



# Phantom shocks in patients with implantable cardioverter defibrillator: results from a randomized rehabilitation trial (COPE-ICD)

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## Aims

The aim of this trial was to assess a combined rehabilitation intervention including an exercise training component and a psycho-educational component in patients treated with implantable cardioverter defibrillator (ICD). The hypothesis was that the intervention would reduce the occurrence of phantom shocks.

## Methods and results

The design was secondary explorative analyses of data from a randomized controlled trial. One hundred and ninety-six patients with first-time ICD implantation (79% male, mean age 58 years) were randomized (1:1) to either combined rehabilitation or a control group receiving 'treatment as usual'. A total of 144 participants completed the 12-month follow-up. Intervention consisted of 12 weeks of exercise training and 1 year of psycho-educational follow-up focusing on modifiable factors associated with poor outcomes, e.g. phantom shocks. Outcome measures were ancillary questions regarding the experience of phantom shocks, date, time, and place. Twelve patients (9.4%) experienced a phantom shock, 7 in the intervention group and 5 in the control group (NS). Neither age, sex, quality of life nor perceived health at baseline was significantly related to the probability of occurrence of phantom shock.

## Conclusion

Phantom shocks were experienced by about one in ten ICD patients, with no interventional effect found and no significant difference found regarding receiving an actual shock therapy among phantom shock patients.

Trial registration: ClinicalTrials.gov (ID: NCT00569478).

## Keywords

ICD • Comprehensive cardiac rehabilitation • Phantom shock • Exercise training • Psycho-education

## Introduction

Treatment with implantable cardioverter defibrillator (ICD) has reduced mortality remarkably over the past 20 years. The average ICD implantation rate in Europe is 140 per million. In the USA, this rate is considerably higher, 416 per million.<sup>1</sup> Although highly effective in preventing arrhythmic death, patients receiving an ICD may still experience psychological difficulties such as fear of shock, reduced quality of life, avoidance behaviour, e.g. social isolation, avoidance of physical activity, and mood disturbances.<sup>2–6</sup>

The phenomenon of phantom shock is the perception of having received an ICD shock without actually having received a shock. The phenomenon was first described in an editorial letter to *BMJ* in 1992. Of 84 patients, 4 experienced nocturnal phantom shocks all having previously received an actual ICD shock.<sup>7</sup> At that time, the phenomenon was interpreted as maladjustment to the ICD, suggesting the need for treatment of secondary psychiatric disorder. A few case reports have been published which echo the 1992 letter,<sup>8,9</sup> suggesting antidepressants or anxiolytics as treatment<sup>9</sup> or participation in peer support groups as supportive care.<sup>10</sup> More recently, descriptive studies have been conducted in

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### What's new?

- Phantom shock is experienced by 9.4% of patients with ICD
- Phantom shocks occur both as a daytime phenomenon and a nocturnal phenomenon and both in activity and during rest.
- No significant difference is found in receiving an actual shock therapy among phantom shock patients.
- The incidence of phantom shock is neither related to age, sex, living alone nor to quality of life or perceived health at hospital discharge.
- Cardiac rehabilitation does not seem to prevent phantom shocks.

larger samples. Prudente *et al.*<sup>11</sup> found phantom shocks in 19 of 75 patients (25.3%) who agreed to retrospectively report their shock experience before ICD interrogation and reported that these individuals were more likely to be clinically depressed and have higher levels of anxiety than other ICD patients and phantom shocks seems therefore to be an important endpoint. Jacob *et al.*<sup>12</sup> found 38 patients who had perceived a phantom shock and compared them to age- and sex-matched patients. They found that the phenomenon primarily occurred in patients with a history of traumatic device shocks, depression, anxiety or substance abuse. They conclude that memory reactivation of traumatic events seems to contribute in the pathogenesis of phantom shock.

The COPE-ICD trial was initiated in 2007, including 197 ICD patients in a randomized controlled rehabilitation trial.<sup>13</sup> The comprehensive cardiac rehabilitation intervention consisted of an exercise training component and a psycho-educational component which included mental coping strategies that could potentially prevent phantom shocks. The primary outcomes were general health and exercise capacity, which were found to be significantly better in the intervention group compared with the control group (unpublished data). No previous study has investigated the impact of rehabilitation on phantom shocks in a randomized design. Therefore, the aims of the present study were (i) to investigate the prevalence of phantom shocks; (ii) to examine the potential effects of rehabilitation in the prevention of phantom shocks; and (iii) to explore predisposing psychosocial factors.

## Methods

The design and methods of the COPE-ICD trial have been described in detail elsewhere,<sup>13</sup> and are briefly outlined in the following:

### Setting and intervention

The COPE-ICD trial was conducted in a large university hospital with a volume of ~300 first-time ICD implantations every year. Inclusion criteria: patients who received a first-time ICD implant and agreed to participate in the entire programme could be included in the trial prior to hospital discharge. The intervention included a comprehensive cardiac rehabilitation approach with exercise-training and psycho-education in addition to usual care and patients were randomized in a 1 : 1 ratio to intervention or usual care.

The approach was inspired by Parse's Human Becoming Practice Methodologies.<sup>14</sup> The topics discussed were: events and experiences leading up to the ICD implantation, present thoughts and questions, implications for everyday life, avoidance behaviour, exercise training, impact on family, information (including technical) and recommendations, shock and phantom shock, body image, driving, and sexuality. The patients consulted the nurse in person or by phone once a month for 6 months, and every 2 months thereafter for the following 6 months. The psycho-educational part of the intervention was performed by two nurses with 10 years of clinical experience each in the care of patients with ICDs. Three months after the ICD implantation, patients began to participate in training sessions twice a week for a 12-week period. The physical training programme consisted of an individual consultation with a physiotherapist and an individually tailored training programme. Patients in the control group followed a usual care programme, which included medical follow-up and an invitation to participate in a 2 h group session, which included information about the ICD and exchange of experiences among patients. The objective of the trial was to describe the effect and meaning of an outpatient programme including psycho-educational consultations and exercise training for patients with ICD.

Because of the nature of rehabilitation, the interventions were open to the staff and the patients. A blinded investigator performed data collection and administration. Blinded outcome analyses were conducted.

## Outcomes

Demographic and clinical data were obtained directly from the patients or from the medical records during hospitalization. Phantom shock outcome was investigated using a questionnaire specifically developed for this trial. The predisposing psychosocial factors were measured using Short Form-36 (SF-36) and Quality of Life Index—Cardiac Version (QLI-CV).

### Phantom shock questions

Two questions were asked in order to learn about the patients shock experiences. (1) Did you ever experience an ICD shock? If yes: date, time, where were you at the time, what were you doing? (2) Did you ever experience that you had an ICD shock and the following reading showed that the ICD had not delivered a shock? If yes: date, time, where were you at the time, what were you doing? The questions were face validated on three patients. They were given the questions to answer in the presence of the primary investigator to test the understanding of the questions before their use in the COPE-ICD trial. That led to the following introductory guide, 'Some ICD carriers are uncertain if what they experience is actually an ICD shock. Please indicate all the experiences that you think were a shock, even if you don't know for sure that it was an actual shock or if the reading at the hospital showed that it was not an ICD shock. It is YOUR experience we ask for'. The information was then confirmed by review of ICD interrogations.

### Short Form-36

The SF-36 is a measure of self-rated health. It contains 36 items to measure 8 components. The content validity of the SF-36 has been compared with that of other widely used generic health surveys.<sup>15,16</sup> Short Form-36 includes eight subscales that are aggregated into two summary scores, a Mental Component Score (MCS) and a Physical Component Score (PCS). Scores range from 0 to 100, higher scores indicate better perceived health.<sup>17,18</sup>

### Quality of Life Index—Cardiac Version

The QLI-CV measures cardiovascular health-related quality of life. The basic version QLI was developed for healthy individuals and comprised two sections ( $2 \times 32$  items), one measures satisfaction with various domains of life and the other measures the importance of the domain. The QLI-CV is based on the same core items, but has six additional items specific to cardiac patients in each section. Highest scores are obtained for items that have both high satisfaction and high importance. Scales range from 0 to 30.<sup>19</sup> The outcome consists of a total score (QLI) and four subscales.

### Statistical methods

The interventional effect was analysed using Pearson  $\chi^2$ . Fisher's exact test was used to determine differences in the number of actual shocks experienced. Since no difference between groups was detected, the groups were pooled to determine related factors: age, sex, living alone, QLI-CV, MCS (SF-36), and PCS (SF-36).

For each baseline variable, a logistic regression analysis was done with the intervention indicator and the baseline quantity as independent variables and the outcome quantity [occurrence of phantom shock (yes/no)] as the dependent variable. Two-sided significance tests were applied at a level of 0.05. The fit of the model was tested using the Hosmer–Lemeshow test.

Prior to the analysis of a continuous variable the latter was divided into six equally sized groups using the 16.6% percentiles as cut-off points and it was assessed if the logits  $[\ln(p/(1-p))]$  where  $p$  is the probability of the occurrence of a phantom shock of these groups was linearly related to the corresponding mean values. Data were analysed using SPSS 17.0. (SPSS Inc.) or SAS 9.1 (SAS Institute).

### Ethics

Patients gave their written informed consent after receiving oral and written information. All data material was treated in confidentiality and patients were assured anonymity. The trial followed the recommendations of the Declaration of Helsinki II.

### Results

During the inclusion period October 2007–November 2009, 610 patients received a first-time ICD implantation at our hospital. A total of 196 patients were included: 99 in the intervention group and 97 in the control group.<sup>13</sup> Of the 196 patients included, a total of 144 patients completed the trial: 73 in the intervention group and 71 in the control group. In all, 49 patients withdrew from further participation and 3 died. The baseline demographics and clinical characteristics of the two groups are shown in Table 1.

In the present study, 12 patients (9.4%; CI = 4.6–15.9) experienced a phantom shock during a 12-month follow-up period. The characteristics of the phantom shocks are shown in the Table 2. Four patients experienced the phenomenon during sleep, seven phantom shocks happened during resting or different activities during the day, and one could not remember in what activity he/she was involved. Only 2 of the 12 patients that experienced phantom shock had an actual ICD shock before, but no significant difference between experiencing an actual shock or not was found ( $P = 0.132$ ).

The distribution of phantom shocks was 7 (12.1%) in the intervention group and 5 (7.2%) in the control group. (Table 3) This difference was not statistically significant ( $P = 0.267$ ).

**Table 1** Demographic and clinical characteristics

	Control group	Intervention
	(n = 97)	group (n = 99)
	n (%)	n (%)
Male gender	76 (78)	79 (80)
Age (mean/SD)	58 (13.4)	58 (12.9)
Living alone (6 months)	20 (29.4)	10 (14.7)
Employed	50 (52)	41 (42)
Primary prophylactic indication	67 (69)	63 (64)
Ventricle fibrillation prior to ICD implantation	20 (20)	21 (21)
Ejection fraction (mean/SD)	32.7 (18)	32.2 (17)

Table 4 shows the odds ratio and 95% confidence interval of sex, living alone, baseline quality of life, perceived mental health, and physical health. None of these baseline variables were significantly related to the probability of occurrence of phantom shock during the course of the trial. Therefore, multiple regression analyses were not done.

Comparing patients with or without phantom shock, no significant difference occurred in mental health and quality of life at 12 months. Short Form-36 mental component scale: phantom shock 48.1 vs. 53.3 points ( $P = 0.08$ ) in non-phantom shock patients. Quality of life—Cardiac Version 23.5 vs. 24.7 points ( $P = 0.3$ ).

### Discussion

Phantom shock was experienced by 9.4% with no interventional effect found and no significant difference was found in receiving an actual shock therapy among phantom shock patients. The incidence of phantom shock was neither related to age, sex, living alone nor to quality of life or perceived health at baseline.

The trial was the first designed to intervene; aiming to prevent phantom shocks by providing psycho-educational follow-up where shock management and coping with the possibility of a shock were central elements. However, the retrospective reporting of phantom shocks is a weakness, as missing data exist, probably due to memory limitations of participants. The phantom shock analyses were *post hoc* analyses, and the trial was not powered to measure this. Actually, in order to detect a reduction of 50%—that means 9% experiencing phantom shock in the control group and 4.5% in the intervention group—a total of 1062 patients would have been needed. Such a trial would need to be a multi-center one. Furthermore systematic standardized outcome measures would have to be developed.

The number of patients experiencing a phantom shock has previously been reported to be 6.7% in the Swyngman *et al.*'s<sup>20</sup> study, while Prudente *et al.*<sup>11</sup> report 25%. Prudente's study was retrospective and even though patients were included consecutively there is no reporting of the inclusion rate. The population may therefore not be representative. Another possible explanation to the discrepancy might have to do with years since implant. Prudente *et al.*<sup>11</sup> found that 70% of patients with phantom shocks

**Table 2** Patients experiencing phantom shock

Pt	Sex	Age	ICD indication	Prior actual ICD shock	Time of day	Where were you?	What were you doing?
1	Male	76	Primary prevention	No	20.00	Home	Got up too fast and fainted
2	Male	64	Primary prevention	Yes	NA	Home	Nothing physical
3	Male	72	Primary prevention	No <sup>a</sup>	Daytime	Home/garden	Gardening
4	Male	60	Primary prevention	No	NA	NA	NA
5	Male	45	Secondary prevention	Yes	03.00	Hospital	Sleeping
6	Female	49	Secondary prevention	No	13.15	Hospital	Tilt table test, fainted
7	Female	60	Primary prevention	No <sup>a</sup>	Night	In bed	Sleeping
8	Female	70	Primary prevention	No <sup>a</sup>	NA	At daughter's house	Sitting quietly and talking
9	Male	74	Primary prevention	No	NA	Home	Woodcutting
10	Female	61	Primary prevention	No	NA	Home	It turned out to be my epilepsy
11	Male	54	Secondary prevention	No	3.00	In bed	Sleeping/dreaming
12	Male	37	Primary prevention	No	Night	In bed	Sleeping

NA, information not available.

<sup>a</sup>Patients reported that they had an actual ICD shock previously but in fact had not done so.

**Table 3** Number of phantom shocks by group

n = 127	Did you ever experience that you had an ICD shock and the following reading showed that the ICD did not deliver a shock?	
	Yes	No
Phantom shock		
Control count	5	64
Per cent	7.2	92.8
Phantom shock		
Intervention count	7	51
Per cent	12.1	87.9
Phantom shock		
Total count	12	115
Per cent	9.4	90.6

No difference between groups (P = 0.267).

**Table 4** Odds ratio (OR) and 95% confidence intervals (CIs) of various baseline variables in a logistic regression of intervention and the baseline variable on the outcome occurrence of phantom shock

Quantity	OR (95% CI)	P value	N
Sex (reference: female sex)	1.85 (0.51–6.70)	0.35	127
Living alone (binary, reference: does not live alone)	0.83 (0.20–3.38)	0.80	118
QLI baseline (continuous variable) <sup>a</sup>	1.00 (0.86–1.17)	0.97	124
MCS baseline (continuous variable) <sup>b</sup>	1.30 (0.89–1.91)	0.18	116
PCS baseline (continuous variable) <sup>c</sup>	1.00 (0.94–1.07)	0.99	116

<sup>a</sup>Standardized quality-of-life scale.

<sup>b</sup>Standardized MCS.

<sup>c</sup>Standardized PCS.

had their ICD for more than 2 years. In contrast, Swygman et al.<sup>20</sup> and Jacob et al.<sup>12</sup> found that phantom shocks were more common in the first 6 months after implantation. Hence, more research is needed to find out what the most vulnerable periods for phantom shocks are after ICD implantation.

Only 4 of 12 patients in our study reported that the phantom shock perception occurred while sleeping. This is in contrast with early studies that found that phantom shocks always occurred after sleep onset<sup>7</sup> and a more recent investigation that observed that 73% of phantom shocks occurred at night.<sup>12</sup> Also case reports demonstrated that the phenomenon was occurring at night in two of three cases.<sup>9</sup> Our study showed that phantom shocks also frequently occur while being awake or being at work. Two patients had episodes of loss of conscious, epilepsy

and syncope on a tilt table. The question asked was if they experienced a shock. However, maybe it is due to deduction: *I fainted so I needed a shock to recover, so there should be a shock.* We do not know, and either way misinterpretation of physical symptoms might be reflecting poor coping.

In the present study, we found no significant difference in the number of actual shocks between patients who experienced a phantom shock and those that did not. This is in line with previous findings.<sup>11</sup> Jacobs et al.,<sup>12</sup> however, state that all patients in their cohort had an ICD therapy prior to a phantom shock. This was due to the fact that they included shock therapies given during implantation while testing. Furthermore, it would be interesting to investigate if patients experiencing a phantom shock have more actual appropriate shocks in the years after, as there seem to be

a connection between anxiety and ICD shock.<sup>21</sup> If phantom shocks are triggered by poor psychological coping, a connection might be found.

Is the phenomenon of phantom shock a reactivation of past memory<sup>12</sup> or a manifestation of anxiety and depression?<sup>11</sup> Both hypotheses still have to be proven. As patients in our study reported the phenomenon while gardening or woodcutting or sitting quietly talking, it is definitely more than a nocturnal problem. Several patients seem to have experienced a physical phenomenon such as fainting, but interpreted this as a shock. This seems to be a plausible interpretation given that they are living at risk of ventricular fibrillation. In patients who experienced it during sleep, the potential explanation is either hypnagogic muscle contraction during onset of sleep<sup>22</sup> or memory reactivation of traumatic events.<sup>12</sup> Overall, three types of phantom shocks were found in the present trial: during sleep, being wide awake or interpreting a physical event (could be the case of sleep onset muscle contractions as well).

The intervention focused on coping with the events that have led to the ICD implantation as well as handling everyday life with ICD, including the risk of shock. Phantom shock was also addressed to prepare for and normalize the experience if it occurred. The issue was addressed for all patients in the intervention group, and they all received individual psycho-educational counseling. All patients got assisted in their coping process but no special treatment was offered to patients experiencing this phenomenon. Our trial was the first to address the problem of phantom shock in an interventional study with a randomized control design. However, the intervention, though improving overall mental health (unpublished data), was not successful in preventing phantom shocks. Further research is needed to seek effective interventions to reduce phantom shocks.

No relation was found between phantom shocks and age, sex, or living alone. This is in keeping with earlier findings.<sup>11,12</sup> Phantom shocks have previously been associated with anxiety and depression.<sup>11,12</sup> However, the current trial did not show a relationship with mental health or quality of life. Maybe these variables are not sensitive enough to capture feelings of anxiety and depression or it could be due to type 2 error.

## Protocol

The trial protocol was published in Berg *et al.*<sup>13</sup> It can be accessed online: <http://www.biomedcentral.com/1471-2261/11/33>.

## Author contributions

S.K.B. in collaboration with J.H.S., A-D.Z., P.U.P., B.D.P., and P.M. designed the study. P.W. and S.K.B. conducted the statistical analyses. S.K.B. drafted the manuscript. All revised the manuscript critically. All have given their final approval of the version to be published.

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