Highlights – research on patients with an ICD

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The implantable cardioverter defibrillator (ICD)

- Used as primary and secondary prevention of sudden cardiac death
- ICD is superior to anti-arrhythmic drugs in saving lives
- The ICD can shock with up to 700-800 volts

Ahmad et al. PACE 2000;23:931-3
ICD therapy: Challenges to patients

- New hardware
- Home monitoring
- Fractured leads
- Symptomatic heart failure
- Expanding indications
- ICD shock

Primary

Secondary
Let’s not forget....

Patient’s personality and pre-implantation psychological functioning

PERSONALITY TYPES

POSITIVE

THE GLASS IS HALF FULL.

NEGATIVE

THE GLASS IS HALF EMPTY.

OBSESSIVE COMPULSIVE

G AH ! NO CLEAN GLASSES !!
Depression: 11% to 28%
Anxiety: 11% to 26%

The prevalence of anxiety and depression in adults with implantable cardioverter defibrillators: A systematic review

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e American Psychiatric Association, Arlington, VA, United States
f Internal Medicine, University of Alabama at Birmingham, Birmingham, Alabama, United States

Subset of patients:
1 in 4 (25%)

• Posttraumatic stress ≈ 12%
• Chronic anxiety ≈ 50%

### Stability of psychological functioning

#### Baseline ICD concerns (n=328)

<table>
<thead>
<tr>
<th>12-month ICD concerns</th>
<th>Normal levels (Score 0-12)</th>
<th>Increased levels (Score • 13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal levels</td>
<td>63.7% [49.0-81.4]</td>
<td>21.3% [13.2-32.5]</td>
</tr>
<tr>
<td>Increased levels</td>
<td>5.8% [2.0-12.8]</td>
<td>9.1% [4.1-17.2]</td>
</tr>
</tbody>
</table>

#### Baseline anxiety symptoms (n=332)

<table>
<thead>
<tr>
<th>12-month anxiety symptoms</th>
<th>Normal levels (Score 0-7)</th>
<th>Probable clinical levels (Score • 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal levels</td>
<td>70.2% [54.7-88.7]</td>
<td>14.2% [7.7-23.8]</td>
</tr>
<tr>
<td>Probable clinical levels</td>
<td>5.7% [2.0-12.7]</td>
<td>9.9% [4.7-18.3]</td>
</tr>
</tbody>
</table>

#### Baseline depressive symptoms (n=332)

<table>
<thead>
<tr>
<th>12-month depressive symptoms</th>
<th>Normal levels (Score 0-7)</th>
<th>Probable clinical levels (Score • 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal levels</td>
<td>69.0% [53.6-87.3]</td>
<td>10.2% [4.9-18.7]</td>
</tr>
<tr>
<td>Probable clinical levels</td>
<td>8.1% [3.5-15.9]</td>
<td>12.7% [6.6-21.9]</td>
</tr>
</tbody>
</table>

- **Majority of patients (i.e., 72% to 81%)** preserved pre implantation level of psychological functioning 12 months post implantation.
- **Around 10% to 21% of patients** crossed over from high to low levels of distress.
- **Around 5% to 8% changed** from low to high levels of distress.
Intra-individual changes in psychological functioning between pre implantation and 12 months stratified by ICD shock*

* A positive mean score change indicates improvement in psychological functioning

* Explained variance in changes:
  - ICD concerns: 5.1%
  - Anxiety: 3.1%
  - Depression: 3.5%

N = 308

Pedersen, Jordaens, Theuns et al. Int J Cardiol 2011;In Press
Predictors of mean score changes in psychological functioning during follow-up

<table>
<thead>
<tr>
<th>Predictor</th>
<th>ICD concerns</th>
<th>Anxiety</th>
<th>Depression</th>
<th>p</th>
<th>Anxiety</th>
<th>Depression</th>
<th>p</th>
<th>Anxiety</th>
<th>Depression</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender</td>
<td>-.01</td>
<td>[-2.02 – 1.56]</td>
<td>.80</td>
<td>-.07</td>
<td>[-.29 – 1.50]</td>
<td>.19</td>
<td>-.03</td>
<td>[-.58 – 1.05]</td>
<td>.57</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>-.04</td>
<td>[-.04 – .09]</td>
<td>.45</td>
<td>.11</td>
<td>[.001 – .07]</td>
<td>.04</td>
<td>-.007</td>
<td>[-.03 – .03]</td>
<td>.90</td>
<td></td>
</tr>
<tr>
<td>Primary prevention indication</td>
<td>.12</td>
<td>[.20 – 3.73]</td>
<td>.03</td>
<td>.16</td>
<td>[.37 – 2.16]</td>
<td>.006 †</td>
<td>-.02</td>
<td>[.02 – 1.61]</td>
<td>.06</td>
<td></td>
</tr>
<tr>
<td>NYHA class III-IV</td>
<td>-.05</td>
<td>[-2.32 – .82]</td>
<td>.35</td>
<td>-.05</td>
<td>[-1.19 – .40]</td>
<td>.33</td>
<td>-.03</td>
<td>[-.95 – .51]</td>
<td>.56</td>
<td></td>
</tr>
<tr>
<td>LVEF ≤35%</td>
<td>-.09</td>
<td>[-3.93 – .22]</td>
<td>.08</td>
<td>-.15</td>
<td>[-2.54 – -.41]</td>
<td>.007 †</td>
<td>-.10</td>
<td>[-1.79 – .13]</td>
<td>.09</td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>.005</td>
<td>[-1.71 – 1.53]</td>
<td>.92</td>
<td>-.12</td>
<td>[-2.01 – 1.77]</td>
<td>.14</td>
<td>.02</td>
<td>.[-.08 – .08]</td>
<td>.88</td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>-.09</td>
<td>[-3.82 – 1.6]</td>
<td>.07</td>
<td>-.03</td>
<td>[-1.33 – .68]</td>
<td>.52</td>
<td>-.07</td>
<td>[-1.55 – .27]</td>
<td>.17</td>
<td></td>
</tr>
<tr>
<td>Type D personality</td>
<td>-.10</td>
<td>[-3.45 – -.05]</td>
<td>.04 #</td>
<td>-.17</td>
<td>[-2.36 – -.49]</td>
<td>.003 †</td>
<td>-.20</td>
<td>[-2.37 – -.66]</td>
<td>.001 †</td>
<td></td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>-.03</td>
<td>[-2.40 – 1.23]</td>
<td>.53</td>
<td>-.005</td>
<td>[-.96 – .87]</td>
<td>.93</td>
<td>.01</td>
<td>[-.76 – .91]</td>
<td>.86</td>
<td></td>
</tr>
<tr>
<td>Psychotropic medication</td>
<td>-.03</td>
<td>[-2.38 – 1.42]</td>
<td>.62</td>
<td>-.06</td>
<td>[-1.55 – .38]</td>
<td>.23</td>
<td>.02</td>
<td>[-.71 – 1.04]</td>
<td>.72</td>
<td></td>
</tr>
<tr>
<td>Shock during follow-up</td>
<td>-.19</td>
<td>[-6.14 – -1.91]</td>
<td>&lt;.001 ‡</td>
<td>-.16</td>
<td>[-2.75 – -.60]</td>
<td>.002 †</td>
<td>-.18</td>
<td>[-2.63 – -.66]</td>
<td>.001 †</td>
<td></td>
</tr>
<tr>
<td>Baseline psychological functioning</td>
<td>.57</td>
<td>[.45 – .64]</td>
<td>&lt;.001 ‡</td>
<td>.54</td>
<td>[.40 – .61]</td>
<td>&lt;.001 ‡</td>
<td>.51</td>
<td>[.30 – .48]</td>
<td>&lt;.001 ‡</td>
<td></td>
</tr>
</tbody>
</table>

**Shock:** ↑ ICD concerns, Anxiety, Depression

**Type D:** ↑ ICD concerns, Anxiety, Depression

**Primary prevention:** ↓ ICD concerns, Anxiety

**Older age:** ↓ Anxiety

**LVEF ≤35%:** ↑ Anxiety

**AF:** ↑ Anxiety

**Baseline psych:** ↓ ICD concerns, Anxiety, Depression
Given that programming of the ICD is changing, leading to fewer shocks and improved quality of life, it may be timely to also examine the influence of other determinants (e.g. heart failure progression and personality) of patient-reported outcomes...
### Correlates of anxiety and depression

<table>
<thead>
<tr>
<th></th>
<th>Anxiety OR [95% CI]</th>
<th>Depression OR [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender</td>
<td>2.38 [1.32-4.29]†</td>
<td>ns</td>
</tr>
<tr>
<td>Age</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>Living with a spouse</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>Non-ischaemic etiology</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>Symptomatic CHF</td>
<td>5.15 [3.08-8.63]‡</td>
<td>6.82 [3.77-12.39]‡</td>
</tr>
<tr>
<td>Co-morbidity</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>ICD-related complications</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>ICD shocks</td>
<td>2.21 [1.32-3.72]†</td>
<td>2.00 [1.06-3.80]*</td>
</tr>
<tr>
<td>Years with ICD therapy</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>Current smoking</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>Other antiarrhythmic medication</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>Psychotropic medication</td>
<td>ns</td>
<td>2.75 [1.40-5.40]†</td>
</tr>
</tbody>
</table>

* * P < 0.05; † P < 0.01; ‡ P < 0.001

**N = 610**

The burden of increased negative emotions and inhibition

No!! I do not want to share my emotions with others...

Worried
Feeling blue
Unhappy
Bad mood

Type D?
Prevalence of anxiety and depression in patients stratified by Type D and shocks


N = 182
Persistent depression 3 months post implantation

Odds Ratios [95% CI]
- 2.60 [1.44-1.71]
- 8.30 [4.42-15.58]
- 2.09 [1.01-4.29]
- 2.47 [1.36-4.48]
- 2.29 [1.26-4.15]
- 1.92 [1.05-3.52]

14% (52/386)

N = 386
Type D personality and high ICD pre-implantation concerns and mortality

Figure 1: Kaplan-Meier curves for the time to mortality stratified by (A) Type D personality and (B) high levels of ICD concerns.

N = 371

HR: 3.65 (95% CI: 1.57-8.45; p = .003)

18.2%

5.2%

Type D and concerns

None or one risk marker
Implantable cardioverter defibrillator (ICD) therapy is the first-line treatment for the prevention of sudden cardiac death. Despite the demonstrated survival benefits of the ICD, predicting which patients will die from a ventricular tachyarrhythmia remains a major challenge. So far, psychological factors have not been considered as potential risk markers that might enhance the prediction of sudden cardiac death. This article evaluates the evidence for a link between psychological vulnerability, ventricular tachyarrhythmias and mortality and the pathways that might explain such a link. This review demonstrates that there is cumulative evidence supporting a link between psychological vulnerability and risk of ventricular tachyarrhythmias and mortality in ICD patients independent of disease severity and other biomedical risk factors. It may be premature to include psychological factors in risk algorithms, but information on the psychological profile of the patient may help to optimize the management and care of these patients in clinical practice.
How to break the vicious cycle?

Figure 4 Supposed vicious circle of shocks and distress.

Braunschweig, Boriani, ... Pedersen et al., Europace 2010;12:1673-90
1. Screen and monitor
Management of patients receiving implantable cardiac defibrillator shocks

Recommendations for acute and long-term patient management

Frieder Braunschweig (Chair)¹*, Giuseppe Boriani (Co-chair)², Alexander Bauer³, Robert Hatala⁴, Christoph Herrmann-Lingen⁵, Josef Kautzner⁶, Susanne S. Pedersen⁷, Steen Pehrson⁸, Renato Ricci⁹, and Martin J. Schalij¹⁰

Table 6 Recommended measures to identify high-risk patients post-shock

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Questionnaire</th>
<th>Number of items</th>
<th>Minutes for patients to complete</th>
<th>Available in ≥3 languages</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD concerns</td>
<td>ICDC³</td>
<td>8</td>
<td>3–5</td>
<td>Yes</td>
</tr>
<tr>
<td>Anxiety</td>
<td>FSAS³</td>
<td>10</td>
<td>3–5</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>HADS-A⁴</td>
<td>7</td>
<td>3</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>STAI (state only)⁴</td>
<td>20</td>
<td>3–6</td>
<td>Yes</td>
</tr>
<tr>
<td>Depression</td>
<td>HADS-D⁵</td>
<td>7</td>
<td>3</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>PHQ-9⁵</td>
<td>9</td>
<td>3</td>
<td>Yes</td>
</tr>
<tr>
<td>Post-traumatic symptoms</td>
<td>IES-R⁶</td>
<td>22</td>
<td>10</td>
<td>Yes</td>
</tr>
<tr>
<td>Type D personality</td>
<td>DS14⁷</td>
<td>14</td>
<td>5</td>
<td>Yes</td>
</tr>
</tbody>
</table>

DS14, Type D Scale; FSAS, Florida Shock Anxiety Scale; HADS, Hospital Anxiety and Depression Scale; ICDC, ICD Concerns Questionnaire; IES-R, Impact of Event Scale Revised; PHQ-9, Patient Health Questionnaire; STAI, Spielberger’s State-Trait Anxiety Inventory.

*Disease-specific.

Generic.
ICD Patient Concerns questionnaire

We want to know what things worry you about living with your ICD. It is important that you answer every question. Don’t spend too long thinking about your answers. For each question please circle one number. Please don’t leave any out.

0 = Not at all 1 = A little bit 2 = Somewhat 3 = Quite a lot 4 = Very much so

I AM WORRIED ABOUT......

1. My ICD firing
2. Doing activities/hobbies that may cause my ICD to fire
3. Time spent thinking about my ICD firing
4. Working too hard/overdoing things causing my ICD to fire
5. Having no warning my ICD will fire
6. The symptoms/pain associated with my ICD firing
7. Not being able to prevent my ICD from firing
8. Getting too stressed in case my ICD fires
2. Psychological and behavioral intervention
# Intervention in ICD patients

## Effect Sizes for Impact of Intervention Versus Usual Care on Changes in Anxiety

<table>
<thead>
<tr>
<th>Authors [reference]</th>
<th>Follow-up Period</th>
<th>Effect size* Intervention</th>
<th>Effect size* Usual care</th>
<th>Anxiety Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Badger and Morris (1989)(^{30})</td>
<td>2 months</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Carlsson et al. (2002)(^{22})</td>
<td>1 month</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Chevalier et al. (2006)(^{23})</td>
<td>12 months</td>
<td>0.72</td>
<td>–0.84</td>
<td>HAM-A</td>
</tr>
<tr>
<td>Dougherty et al. (2004, 2005)(^{24, 32})</td>
<td>12 months</td>
<td>0.38</td>
<td>0.15</td>
<td>STAI-S</td>
</tr>
<tr>
<td>Fitchet et al. (2003)(^{25})</td>
<td>6 months</td>
<td>1.79</td>
<td>–</td>
<td>HADS</td>
</tr>
<tr>
<td>Frizelle et al. (2004)(^{26})</td>
<td>3 months</td>
<td>0.34</td>
<td>–</td>
<td>HADS</td>
</tr>
<tr>
<td>Kohn et al. (2000)(^{27})</td>
<td>9 months</td>
<td>0.89</td>
<td>0.30</td>
<td>STAI-S</td>
</tr>
<tr>
<td>Molchany and Peterson (1994)(^{31})</td>
<td>6 months</td>
<td>0.14</td>
<td>0.20</td>
<td>STAI-S</td>
</tr>
<tr>
<td>Sneed et al. (1997)(^{28})</td>
<td>4 months</td>
<td>–</td>
<td>–</td>
<td>POMS</td>
</tr>
</tbody>
</table>

* Based on \(\text{mean}_1 - \text{mean}_2 \)/pooled standard deviation.

1 Pre- and posttreatment scores were not reported separately for the intervention and usual care groups, but only for the total group (i.e., when all patients including the waiting group had undergone the intervention).

HADS = hospital anxiety and depression scale; HAM-A = Hamilton anxiety scale; POMS = profile of mood states; STAI-S = state-trait anxiety inventory (state scale).
More new studies added...

<table>
<thead>
<tr>
<th>Authors</th>
<th>N (design)</th>
<th>FU-period</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dunbar</td>
<td>246 (RCT)</td>
<td>12 mths</td>
<td>↓ anxiety; ↓ depression; ↓ health care consumption and disability days</td>
</tr>
<tr>
<td>Kuhl</td>
<td>30 (RCT)</td>
<td>1 mth</td>
<td>no change in knowledge perception</td>
</tr>
<tr>
<td>Lewin</td>
<td>192 (RCT)</td>
<td>6 mths</td>
<td>↓ anxiety; ↓ depression; ↓ admissions; ↑ QoL</td>
</tr>
<tr>
<td>Sears</td>
<td>30 (RCT)</td>
<td>4 mths</td>
<td>↓ anxiety; ↓ cortisol ↑ depression in 1-day workshop group</td>
</tr>
</tbody>
</table>

How to break the vicious cycle?

Cardiac psychology has something to offer to patients

- Reduce catastrophic thinking
- Alleviate symptoms of anxiety and depression
- Improve quality of life
- Effect on survival?
E-health the future?

Pedersen et al. Trials 2009;10:120

Trials

Study protocol
Rationale and design of WEBCARE: A randomized, controlled, web-based behavioral intervention trial in cardioverter-defibrillator patients to reduce anxiety and device concerns and enhance quality of life

Susanne S Pedersen*1,2, Viola Spek1, Dominic AMJ Theuns2, Marco Alings3, Pepijn van der Voort4, Luc Jordaens2, Pim Cuijpers5, Johan Denollet1 and Krista C van den Broek1

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Intervention – web application

Leef met je hart
problemen en zorgen overwinnen door zelfanalyse

Vooraf
Wat is voor u acht belangrijk in uw leven? Blijf u nemen dat het niet meer een antwoord klaar op deze vraag, zodat u in beslag genomen door de dingen van alles g. Voor mensen die chronisch ziek zijn, lijkt dit vaak nog net even wat te weken kwalder. Uw leven staat op zijn kop. Vaak dingen veranderen doordat u MS heeft. Misschien wat u niet goed maar wat belangrijk voor u is. Of vraagt het Verwerkingsproces zo veel van u, dat u er niet aan aan toekomt om over die vraag na te denken. Misschien voelt u zich ook te zenuwachtig of gepest door uw ziek te zijn. De belangrijkste dingen in uw leven blijven dan over u vanwege deze treden, maar wat u acht belangrijk vindt, kunt u altijd helpen om uw zorgen en spanningsvorm te overwinnen.

Stap voor stap
In deze cursus leert u stap voor stap problemen en veranderingen in uw leven aan te pakken. U leert om minder te pleuren en onbelangrijke dingen. En u leert hoe u kunt omgaan met ingrijpende gebeurtenissen in uw leven. Zo krijgt u langzaam weer meer grip op uw algemene leven.
Intervention (fixed, 3-month duration)

COMPONENTS

- Psycho-education about the ICD
- Problem-solving skills
- Cognitive restructuring
- Relaxation training
- Personalized feedback by a therapist via the computer

TOPICS DEALT WITH

- Emotional reactions to ICD therapy
- Which aspects of ICD therapy may lead to distress
- How to deal with shocks
- Disease-specific issues and fears
- How to prevent the avoidance of activities
- Interpretation of bodily symptoms
- How to cope with uncertainty
- Help-seeking behavior
- How to cope with stress
Management of patients receiving implantable cardiac defibrillator shock

Recommendations for short- and long-term patient management

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