EHRA/publications/ep-case-reports/Documents/narrow-QRS-morphology.pdf

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