Fakultät für Sport-und Gesundheitswissenschaften

Lehrstuhl für Sportpsychologie

End-of-Life Management of Patients with Implantable Cardioverter-Defibrillator (ICD)

A survey-based investigation on problem awareness, attitudes and preferences of ICD carriers

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Vollständiger Abdruck der von der Fakultät für Sport- und Gesundheitswissenschaften der Technischen Universität München zur Erlangung des akademischen Grades eines Doktors der Philosophie genehmigten Dissertation.

Vorsitzende: Univ.-Prof. Dr. R. Oberhoffer

Prüfer der Dissertation:

1. Univ.-Prof. Dr. J. Beckmann
2. apl. Prof. Dr. K. H. Ladwig

Die Dissertation wurde am 27.08.2013 bei der Technischen Universität München eingereicht und durch die Fakultät für Sport- und Gesundheitswissenschaften am 16.04.2014 angenommen.

Summary

The therapy with an Implantable Cardioverter-Defibrillator (ICD) is highly effective in saving lives of cardiac patients at high risk for sudden cardiac death (SCD). The number of patients carrying an ICD is increasing. The primary goal of the ICD therapy is to prolong life. However, the primary goal of the therapy might loose significance during the end-stage of patients' lives. ICD therapy may interfere with the quality of dying. Therefore deactivation of the ICD becomes an option, but this decision may constitute a dilemma for physicians and patients. Research on patients' attitudes and preferences regarding ICD management at the end-of-life, in particular regarding ICD deactivation is scarce. The option of ICD deactivation finds little mentioning in practice guidelines and the discussion of ICD deactivation is no integral part during the process of ICD therapy. With the objective to ultimately improve long-term ICD therapy, data was collected and evaluated on problem awareness, communication between physician and patient, as well as attitudes and preferences of patients regarding ICD management at the end-of-life.

A questionnaire based nationwide survey of ICD patients was conducted in cooperation with the German Defibrillator Association support groups. Of 1242 registered support group members, 394 (29 %) returned the survey**.** The responses were analyzed using Microsoft Excel and SPSS 20. For univariate associations Pearson's χ^2-test and for multivariate analysis binary logistic regression was used. A significant number of ICD patients (59.9 %) knew about the possibility of ICD deactivation, yet only half (52 %*)* of the study patients had considered issues related to "dying with the ICD". Communication between physician and patient was rare (6 %). Proactive patients, who approached their physicians, perceived their physicians to be inadequately informed about the issue. Many patients expressed the need for more information (67 %).

Patient characteristics (gender, age and duration of ICD therapy) did have an influence on patient awareness and their preferences regarding ICD management at the end-of-life: More women (66.1 %) had considered the issue of dying with the ICD, compared to the male participants (46.3 %). Fewer older patients (45.5 %) considered the issues regarding dying with the ICD, compared to the younger ICD carriers (64.2 %). More patients with an ICD in situ for < 4 years (22.8 %) approached their physicians to discuss ICD management at the end-of-life, compared to those patients who carried an ICD for ≥ 4 years (7.4 %). A significant number of ICD patients (42.1 %) associated ICD deactivation with physician assisted-suicide. Patients who were aware of the potential problem of ICD therapy at the end-of-life were more likely to implement Advance Directives (AD). The opinions on when the discussion about ICD deactivation at the end-of-life should be initiated varied greatly across the studied patient population: 42% preferred a discussion at the onset of ICD therapy, the remainder as late as at the end-of-life. The preferred conversation partner to discuss ICD deactivation was the cardiologist (63.8 %). The issues of ICD deactivation at the end-of-life have been neglected. Patients recognize the relevance of the issue and need more information. Communication on the issue is lacking. ICD management at the end-of-life should become an integral part of the process of ICD therapy. The results from this study may provide a basis for improved management of ICD patients as well as the formulation of guidelines covering the end-of-life issue.

Zusammenfassung

Implantierbare Kardioverter-Defibrillatoren (ICD) werden zur Prävention des plötzlichen Herztodes (Sudden Cardiac Death, SCD) bei kardialen Risikopatienten eingesetzt. Die ICD Therapie hat sich als sicher und effektiv erwiesen und die Zahl der ICD Implantationen nimmt zu. Ziel der ICD Therapie ist die Lebensverlängerung von Patienten mit hohem Risiko für tödliche Herzrhythmusstörungen. Am Ende des Lebens steht diese Indikation meist nicht mehr im Vordergrund, vielmehr kann die ICD Therapie in dieser Lebensendphase kontraproduktiv sein und durch Schockabgaben den Sterbeprozess traumatisieren, d.h. die Qualität des Sterbeprozesses beeinträchtigen. Deshalb kann die Entscheidung zur ICD Deaktivierung genutzt werden, die allerdings ein Dilemma für Ärzte und Patienten bedeuten kann. Über die Einstellungen von ICD Trägern zur Handhabung der ICD Therapie am Lebensende bzw. zur ICD Deaktivierung ist bisher wenig bekannt. Das ICD Management am Lebensende findet in den bisherigen Richtlinien zur ICD Therapie keine ausreichende Berücksichtigung und ist kein Bestandteil einer langfristigen Therapiebetreuung von ICD Patienten. Mit dem Ziel, die ICD Therapie patientenorientiert zu verbessern, wurden Daten erhoben und ausgewertet zu Problembewußsein, Einstellungen, Kommunikation und Wünschen von ICD Patienten bezüglich Handhabung der ICD Therapie am Lebensende. Eine bundesweite fragebogenbasierte Umfrage bei ICD Patienten wurde in Kooperation mit den deutschen ICD Selbsthilfegruppen durchgeführt. Von 1242 registrierten ICD Patienten (Mitgliedern der Selbsthilfegruppen) retournierten 394 (29 %) den ausgefüllten Fragebogen. Zur statistischen Analyse wurden Microsoft Excel und SPSS 20 verwendet. Pearson's χ^2-test wurde für univariate Assoziationen und binäre logistische Regression wurde für multivariate Analysen eingesetzt.Von den befragten Patienten wussten 59.9 % um die Option der ICD Deaktivierung, nur etwa die Hälfte der Patienten (52 %) hatte sich mit dem Thema "Sterben mit dem ICD" auseinandergesetzt. Eine Unterhaltung zwischen

Arzt und Patient bezüglich ICD Management am Ende des Lebens kommt eher selten vor (6 %). ICD Patienten, die auf Ihren Arzt zugegangen sind, berichteten von einem Informationsmangel seitens der Ärzte. Mehr als die Hälfte (67 %) der befragten ICD Patienten wünschten sich mehr Informationen zu diesem Thema. Patientencharakteristika wie Geschlecht, Alter und Therapiedauer beeinflussen das Problembewußtsein und die Einstellungen der Patienten: Weibliche (66.1 %) und jüngere (64.2 %) ICD Patienten dachten häufiger über das Sterben mit dem ICD nach als die männlichen und älteren Patienten (46.3 % vs. 45.5 %). Patienten mit kürzerer Therapiedauer (22.8 %) initiierten häufiger ein Gespräch mit dem Arzt zu diesem Thema als ICD Patienten mit längerer ($\geq$ 4 Jahre) Therapiedauer (7.4 %). Eine Assoziation zwischen einer ICD Deaktivierung und ärztlich-assistierten Suizid bestand bei 42.1 % der Patienten. Die Teilnehmer, die sich dem potenziellen Dilemma bei der Entscheidung zur ICD Deaktivierung bewußt waren, gaben auch an, dass sie eine Entscheidung über eine ICD Deaktivierung in ihrer Patientenverfügung festlegen würden. Die Meinung der Patienten darüber, wann eine Thematisierung über den Umgang mit dem ICD am Lebensende stattfinden sollte, fällt sehr unterschiedlich aus: Es besteht sowohl der Wunsch, diese Thematik früh im Therapieprozess zu thematisieren (42.0 %), als auch erst am Lebensende. Als bevorzugten Gesprächspartner nannten 63.8 % ihren Kardiologen. Die Problematik der ICD Deaktivierung am Lebensende wurde bisher vernachlässigt, Patienten erkennen aber deren Bedeutung und benötigen mehr Informationen. Die Kommunikation mit den Ärzten zu diesen Fragen ist ungenügend, um Patienten aufzuklären und während eines Entscheidungsprozesses zu unterstützen. Die Ergebnisse dieser Studie könnten eine Grundlage für eine verbesserte und patientenorientierte ICD Therapie sein und die Formulierung von Richtlinien ermöglichen.

Meinen Eltern und meiner Tochter gewidmet

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1. Introduction

1.1 Implantable Cardioverter-Defibrillator (ICD) Therapy

Implantable Cardioverter-Defibrillator (ICD) therapy is used to prevent sudden cardiac death (SCD) in patients at high risk for lethal cardiac arrhythmias. The ICD asserts and rapidly aborts ventricular tachycardia (VT) or ventricular fibrillation (VF) and has proven to be highly effective in primary and secondary prevention of SCD (DiMarco, 2003). A SCD recurrence rate of only 1% to 2 % annually is reported after device implantation compared to 15% to 25% without device therapy (Gregoratos et al., 1999). Besides ICD-therapy, antiarrhythmic drug therapy (e.g Amiodarone) is widely used for treatment of life threatening arrhythmias. Several large randomized trials have shown that ICD therapy is more effective than drug treatment in preventing SCD and in prolonging survival in at risk patients (Connolly et al., 2000; Moss et al., 1996; The AVID Investigators, Zipes et al., 1997). Also, quality of life was shown to be better with ICD therapy rather than Amiodarone therapy (Irvine et al., 2002). However, adverse effects of either therapy, medical or ICD, specifically including sporadic ICD shocks, were perceived as reducing quality of life by the studied patients (Schron et al., 2002). The ICD is a battery-powered pulse generator, most commonly implanted under the skin of the upper chest, and is connected to the heart via one or more electrodes (Figure 1). The ICD monitors the patient’s heart rhythm and, if needed, delivers electric shocks until termination of VT or VF is achieved (Reiffel & Dizon, 2002).

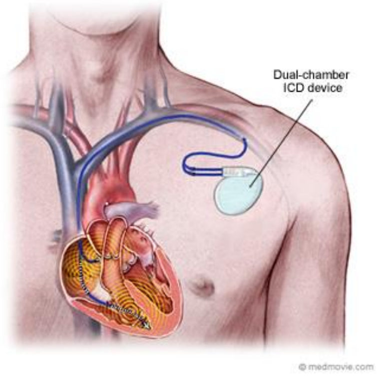

Figure 1. Implanted Cardioverter-Defibrillator (ICD)

An ICD can be acutely deactivated by placing a magnet on the chest on top of the device or – for longer term purposes - by reprogramming of the device preferably by a cardiologist/ electrophysiologist (Padeletti et al., 2010), or a specifically trained physician or technician (Lampert et al., 2010). Nearly fifty years have passed since the principal concept of the defibrillator first emerged in the 1960s. The first ICD was implanted in the early 1980s. Evidence on the clinical benefits of ICD therapy reaches from initially observational studies to large randomized clinical trials, including both indications, primary and secondary prevention (Myerburg, Reddy, & Castellanos, 2009).

The indication for ICD implantation for *primary prevention* includes patients who are considered at high risk of malignant arrhythmic events due to progressive structural heart disease (Schaer, Kuhne, Koller, Sticherling, & Osswald, 2009). ICD implantation for *secondary prevention* includes patients with proven severe ventricular arrhythmias and survivors of sudden cardiac death (e.g. due to myocardial infarction) (Schaer et al., 2009).

Outcome of ICD therapy has also been improved by technological progress and modified programming of the ICD. A recent study could show that patients with defibrillators programmed to reduce shock exposure have less morbidity and improved survival, as compared to patients with conventionally programmed devices (Moss et al., 2012). The technical integration of ICD function into devices designed to improve cardiac function in symptomatic heart failure (Cardiac Resynchronization Therapy = CRT, CRT-D=Cardiac Resynchronization Therapy with ICD function) will also add to the increasing number of ICD carriers (Grubb & Karabin, 2011; DiMarco, 2003).

Sudden Cardiac Death and increasing use of ICD therapy

The numbers of deaths due to SCD are important: According to numbers reported by Mewis et al. (2006), 100-200.000 people experience SCD in Germany yearly, in the USA about 300-350.000 (Katritsis, 2012) The incidence of SCD increases with age and is almost 3 times higher in men versus women: In the age-group 35-40 years, 3 in 10.000 men die yearly, compared to 1 in 10.000 women. In the age-group of 75 -84 years, 136 in 10.000 men compared to 93 in 10.000 women die of SCD yearly.

ICD implantations have significantly increased: According to numbers presented in the german *"Herzbericht"* of 2011 (Meinertz et al., 2011) 1975 ICDs were implanted in 1995, and 10174 in the year of 2011. The number of ICD implantations has been increasing due to the proven safety and efficacy of the device to prevent SCD and as a result of the continued technological advances. In addition to progress in technology and improved programming, broadening of indications and an aging and sicker population will inevitably lead to a higher number of patients who reach the end of their lives carrying an ICD (Grubb & Karabin, 2011).

Primary Goal of ICD Therapy

Whilst ICD therapy aims to protect the patient with cardiac disease from premature arrhythmic death it does not alter the progression of any other (underlying) cardiac or malignant disease. All ICD patients will face death eventually, related or unrelated to the cardiac disease that triggered ICD therapy (Thanavaro, 2013). The overriding principle in establishing the indication for ICD implantation is to prolong and sustain life (= quantity of life) (Ladwig, Ischinger, Ronel, & Kolb, 2011). Another ethical principle of medical intervention is, that an irreversible process of dying should not be artificially prolonged by life-sustaining therapies (= quality of death) (Bundesärztekammer, 2011). In this context, according to the Bundesärztekammer (2011), the Heart Rhythm Society (HRS), and the European Heart Rhythm Association (EHRA) Consensus Statements, it is ethically and legally justifiable to remove, limit or terminate any life-sustaining treatments. By not prolonging the dying process and by eliminating any possible sources of pain a quality of life at the end-of-life (= quality of death) can be assured (Bundesärztekammer, 2011; Lampert et al., 2010; Padeletti et al., 2010). When managing ICD patients who reached the end of their live, both principles, prolongation of life (= quantity of life) and quality of death (= quality of life at the end of life) may conflict. The decision about the goals of care during the end-of-life should solely lie with the patients and their families. If the goal is to ensure quality of death, the option to deactivate the ICD becomes a relevant issue.

1.2 Guidelines of the ICD therapy

ICD therapy is well established. The number of publications on ICD therapy and respective guidelines have increased over the last years. According to Padeletti et al. (2010) the decision to deactivate an ICD should be a well-deliberated and transparent process, following the patient’s wish to die at peace and live without pain for as long as possible. Recommendations on how the process of an ICD deactivation may be structured, were formulated and turned into guidelines (Epstein et al. 2008) and consensus statements (Lampert et al., 2010; Padeletti et al., 2010). However, a critical analysis of both the consensus statements and guidelines shows that until the year of 2010 the guidelines mainly encompass questions about technical issues and indications. Issues concerning patient-centered care during the process of therapy, more specifically those questions concerning end-of-life with an ICD, do not receive a great amount of attention. Not until recently, publications begin to deal with end-of-life issues of ICD patients (Dunbar et al., 2012), still ignoring essential questions about the option of deactivating the ICD. Issues surrounding ICD deactivation are no integral part of long term ICD-therapy; structured guidelines on management of the ICD at the end-of-life do not exist. The consequence is twofold: Physicians lack knowledge about the potential problems with an active ICD at the end-of-life as well as the option of ICD deactivation and the issues associated, and patients lack information about ICD deactivation, as they are not commonly introduced to the topic, neither at time of initial decision-making for ICD therapy, nor during follow up.

In summary, current guidelines broadly agree on the relevance of touching the issues of ICD deactivation and suggest a sequence of steps leading to the decision for ICD deactivation. Guidelines do advise proactive and timely discussion of ICD deactivation at the end-of-life, but do not present a structured process on how and when to approach the issue. Available recommendations so far have failed to be turned into practice. The common denominator of all guidelines and consensus statements is the call for thoughtful communication between physician and patient before implantation and throughout the process of therapy. The European and American consensus statements (Lampert et al., 2010; Padeletti et al., 2010) still have to be adjusted to other national law systems. Nevertheless, it is the nature of guidelines to be rather technical, therefore they will not obviate the need for dedicated psychological assistance in the management of end-of-life issues of ICD patients, made available already early in the disease process. Comprehensive guidelines likely will facilitate the routine approach to the problem for physicians and pave the way for an improved decision-making process and patient-centered care at the end-of-life of ICD patients.

1.3 Issues with ICD deactivation at the end-of-life

The ICD in its unobtrusive nature is often regarded as an intrinsic part of the body by both, physicians and patients. This might present a problem, as patients develop a complex relationship with the device (Goldstein et al., 2007), often overestimating the lifesaving capabilities. Patients are often unaware of the implications of ICD management, such as deactivation towards end-of-life (Tanner, Fromme, & Goodlin, 2011).

When ICD patients reach the end stage of life the option of ICD deactivation may become an urgent issue. Patients may receive unnecessary shock therapy at the end of their lives, when pain, hypoxia, sepsis and electrolyte disturbances (Lewis et al., 2006) may expose them to arrhythmic events. Several studies have shown, that the experience of electrical shock-therapy at the end-of-life may be physically and psychologically distressing for patients, relatives, family members and other care givers involved (Beets & Forringer, 2011; Grassman & Fromme, 2005; Nambisian & Chao, 2004; Quill, Barold & Sussman, 1994). Carrying an active ICD at the end-of-life may deny patients with comorbidities the chance of SCD and instead cause a slower and more painful decline. Pain and resulting fear of ICD discharge might unnecessarily aggravate an irreversible process of dying and consequently turn it into a traumatizing experience (Ladwig et al., 2011; Russo, 2011; Thanavaro, 2013).

The first investigation on this topic by Goldstein et al (2004) reported, that 30% (8/27) of ICD patients received a shock during the last minutes of their lives. A recent multicenter study based on a chart review conducted by Sherazi et al (2013) discovered, that 19% (9/47) of the deceased ICD patients had received ICD shocks during the last 24 hours of their lives. The following section underlines the clinical relevance of the ICD deactivation by reporting some of the adverse experiences ICD patients and their families reported.

“Case studies”: clinical relevance of shock therapy at the end-of-life

Several case studies, from as early as 1994 (Beets & Forringer, 2011; Fromme, Stewart, Jeppesen & Tolle, 2011; Grassman & Fromme, 2005; Nambisian & Chao, 2004, Quill et al., 1994) confirm the painful and stressful situations ICD patients and all involved may experience at the end-of-life. The earliest case study reported by Quill et al. (1994) was that of a 67-year old patient with a multicomorbid condition who had received an ICD after multiple cardiac arrests. Due to his co-morbidities the patient’s condition worsened, but at the same time, the patient was well aware that the ICD was keeping him alive. During the last 9 months of his life the ICD exerted 6 shocks. After the patient’s request to deactivate the ICD was ignored, the patient attempted suicide and was subsequently treated with antidepressants and psychotherapy. The deactivation of the ICD was finally agreed to one year after the patient’s initial request. He died 3 weeks after device deactivation. The case underlines the ethical insecurities of physicians as to patients’ abilities for decisions making due to underlying psychological issues. It is assumed that the quality of life of the patient during the last months of life (=quality of dying) was severely and negatively affected by the “shocking experience”.

Another case by Nambisian & Chao (2004) tells the story of a 59-year old woman with an active ICD for two years who was diagnosed with a primary lung carcinoma. When the patient reached the end-stage of her life she decided on a “Do-Not-Attempt Resuscitation” (DNR) order and was assured to die in comfort. The nursing staff reported the patient received 38 episodes of ICD shock delivery causing great distress to the patient, her family, and the other caretakers. The responsible cardiologist eventually deactivated the ICD. The patient died the same day. This case shows that the unexpected need for ICD deactivation was not prepared for as no such policies to act in the patient's best interest were in place. The dying process of this patient was prolonged in an unnecessary and traumatizing way.

In 2011 (Beets & Forringer, 2011) the case of a 78-year old ICD patient with severe ischemic cardiomyopathy is reported. The patient was in palliative care. Although he was warned about the possibility of receiving recurrent shocks he declined deactivation of the device. Soon after his condition started to decline, his ICD began to shock, approximately every minute and the patient requested the deactivation of the device. Again, the actual process of deactivation was difficult and delayed due to lack of technical information on the device as a result of a lack of established procedural policies. Finally the device was deactivated, by placing a magnet on top of the patient's chest. Later the ICD was programmed to off-mode. The patient had been shocked 44 times during a 35-minute period.

One case of an "electrical storm" was reported by a practice nurse who described how a patient and his wife characterized the last hours of the man's life as frightening and traumatizing: The defibrillator exerted a total of 33 shocks. One of the relatives literally reported: ”The defibrillator became so hot, it burned through his skin" (Grassman, 2005).

These cases reflect the dramatic and traumatizing effects ICD shocks may exert in end-of-life situations upon patients and families. The lack of standardized processes and policies of ICD deactivation paired with ethical dilemmas and insecurities among physicians (Sherazi et al., 2008) regarding ICD deactivation are obstacles on the way to improved patient-centered ICD management at the end-of-life. It should be assumed that hospitals and hospices are prepared to deal with ICD patients at the end-of-life. A finding by Fromme et al. (2011) counteracts this assumption: The researchers investigated the incidence of adverse experiences with active ICDs at the end of patients' lives in hospice programs in Oregon (USA) and to what degree anticipatory actions had been taken. Of all hospice programs included in the survey (N=36), as many as 31 (86%) reported adverse experiences with end-stage ICD patients whilst only 16 (38%) had established policies for managing patients carrying an ICD. Only 19 (42%) hospices screened new patients admitted to hospice for ICDs. According to a study by Goldstein, Carlson, Livote, and Kutner (2010) the awareness of ICD associated problems at the end-of-life is insufficient amongst institutions for palliative care, where it may be needed most. Only 10% of 414 hospices had guidelines on the management of ICD patients.

Ethical consideration and definitions

The insecurity about ethical and legal aspects of ICD deactivation represent a frequent barrier for both physicians and patients to timely and appropriately deal with the end-of-life issues of ICD patients (Goldstein, Mehta, Teitelbaum, Bradley & Morrison, 2007). According to Berger (2005), the principle of patient autonomy justifies a patient’s request (with decision making capacity) for ICD deactivation. While the policy to respect the patient’s wish to terminate external life- sustaining treatment (Epstein et al., 2008; Padeletti et al., 2010) is widely accepted, this policy is not readily adopted in case of ICD deactivation, presumably because the ICD in its intrinsic nature has become part of the patient and is somewhat imperceptible (Kapa, Mueller, Hayes, & Asirvatham, 2010). Lack of clear distinction of ICD deactivation from euthanasia and physician-assisted suicide might create confusion and cause ethical conflicts amongst physicians, patients and care providers (Kapa et al., 2010; Kramer, Kesselheim, Salberg, Brock & Maisel, 2011).

Euthanasia and/or physician-assisted suicide require an action taken by the physician with the intention to end the patient’s life (Grubb & Karabin, 2011; Mueller, Hook, & Hayes, 2003). ICD deactivation does not meet such definition, as the deactivation of the device is not causing the death of the patient. The ICD can be deactivated without immediate effect and the unpredictably occurring lethal arrhythmic event is not the result of the deactivation but of the underlying disease. In case of deactivation, the withdrawal of the ICD therapy removes what might be a burden for the patient rather than a benefit and hereby permitting an undisturbed process of dying from an irreversible disease progression. If a patient with terminal condition(s) does not wish to be resuscitated (or wishes to refuse medical treatment), a Do Not Resuscitate order (DNR) can be completed in hospital or hospice settings (Berger, 2005). Careful communication is one crucial part during the execution of a DNR order, i.e., a process of "informed consent" should document if the DNR order includes the deactivation of ICD therapy. A DNR order does not automatically imply the deactivation of the ICD (Berger, 2005). The principle of patient autonomy as a precondition for device deactivation should in all cases be applicable.

1.4 Quantity of life and quality of death

With regard to the goals of care during the end stage of patients' lives, preferences may differ and/or may have changed over time. Some patients might choose prolongation of life (= quantity of life) over quality of life at the end-of-life (= quality of death) (Lewis et al., 2006; Brunner-La Rocca et al., 2012). Sears et al. (2006) described quality of death as: "the ultimate cessation of life after medical care has been deemed futile, with full engagement of patient and family desires" (p.637). In order to achieve such, the focus should lie on minimizing pain and suffering, whilst maximizing the autonomy of the patient's wishes (Sears et al., 2006).

The common and premier therapeutic goals of medicine to sustain life may not be valid towards the end-of-life. In the light of the adverse experiences described above, it could be assumed that during this terminal phase, the process of dying without pain and in dignity, should become the predominant concern (=quality of dying). (Martinez-Selles et al., 2009; Sears et al., 2006).

Not every ICD patient suffers from inappropriate shocks during or at the end of his life (Carlsson, Paul, Dann, Neuzner & Pfeiffer, 2012). However, ample evidence (=case studies) suggests, that ICD shocks during the end-stage of life, let alone inappropriate multiple shock delivery ("electrical storms"), constrain the possibility for patients to die at peace and without pain (= quality of death).

1.5 Patient-centered end-of-life-care

A former, more paternalistic health care approach to end-of-life care has been outdated by a more patient-centered approach Patient-centered end-of-life care refers to care providing symptom relief, comfort and support of the patient and families when death is imminent in order to secure a quality of life to the extent possible, thus following the patients' best interests during the terminal life stage of patients (Stewart & Brown, 2001). Building on the fact that many patients are experiencing lengthy and painful deaths, the development of end-of-life care towards a more focused patient-centered approach has become a priority for medical societies and health-care organizations (Steinhauser et al., 2000).

Literature on issues surrounding end-of-life care, in particular patients' preferences, emphasize the occurrence of "human development" or "individual growth" patients may experience during the end-of-life stage. One expression of a patients' growth during this phase may be a shift of attitudes and desires towards self-determined dying at mental and physical peace (Lewis et al., 2006). The primary goal of ICD-therapy, preservation and prolongation of life, might lose priority with these end-stage patients. This finding is in contrast with the outcome from a recent study using interviews with 30 ICD candidates for most of whom the chance to prevent SCD had clear priority over concerns about end-of-life issues surrounding such treatment (Strachan, Carroll, de Laat, Schwartz & Arthur, 2011). At the same time all of them confirmed their preference to maintain a high quality of life as long as possible, viewing ICD therapy an appropriate means to achieve such goal. This attitude may reflect both a gap of knowledge and of personal consideration. For this reason, the management of patients at the end of their lives requires special and individualized attention. The decision making process to deactivate the device in end-of-life circumstances appears to be difficult due to the range of perceptions and attitudes and lack of problem awareness of physicians and patients, different ethical attitudes, lack of formal authorization to deactivate an ICD and lack of guidelines. Little progress towards a more patient-oriented approach to deactivation of ICD at the end-of-life has been achieved over the past years (Ladwig et al., 2010; Russo 2011, Thanavaro, 2012), despite the fact that ICD patients with an "end-of-life dilemma" are becoming more frequent.

Despite the recommendations regarding device therapy and ICD deactivation (Dunbar et al., 2012; Epstein et al., 2008, Lampert et al., 2010, Padeletti et al., 2010) both physicians and patients are still facing challenges in discussing ICD deactivation (Ladwig et al., 2011, Russo 2011, Thanavaro, 2012).

1.6 Literature Review

Research of the pertinent literature identifies current clinical practice of management of the ICD therapy at the end-of-life, including the status of problem awareness, preferences and attitudes of both physicians and patients. The first of the following sections summarizes relevant studies concerning physician awareness and attitudes regarding the management of ICD therapy at the end-of-life.

Physician awareness and attitudes regarding ICD deactivation

Physicians and cardiologists remain little involved in discussions regarding ICD management during end-of-life with their patients (Ladwig et al., 2011, Russo, 2011, Thanavaro, 2012). A series of physician surveys reveal a lack of knowledge and overall recognition of the problems associated with ICD at the end-of-life (Goldstein et al., 2007; Goldstein et al., 2009; Kelley, Reid, Miller, Fins & Lachs, 2009; Kramer et al., 2010; Marinskis & van Erven, 2010; Mueller, Jenkins, Bramstedt & Hayes, 2008; Sherazi et al., 2008).

Goldstein et al. (2007) studied physicians' awareness of the problems associated with dying with an active ICD. Twelve physicians from different disciplines were interviewed about their attitudes towards ICD deactivation. All of them recognized the relevance to timely discuss the end-of-life situation with an ICD patient, however, had never or rarely conducted such conversation themselves. Reasons were time constraints, lack of close personal relationship, as well as insecurity about the legal and ethical implications. The authors assumed, that physicians are insufficiently trained for such verbal interventions with ICD patients.

Similar surveys confirm a relatively low level of knowledge of private or hospital based physicians in the US and Europe about ICD therapy in general, the difference between ICD and pacemaker therapy, about painfulness of shocks and the ethical and legal questions associated with deactivation (Kelley et al., 2009; Sherazi et al., 2008). Interestingly, after physicians were adequately educated about the ethical legality of ICD deactivation, almost all physicians considered a conversation about the deactivation option relevant.

In contrary, surveys of 787 cardiac specialists (mainly electrophysiologists and ICD specialists) (Mueller et al., 2008) show better understanding of the issues surrounding ICD patients at the end-of-life: The majority of the physicians reported to have been involved in processes of ICD deactivation. A study on the identification of potential barriers to conversations about ICD deactivation (Goldstein et al., 2009) revealed false and unrealistic assumptions amongst physicians caring for ICD patients: Many physicians thought that ICD shocks can be predicted and that ICD carriers have sufficient knowledge about their device therapy (including the deactivation option) making a discussion with their patient unnecessary.

The insecurity of physicians on legal and ethical aspects of ICD deactivation is confirmed by several reports (Farber et al., 2006; Goldstein et al., 2007; Sherazi et al., 2007). There is broad consensus that patients with maintained decision competence have the right to deny life-sustaining measures and that physicians have the obligation to respect such decisions. However, physicians show a greater inhibition to deactivate an ICD than to withdraw life- sustaining measures as ICD deactivation was more frequently considered physician-assisted suicide (Kramer et al., 2010). In the study of Farber et al. (2006) with american internists, termination of a life-sustaining therapy was emotionally a more difficult decision, since it was considered the reason for dying, than denial of a therapeutic option, which was considered a decision against interruption of the natural process of dying.

A recent study by Matlock et al. (2001) reveals the discrepancy between physicians' perceptions of benefits and risks associated with ICD implantation with patients. Cardiologists clearly put more emphasis on the potential benefits of ICD therapy versus its potential downsides. They tend to follow published guidelines, which emphasize the benefits and neglect the downsides, which may complicate shared-decision making between patients, physicians, and family members. In summary, the level of awareness amongst physicians regarding ICD management at the end-of- life is low. Physicians are generally insecure about legal and ethical aspects of the ICD therapy. Timely communication with the patients about the deactivation option rarely takes place and is no integral part of ICD therapy. Further, physicians highlight benefits respective the indication of the ICD therapy whilst leaving risks of the therapy and potential dilemmas which may develop during the end-stage of a patient's life, unmentioned. Although the number of physician studies is limited, the available results help understand the status of the current "physician approach" to ICD patients.

Patient awareness and attitudes regarding ICD deactivation

Questions related to managing ICD patients at the end-of-life have gained attention over the last couple of years, presumably as appalling reports on patients' deaths with active ICDs have increased. Nevertheless, empirical research on patients' perspectives regarding the issue of ICD management at the end-of -life is scarce. To date, five questionnaire-based surveys have been conducted (Dodson et al., 2013; Herman, Stros, Curila, Kebza & Osmancik, 2013; Kramer et al., 2011; Stewart et al., 2010; Pedersen, Chaitsing, Szili-Torok, Jordaens & Theuns, 2013). A number of retrospective and qualitative studies (Goldstein et al., 2004; Goldstein et al., 2007; Kirkpatrick et al., 2011; Kobza & Erne, 2007; Lewis et al., 2006; Matlock et al., 2011; Raphael et al., 2011; Strachan et al., 2011; Tajouri, Ottenberg, Hayes & Mueller, 2012) investigated the incidence of communication about the topic of ICD deactivation as well as patient attitudes and preferences concerning the handling of this issue. Table 1 summarizes all relevant patient studies to date.

Table 1: *Summary of patient studies regarding the issue of "Management of the ICD at the end-of-life"*

Study	**Patients**	**Design**	**Results**	**Limitations**
Goldstein et al (2004)	N=100	Retrospective cohort study	27/100 had conversation regarding ICD-DA 27/100 received shocks during last month of life, 30% during last minutes	Information via next of kin
Kobza und Erne (2007)	N=36	Retrospective charts	6/8 (75%) of patients with malignant tumor discussed ICD-DA No patient wanted deactivation	Small sample size Retrospective study
Goldstein et al (2007)	N=15	Qualitative focus groups	0/15 had conversation regarding ICD-DA 0/15 knew of ICD-DA option-high information need	Small sample size No co-morbidities "Single center "
Stewart et al (2010)	N=105	Survey questionnaire	70% would keep ICD on if dying of cancer problem awareness /knowledge about benefits and disadvantages of device=low	"single center"
Kirkpatrick	N=278	Telephone	50% with AD	"single center"

Study	Patients	Design	Results	Limitations
et al (2011)		interview	2% included ICD-DA in AD 95% pro AD communication/ problem awareness=low	
Kramer et al (2011)	N=311	Survey questionnaire	46% had AD 8% had mentioned ICD-DA in AD 57% insecure about legality of ICD-DA	High selectivity of patients No co-morbidities/little relation to EoL planning
Raphael et al (2011)	N=54	Qualitative interview	Only 3 % recall conversation about ICD-DA, 84% want discussion	“single center”, small sample
Matlock et al (2011)	N=14	Qualitative study interviews	Patients delegate decision about ICD-DA to physician Knowledge solely on benefits of ICD	Small sample
Strachan et al (2011)	N=24	Qualitative study interviews	Patients focus on life-prolonging function of ICD Do not consider death by other causes than SCD	Small sample size “Single center”
Tajouri et al (2012)	N=420	Retrospective charts	127/420 (30%) had AD 2/127 (2%) mentioned ICD-DA in their AD	“Single center”

Study	**Patients**	**Design**	**Results**	**Limitations**
Herman et al. (2013)	N=109	Survey questionnaire	46% had never considered ICD-DA 40% wanted information about ICD-DA Survivors of SCD did not want information	“single center” survey not based on validated constructs
Dodson et al (2013)	N=95	Survey questionnaire	60% unaware of ICD-DA related issues 71% of patients wanted ICD-DA in at least one scenario (terminal illness, bedridden)	“single center”
Pedersen et al (2013)	N=294	Survey questionnaire	68% of patients aware of ICD-DA, 79% favor IC-DA Information need high (95%) Preference to be informed in writing or orally 49% wished for discussion prior to implant	“single center”

Abbreviations: ICD-DA=ICD deactivation, AD=Advance Directive, EoL=End-of-Life

Goldstein et al. (2004) first dealt with the issue of ICD deactivation in 2004. In a retrospective cohort study the authors interviewed 100 family members of ICD patients who had died within 2.5 years prior to the survey about whether the issue of deactivation had been discussed and whether those patients had received shocks during their last moments of life. Discussions of ICD deactivation had taken place in 27 of 100 cases (27 %). Moreover, these discussions were neither structured nor planned but acutely performed, usually as a reaction to a particular stressful situation shortly (in the hour or the minutes) before death of the patient. Almost one third, 27/100 (27 %) of the patients in this study had received ICD shocks within one month, 8 of which (30 %) within the minutes before death. The “sensitivity” of the subject is underlined by another study of 36 ICD patients who had passed away during follow up, 8 of these patients suffered from a malignant tumor: None of the patients had consented to deactivation of the ICD during a structured patient conversation (Kobza & Erne, 2007). The authors had assumed that patients would prefer sudden arrhythmic death to dying from cancer. Patients seem reluctant in making decisions in critical situations as such. The results further confirm a lack of knowledge amongst patients regarding possible side effects and impacts of the ICD therapy at the end-of-life.

In a qualitative study Goldstein et al. (2007) investigated the incidences of discussions about ICD deactivation as well as identifying potential barriers to conversations. None of the studied patients had received information on the option of ICD deactivation and none had ever discussed the topic with their physician. The majority of the patients showed little interest to actively engage in a discussion about the deactivation issue and preferred the physicians to take the initiative in this matter.

Matlock et al. (2011) used semi-structured interviews to better understand patients’ attitudes towards decision making surrounding ICD implantation. ICD patients had not weighed the risks against the benefits of the device and instead, again, relied on their physician’s decision completely. Motivation to learn about risks of the ICD therapy only grew as a consequence of experiencing problems or side effects with the therapy.

A British group of researchers investigated patients' wish to be informed about ICD therapy prior to device implantation. Raphael et al. (2011) interviewed 54 ICD patients and divided them into two groups: The first group included patients who only recently had an ICD implanted and had not yet received any shocks while the second group consisted of patients with an ICD in place for a minimum of 6 months and who had received at least one shock. Strikingly, the majority of both groups wanted to be involved in the deactivation decision process, preferably discussing the topic prior to implantation. Patients further reported, that benefits of the ICD therapy received the most attention during communication with their physician. These results corroborate with the findings from Strachan et al. (2011) who analyzed 24 ICD patients: Most patients focused on the life-saving aspects of the ICD therapy, neglecting its possible negative effects during end-of-life. The debut in questionnaire-based research on this issue was conducted by Stewart et al. (2010). The authors surveyed 105 heart failure patients from two referral centers in Boston, USA, about their perceptions of survival by ICD benefits and attitudes about the option of ICD deactivation. Again, results revealed an overall lack of understanding about the potential downsides of the ICD therapy: 55 % of the patients preferred to maintain activation of their ICD despite the perspective of receiving daily shocks, 70% would maintain ICD activation in the face of cancer or imminent death from a non-cardiac cause, none of the patients wanted the ICD to be deactivated in the case of constant dyspnea**.** More recently a group of investigators (Dodson et al., 2013) analyzed 95 patients' preferences for ICD deactivation in the context of several health conditions: 71 % of the patients agreed to ICD deactivation in at least one scenario, 60 % in case of an incurable disease course. Another study conducted in 2013 (Herman et al., 2013) showed, that patients who had survived SCD (40% of all study patients) refused any information on ICD management at the end-of-life, while most other patients with primary indication wished to obtain more information. Pedersen et al. (2013)

identified the patients' wish for a worthy death (desire to "die in peace and dignity") as the driving force behind the decision for ICD deactivation.

The role of Advance Directives

According to the HRS consensus statement, patients who are approaching the end-of-life are advised to complete an Advanced Directive (AD). Advance directives are documents stating personal preferences for medical care (Lampert et al., 2010). They might be crucial in creating space for timely and consistent discussions about ICD deactivation. ICD related dilemmas at the end-of-life may be avoided or reduced by using ADs (Lampert et al., 2010).

A small number of studies investigated the prevalence of ADs and whether they had included a management plan for ICD deactivation: A telephone survey of 278 ICD patients showed that although more than 50 % of the patients had completed some form of an AD, only 2 % of those patients specifically addressed management ICD therapy at the end of their lives. Most of the patients interviewed (86 %) had not considered the potential implications from ICD therapy when suffering from an underlying terminal (non cardiac) disease (Kirkpatrick et al., 2011). 42 % of the patients interviewed were reluctant in deciding over the ICD deactivation option, 26 % associated ICD deactivation with an act of physician-assisted suicide.

Similarly, Tajouri et al. (2012) determined the prevalence of ADs amongst patients carrying an ICD (N=420) and the prevalence of ADs, which included ICD deactivation by reviewing medical records. Only 30 % of patients with ICDs had completed an AD, 65 % of which had completed the AD more than 12 months before ICD implantation. Older and more chronically ill patients felt more obligated to complete an AD than younger patients. In only 2 % of the ADs the issue of deactivation of ICD at the end-of-life found mentioning, while more conventional life-sustaining treatments such as cardiopulmonary resuscitation, tube feeding, mechanical ventilation, hemodialysis and the desire for pain control were included. Similar were the results from a large survey-based study by Kramer et al. (2011): Only 8 % of 311 patients with ICD had included a decision about ICD deactivation in their AD.

In summary, data from retrospective, qualitative and questionnaire-based studies show, that the importance and delicacy of the issue of ICD management at the end-of-life are often underestimated by both physicians and patients. Communication between patient and physician is inadequate and insufficient, patients are neither educated thoroughly about end-of-life related issues with the ICD at the beginning of the treatment nor consistently throughout the treatment process. Further, patients delegate the decision about ICD deactivation to their physician. Problem awareness is deficient and knowledge about risks and potential downsides of the therapy is scarce. The advantages and life-saving function of the ICD are the main focus throughout the therapy. Nevertheless, patient information need seems to be high, patients wish to be adequately informed, preferably prior to implantation. Although the use of ADs is recommended, ICD patients do not commonly include ICD deactivation related issues in their AD, nor have most of the ICD patients completed an AD in the first place. Both, physician and patient research have shown that timely early and continued long term communication about the option of and issues associated with ICD deactivation are no integral part of current ICD therapy.

Limitations of former studies

Despite the increasing relevance of this subject, only a limited number of patient studies have investigated the issue of dying with an ICD. Seven studies have qualitatively examined patients' attitudes, preferences, and communication with the physician regarding ICD management at the end-of-life. Questionnaire-based surveys were only used in five studies with ICD patient samples from 95 (Dodson et al., 2013) to 311(Kramer et al., 2011). In the majority of the studies, patients were selected from single centers. Such data may not be representative of wider populations. No studies have yet quantitatively examined more specific aspects of ICD management at the end-of-life, such as associations between physician/patient communication, problem awareness and patients' preferences and attitudes.

The study presented in this dissertation is intended to fill this gap. It is the largest questionnaire based investigation in unselected ICD patients on the issues of ICD management at the end-of-life.

2. Objective of the study

The overriding goal of this exploratory study was to collect patient data, with the projected outcome of understanding how to improve the treatment of ICD patients and to develop a more patient-centered therapy. The study is subjective and attitudinal in nature, identifying how and when patients like to be informed, with whom they like to discuss issues surrounding end-of-life with the ICD, as well as their attitudes and preferences regarding the handling of the therapy during the end stage of life.

Participants were asked about their own subjective degree of awareness of the ICD deactivation option, the quality of communication with their physician regarding ICD management during end-of-life and their personal preferences regarding the handling of ICD management at the end-of-life.

The results from this study aim to provide a deeper understanding of patients’ needs in this field and to identify the practical implications of improving the quality of ICD therapy. A basis may be laid for further and more specific research regarding the management of ICD patients at the end-of-life.

3. Method

3.1. Background of the study

Initiative for the improvement of long-term care and treatment of ICD patients

In 2009 the Institute of Epidemiology II, Helmholtz Zentrum München, German Research Center for Environmental Health in Neuherberg, Germany, started a research initiative in collaboration with the German Defibrillator Association of Support Groups (GDA) (Defibrillator (ICD) Deutschland e.V). Its goal was to contribute to an improved patient-centered care of ICD patients, in particular promoting innovation and improvements in the management and treatment of ICD patients at the end-of-life. The initiative was designed to identify deficiencies in current care of ICD patients by collecting data on patients' knowledge, their attitudes and preferences regarding issues (e.g. satisfaction with device, patients' emotional status, management of ICD therapy at the end-of-life) related to life with an ICD.

German Defibrillator Association of support groups (GDA)

The GDA is a nationwide and special interest group for ICD patients and their family members. The goal of the GDA is to represent needs of ICD patients nationwide. By networking with institutions, organizations, physicians and hospitals, the existence and development of regional support groups are promoted. ICD patients can obtain information via the GDA online platform: www.defibrillator-deutschland.de as well as via the online forum for ICD patients: www.defi-forum.de. The Association offers educational training for ICD patients covering various issues of life with the device. The yearly convention of the GDA offers ICD patients a chance to exchange information across the support groups. Further, the GDA publishes (2 or 3 times per year) an informational magazine, *"ICD -*

AKTUELL" containing information on medicine, technological developments, reports from support groups and other topics relevant for ICD carriers.

Support groups

The purpose of the regional defibrillator support groups (RSG) is to offer ICD patients a platform to meet and exchange experiences with ICD therapy. Patients approach the GDA or the regional support group directly to become a member. The support groups meet regularly, either monthly or every other month. Each support group has a group leader selected by the group members. All registered members of a support group are ICD patients.

3.2 Patient selection and Participants

As for this initiative, the RSG were considered the crucial and most relevant transmitter of a representative and collective opinion of ICD carriers. All ICD patients who were members of their regional support group were asked to participate in the study. 42 support groups with a total of 1242 registered members received the study questionnaire. Prior to receipt of the questionnaire oral presentations at GDA meetings were organized in order to prepare the ICD patients for the research project. 394 ICD patients eventually participated by returning the completed questionnaire, resulting in a response rate of 29 %. Of the 394 participants age ranged from 30 to 94 years (Mean: 68.6, SD: 10.4), 74.1 % were male, 78.7 % lived together with their partner, and the majority of the patients, 63.5 %, were retired.

3.3 Topics and Materials

Topics

The topics covered by the questionnaire as part of the "Initiative" (3.1.1.) were decided together with the project leader Prof. Dr. K-H Ladwig, Institute of Epidemiology II, Helmholtz Zentrum, German Research Center for Environmental Health, Neuherberg and

Department for Psychosomatic Medicine and Psychotherapy, Klinikum Rechts der Isar, Technische Universität Munich, Germany, and in collaboration with the former Chief Executive Officer (CEO) of the GDA. Patients were challenged with the issues associated with management of the ICD at the end-of-life.

Materials

Two questionnaires were designed for the purpose of this study. The original questionnaires (in german language) are enclosed (Appendix, 7.4). For use in this dissertation the questionnaires were translated into the english language. Some of the items were *yes* and *no* questions, some allowed multiple responses.

Socio-demographic Questionnaire

The socio-demographic questionnaire (Appendix, 7.4) consisted of questions regarding gender, age, the living situation of the patients, their professional status, details about their device (make, date of implantation) and information about cardiovascular risk factors.

End- of- Life Questionnaire

The “ End-of-life” questionnaire (7.4) consisted of 40 items measuring the following:

- Problem awareness of the patients, technical knowledge about ICD therapy
- Interaction between physician and patient and the quality of communication
- Attitudes and preferences of patients about the handling of the ICD therapy at the end-of-life

3.4 Procedure of the study

Preparation

In preparation for the study, actions were undertaken to familiarize the patients with the delicate issue of ICD management at the end-of-life. The research team published several articles in the *"ICD-AKTUELL"* magazine announcing the "Initiative" and relevance of the topic (7.5). Further, the responsible member of the research team (N.I) gave a talk about the management of ICD therapy at the end-of-life at the annual convention of the GDA in March of 2011, motivating the RSG leaders to raise and discuss the importance of the issue within their regular group meetings.

Procedure

In September of the year 2011, the "End-of-Life" questionnaires were sent out to the respective leaders of 42 regional support groups (RSG), which registered a total of 1242 members. The questionnaire to collect socio-demographic data had been sent out separately a few months earlier at the inception of this research initiative of which the "End-of-Life" project represents the second part. During the regular support group meetings the group leaders handed out the questionnaires to the patients present. Alternatively, the group leaders sent the questionnaires to their group members via E-mail. Participation was voluntary. Patients were instructed by their group leaders to complete the questionnaires in their own time and to hand completed questionnaires back to the group leader over a time frame of 6 months. All completed questionnaires of all groups were then sent to the CEO of the GDA who then delivered them to the Institute of Epidemiology II, Helmholtz Zentrum München, German Research Center for Environmental Health, Neuherberg, Germany, for analysis.

Confidentiality/Anonymity

A coding system was developed to assure anonymity of both the RSG as well as each participating patient: The CEO of the GDA sent the questionnaires to the leaders of the RSG. Codes, only known to the RSG leaders, were assigned earlier from the GDA to each RSG (RSG code). The RSG code was entered into the questionnaire by the RSG leader. A participant code number (from 001 to 999) was assigned to each participant by RSG leader and also entered into the questionnaire. The RSG leader was the only person aware of the number allotted to each patient. The group leader kept a list with the numbers and respective participants. The study center and all coworkers involved in data management have been unaware of the identity of the study participants.

Protocol of data entry and quality control

The data was entered into an Excel spreadsheet at the Institute of Epidemiology II, Helmholtz Zentrum München, German Research Center for Environmental Health, Neuherberg, Germany. Discords were noted, e.g. missing questionnaires, double versions of questionnaires with different data. For quality control, 20 questionnaires had to be randomly selected and compared to the data in the Excel-sheet. Wrong data entries had to be corrected and the procedure was repeated with a new sample of 20 questionnaires until such sample was found to be correct. In this study this procedure needed one repetition.

3.5 Statistical Analyses

A cross-sectional study of 394 participants with ICD was undertaken. Data analyses were carried out using SPSS, Version 20. Demographics and frequencies were calculated using Microsoft Excel. Continuous variables were reported with mean, median, standard deviation, lower and upper quartile, minimum and maximum. Discrete variables are shown with frequencies and percentages. For two-group comparisons Pearson's χ^2 test was calculated. For multivariate analysis, binary logistic regression was used. A p-value of ≤ 0.05 was considered statistically significant.

3.6 Definition of constructs

In order to conduct a binary logistic regression analysis the two constructs “patient problem awareness” and “communication with the physician” were categorized in two sub-sets. “Patient problem awareness regarding ICD management at the end-of-life” was grouped into: “aware” and “not aware”. This construct consisted of two questions:

1. Whether patients were aware of the possibility of ICD deactivation.
2. Whether patients had considered issues related to dying with an ICD.

Patients designated as “not aware of ICD deactivation” had responded *no* to both questions. Those designated as “aware” had responded *yes* to at least one of the questions.

“Communication with physician regarding ICD management at the end-of-life” was grouped into: “yes” and “none”. This construct consisted of three questions:

1. Whether patients had had a discussion with their physician about ICD management at the end-of-life.
2. Whether the physician had initiated any discussion on the subject.
3. Whether the patient had approached the physician on the subject.

If the patient responded *no* to all three questions, communication was defined as “none”, communication was considered “present” if one or more of the questions were answered with *yes*.

4. Results

4.1 Basic data

Socio-demographic description

Table 2 shows the demographic results of all 394 patients who participated in this study. The mean age of the patients was 68.6 years (±10.4). The youngest participant was 30 and the oldest 94 years old. Two groups of patients were analyzed, up to and including 70 years and 71 and older. Three quarters of the participants were men (74.1 %). One-fifth of the cohort either lived alone (18.2 %) or in an institution (1.3 %) and the majority of the ICD patients were retired (84.1%).

Table 2: *Socio-demographic characteristics of the patients with ICD, N= 394*

Age	Mean (SD)	68.6 (10.4)
	Median (25th to 75th percentile)	71 (62 to 76)
	Minimum to Maximum	30 to 94
Gender	Male n (%)	166 (74.1 %)
	Female n (%)	58 (25.9 %)
Living situation	Alone n (%)	41 (18.2 %)
	With partner n (%)	177 (78.7 %)
	With children n (%)	31 (13.8 %)
	In an institution n (%)	3 (1.3 %)
Employment status	Full time n (%)	16 (7.2 %)
	Part time n (%)	11 (5.0 %)
	Early retirement n (%)	44 (19.8 %)
	Retired n (%)	141 (63.5 %)
	Other n (%)	10 (4.5 %)

Cardiovascular risk factors

Table 3 shows the frequencies of the cardiovascular risk factors of the total sample (N=394). A diagnosis of hypertension was present in 71.3 %, 38.4 % were diabetic and 41.1 % had a diagnosis of high cholesterol. Only 6.4 % reported current smoking and one in four of the patients had a family history of cardiovascular risk factors (23.9 %). The median duration of ICD therapy was 4 years.

Table 3: *Cardiovascular risk factors of the patients with ICD, N= 394*

Hypertension	Yes n (%)	144 (71.3 %)
Hypercholesterolemia	Yes n (%)	78 (41.1 %)
Diabetes	Yes n (%)	73 (38.4 %)
Smoking	Yes n (%)	12 (6.4 %)
Family history of CV risk factors	Yes n (%)	44 (23.9 %)
Overweight	Yes n (%)	86 (45.0 %)
Duration of being on ICD in years	Mean (SD)	1 (3.8)
	Median (25th to 75th percentile)	4
	Minimum to Maximum	1 to 21

4.2 Patients' responses to the "End-of-Life" questionnaire

This section reports on patient awareness and physician/patient interaction and the most meaningful results of patient preferences and attitudes respective ICD deactivation are reported. All results are based on the total sample (N=394). The frequencies of responses to all questions are listed in the Appendix, 7.5.

4.2.1 Patient problem awareness

Awareness of the possibility that the ICD could be deactivated was present in 59.9 % of studied patients as shown in Figure 2.

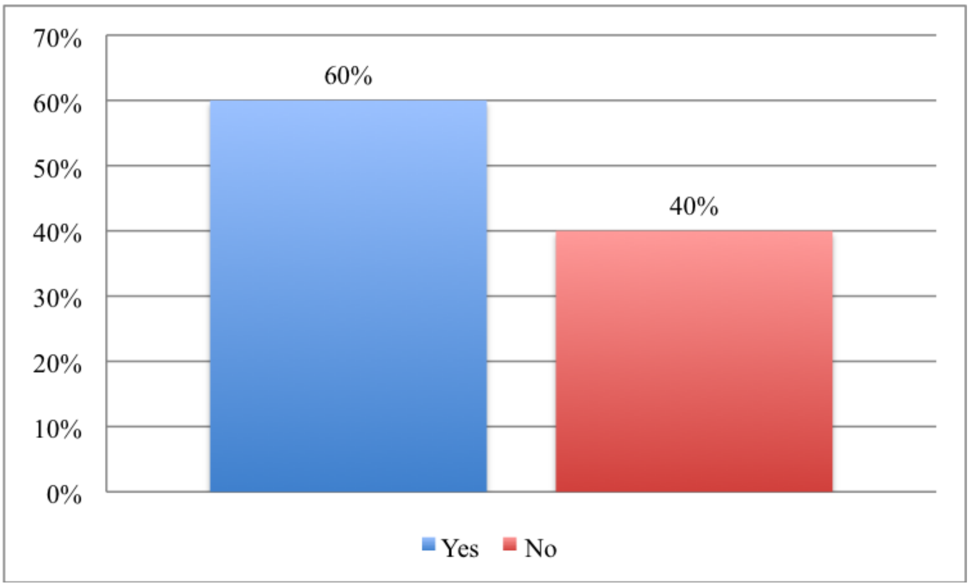

Figure 2. "Awareness about option of ICD deactivation" (N=384)

Issues related to dying with the ICD had been considered by only about half (51.8 %) of the ICD patients as shown in Figure 3.

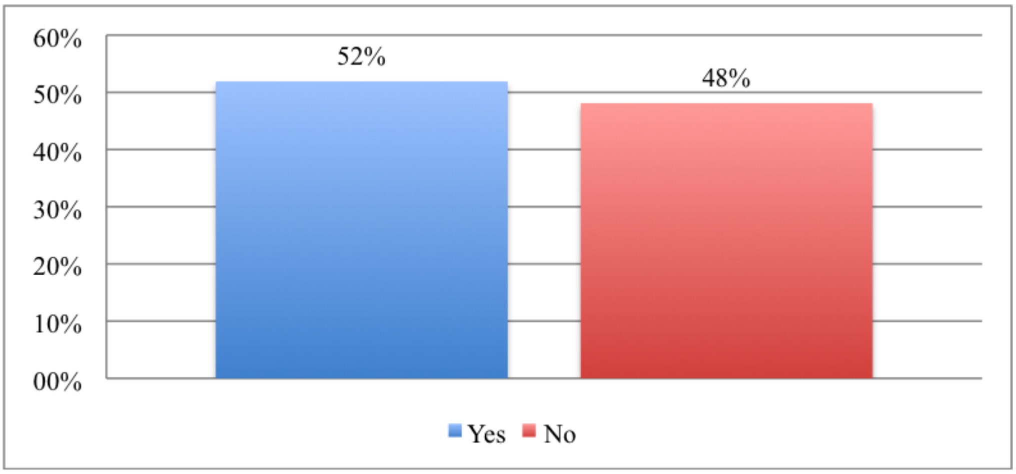

Figure 3. "Have you considered issues of dying with an ICD?" (N=386)

The issue of ICD deactivation does not seem to be a regular topic of discussion amongst the ICD patients: Figure 4 shows, that only 17.8 % of the surveyed ICD patients had discussed this issue with the other ICD patients.

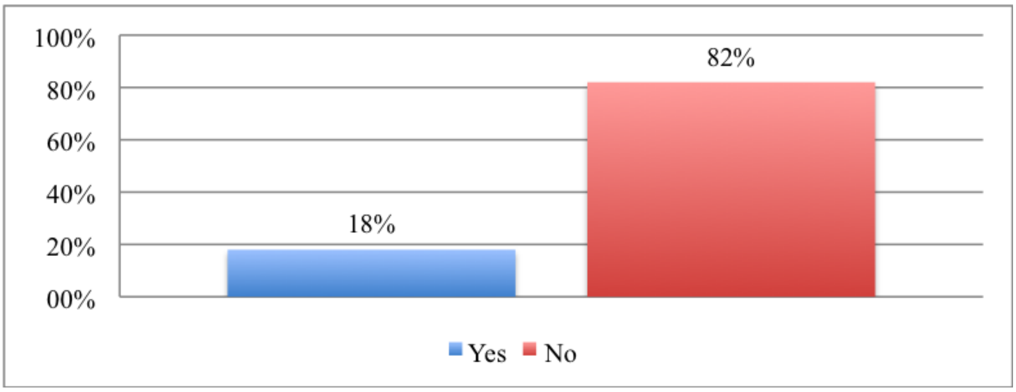

Figure 4. “Have you talked with other patients about the issue of ICD deactivation?” (N=383)

Recognition of the relevance of the end of life issue was high: 76.9 % consider the ICD management at the end-of-life to be important, as shown in Fig 5.

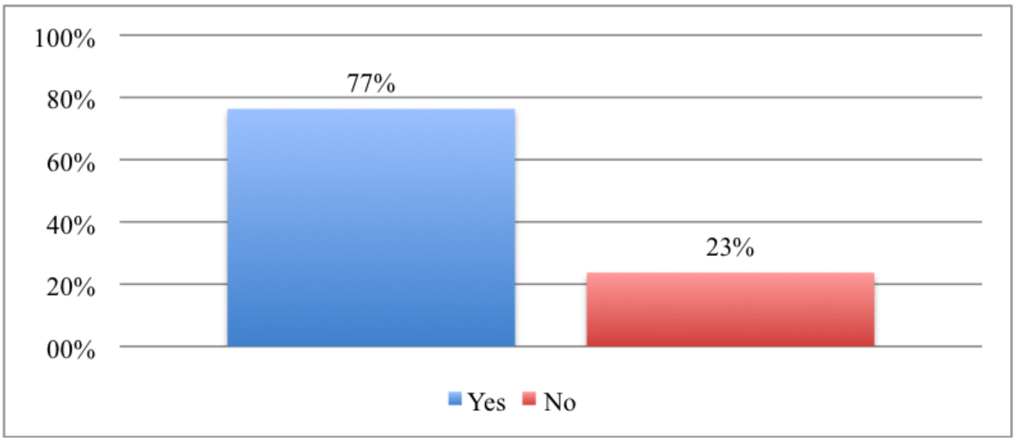

Figure 5. " Is the management of ICD at the end-of-life important to you?" (N=386)

4.2.2 Communication between physician and patient

Communication between the physician and patient regarding the issue of ICD deactivation at the end-of-life was reported as rare: only 6.2 % of the surveyed ICD patients report to have had a conversation with their physician about ICD end-of-life management, as shown in Figure 6.

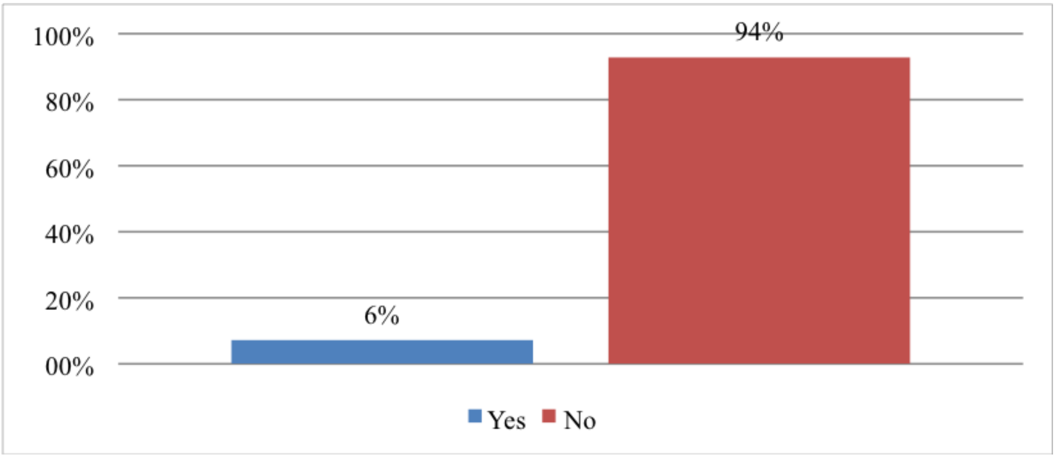

Figure 6. “Did your physician discuss ICD management at the end-of-life with you?” (N=388**)**

Interaction between physician and patient was insufficient: only 7.3 % of the ICD patients report, that their physician approached them and initiated a discussion about the possibility of ICD deactivation at the end-of-life.

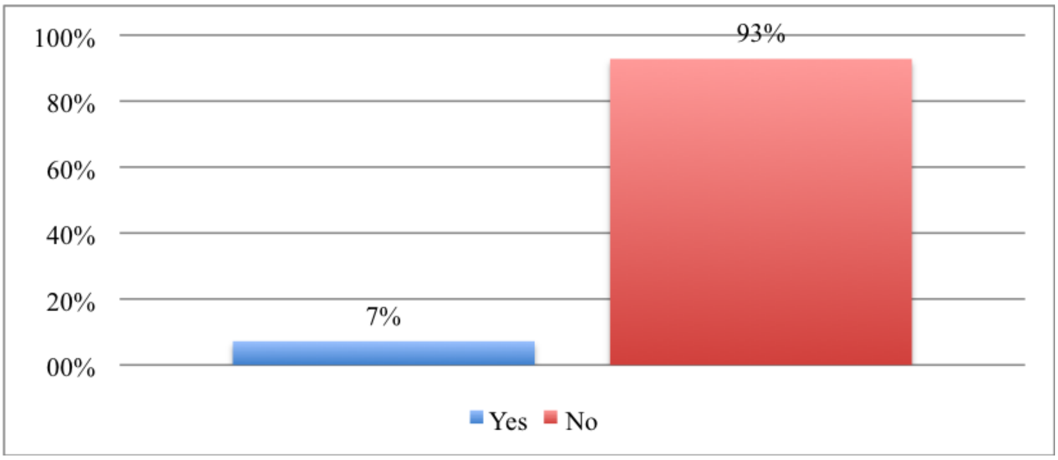

Figure 7. "Did your physician approach you regarding ICD management?"(N=385)

Barriers in communicating with their physicians reported 14.9 % of ICD patients, as depicted in Figure 8.

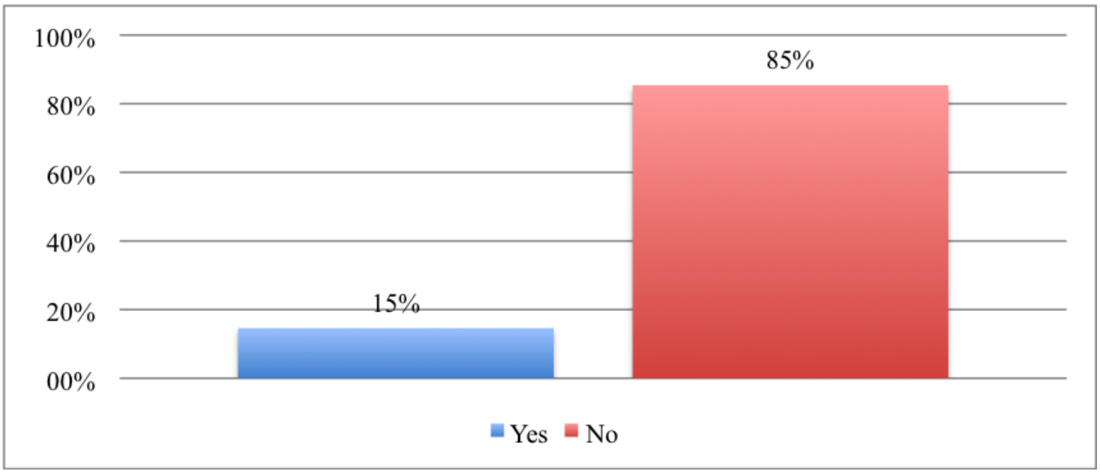

Figure 8. "Do you have barriers in discussing the topic?" (N=388)

Determinants of insufficient physician/patient interaction

The patients' subjective perceptions as to why the interaction with their physician was insufficient are presented in Figure 9. Mainly, the patients (67.3 %) considered insufficient time during the consultations with their physician to be the reason behind the lack of interaction. Also, the quality of the physician/patient relationship did not allow such "delicate" discussions (38.2 %) such as the end-of-life with active ICD therapy. One in four patients expressed, that the general avoidance of the topic negatively influenced the communication between physician and patient (26.0 %). A significant proportion also felt that physicians had a lack of knowledge and information (20.3 %), which also negatively influenced the ability to discuss such issues. Patients also perceived ethical and legal insecurities about the handling the issue of ICD management at the end-of-life (9.2 %).

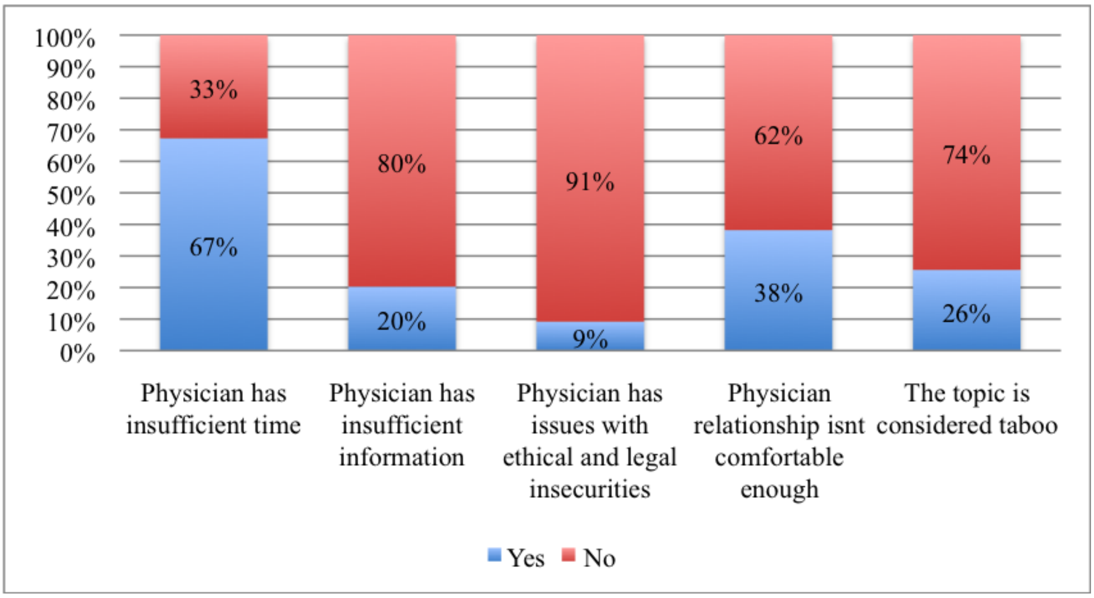

Figure 9. "Reasons for insufficient communication" (N=394)

4.2.3 Patient attitudes and preferences

The option of ICD deactivation represented a dilemma for many ICD patients: 42.1 % associated ICD deactivation with committing suicide, as shown in Figure 10.

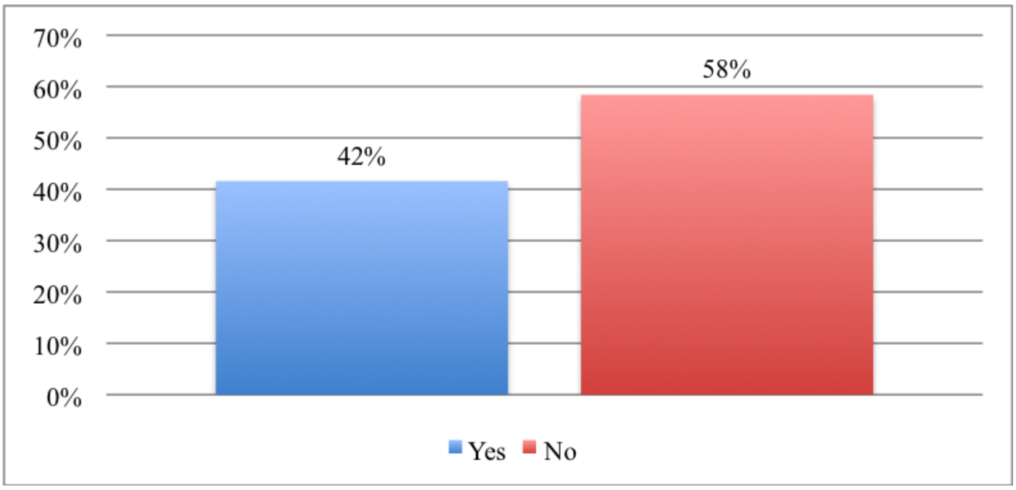

Figure 10. "Association between ICD deactivation and suicide" (N=354)

Readiness to include ICD deactivation in their Advance Directive (living will) expressed 74.9% of the interrogated patients, as shown in Figure 11

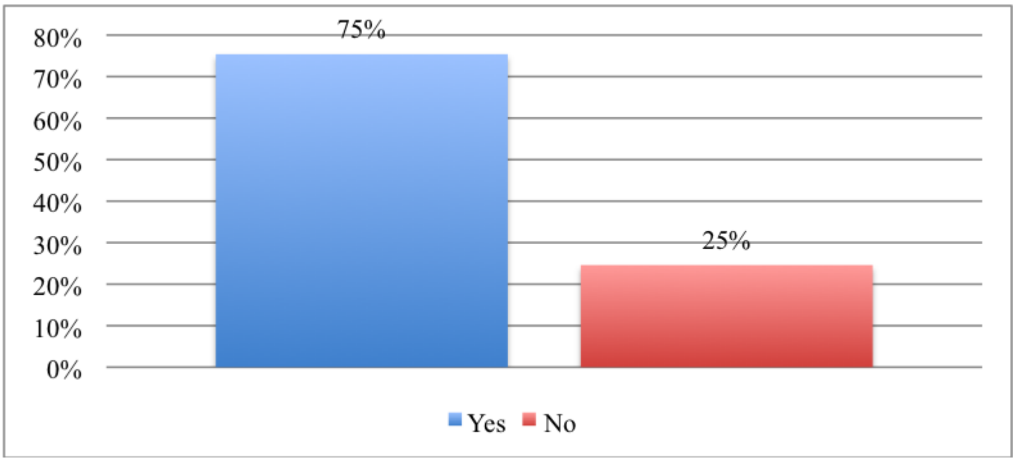

Figure 11. "Include ICD deactivation in living will" (N=367)

All of the following questions allowed multiple answers.

Preferred time of discussion of ICD management at the end-of-life

Patients' preferences about when to discuss the management of the ICD at the end-of-life vary widely, as illustrated in Figure 12. Almost half of the patients wished to discuss the management of the ICD either at the point of establishing the ICD indication (24.0 %) or before implantation (18.0 %). A fairly even amount of patients indicated to raise this topic and its related issues either at a control appointment after implantation (23.2 %), or at some point during the course of the ICD therapy (27.9 %). Three quarters of the patients expressed their wish to discuss ICD deactivation in case of a life-threatening situation (42.0 %), or as late as their terminal phase of life (21.5 %).

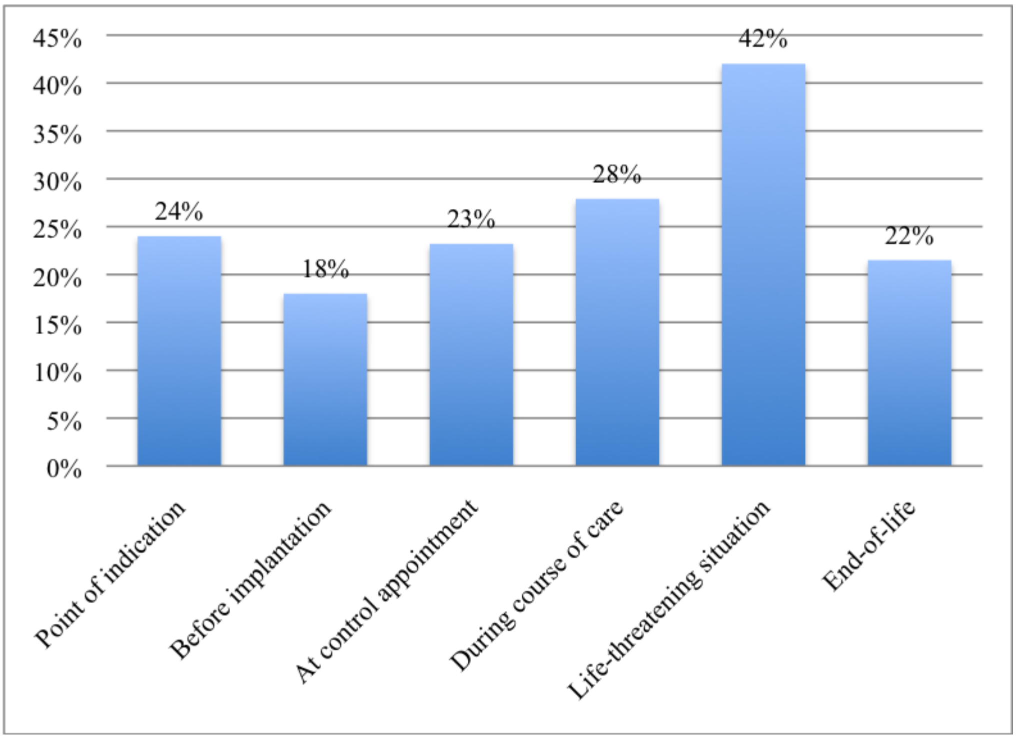

Figure 12. "Preference for time of discussion" (N=394)

Preferred source of information about ICD management at the end-of-life

As depicted in Figure 13, a high proportion of the surveyed patients wished to obtain information about ICD management at the end of life via in-group discussions with other ICD patients (62.3 %). About half of the patients (50.3 %) wished to obtain written material (information brochure, magazine), whilst only a small amount preferred to retrieve information from the world-wide-web (13.8 %).

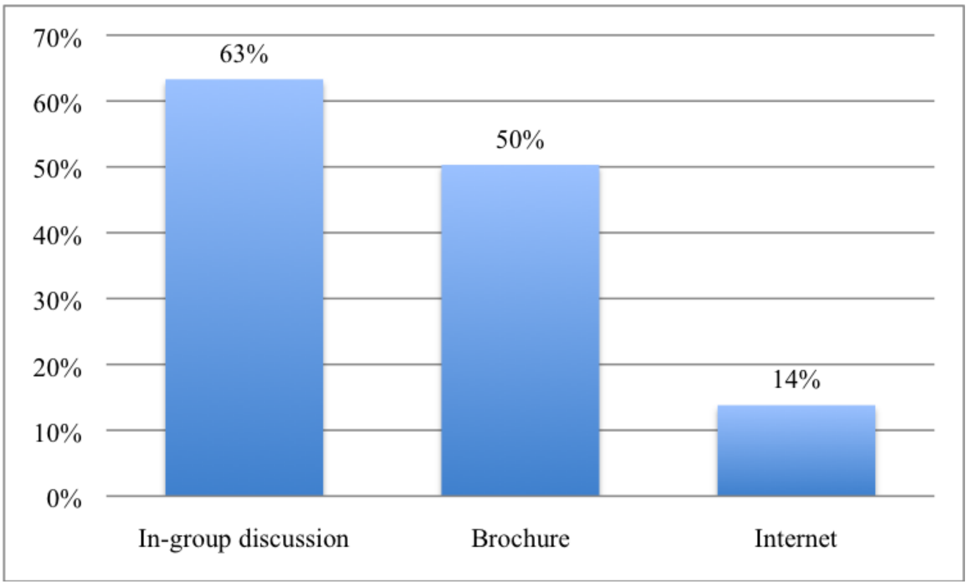

Figure 13. "Preference for source of information” (N=394)

Preferred person for discussing ICD management at the end-of-life

Almost all patients (95.7 %) were interested in talking to somebody about the end of life issues. The majority wanted to talk to a cardiologist (63.8 %) but almost as many wanted to involve their partners or family in the discussions (54.5 %). An even percentage of patients desired to talk to their general practitioner (GP) (31.5 %) or to other ICD patients (28.0 %). Involving those persons closest to the ICD patient appears to be relevant for the patients for understanding the options and consequences of their decisions for end of life care. Only a small number of the patients (6.6 %) wished to talk with a psychologist or psychotherapist. Figure 14 summarizes the results.

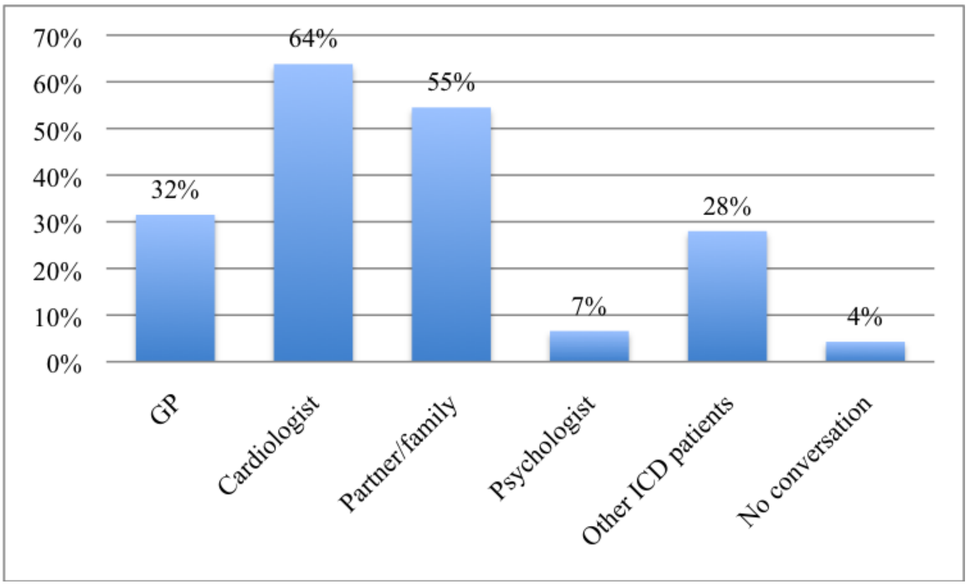

Figure 14. "Preference for person to talk to about ICD deactivation” (N=394)

Preferred ICD deactivation decision maker

Although 2 in 3 ICD patients were prepared to take the decision themselves (62.8 %), still a significant proportion wanted the decision to come from a third person source, whether this was the family (26.9 %) or partner (40.8 %). Hardly any ICD patients wished to assign this decision to anybody else in their close circle (1.6 %). Figure 15 summarizes the patient preferences for the key decision maker.

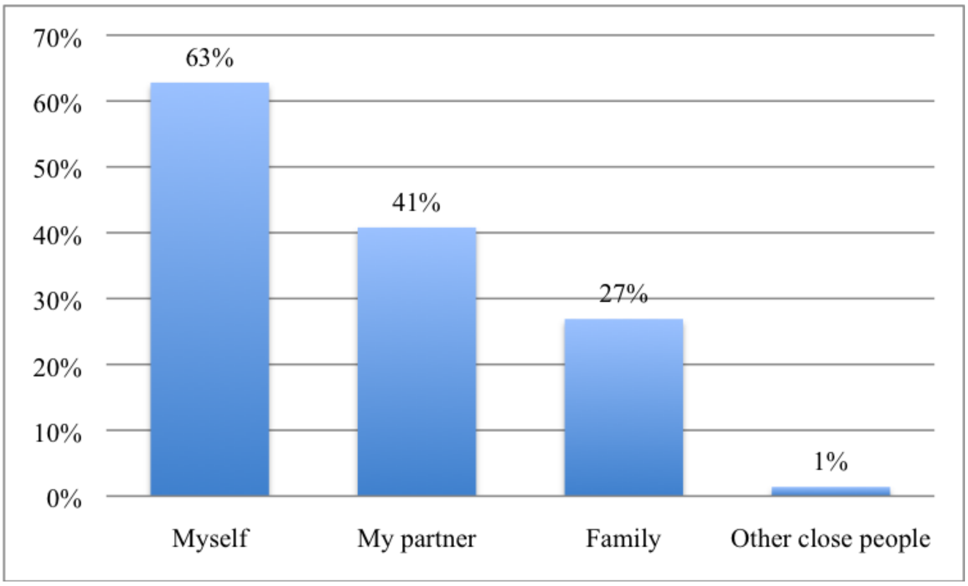

*Figure 15***.** "ICD deactivation decision maker"(N=394)

4.3 Influence of patient characteristics on patient awareness, communication and attitudes towards ICD deactivation

It was attempted identify the influence of patient characteristics on patient awareness, communication between physician and patient and patients’ attitudes and preferences. The patient characteristics included were: Gender (female/male), Age (up to and including 70 years, 71 years and older), ICD therapy duration ($<$ 4 years, $\geq$ 4 years), living-situation (alone/not alone) and job-situation (working/retired). Pearson’s χ^2-test was applied to determine any significant differences. All significant results are reported in the following section. The basis for each result was the number of patients who answered the question in the affirmative.

4.3.1 Age-group differences

More than half (55 %, N=219) of the patients knew about the option of ICD deactivation. This knowledge is significantly linked (p=0.005) to the age of the patients: Older patients were less likely to be aware of the possibility of ICD deactivation than the younger patients. Figure 16 shows that 64.2 % (70/109) of the ICD patients up to and including the age of 70 years knew about the option of ICD deactivation versus only 45.5 % (70/110) of the patients 71 years and older (Figure 16).

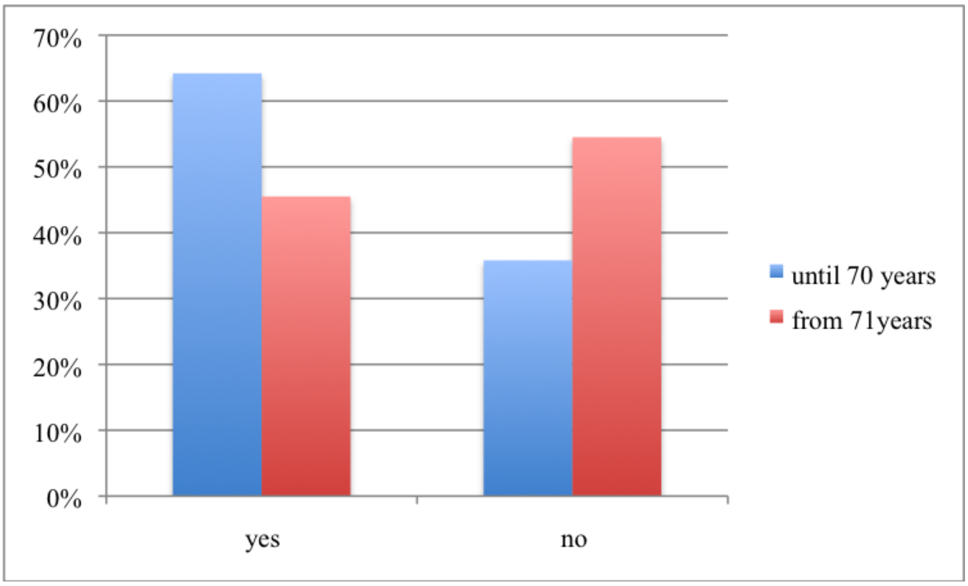

Figure 16. "Age-group difference for ICD deactivation awareness" (N= 219)

4.3.2 Gender differences

Half of the patients (51 %, N=113) had already considered issues relating to dying with the ICD. Women were significantly more likely (p=0.011) than men to have such considerations. As shown in Figure 17, 66.1 % (37/56) of the women but less than half the men, 46.3 % (76/164) had considered issues surrounding ICD deactivation.

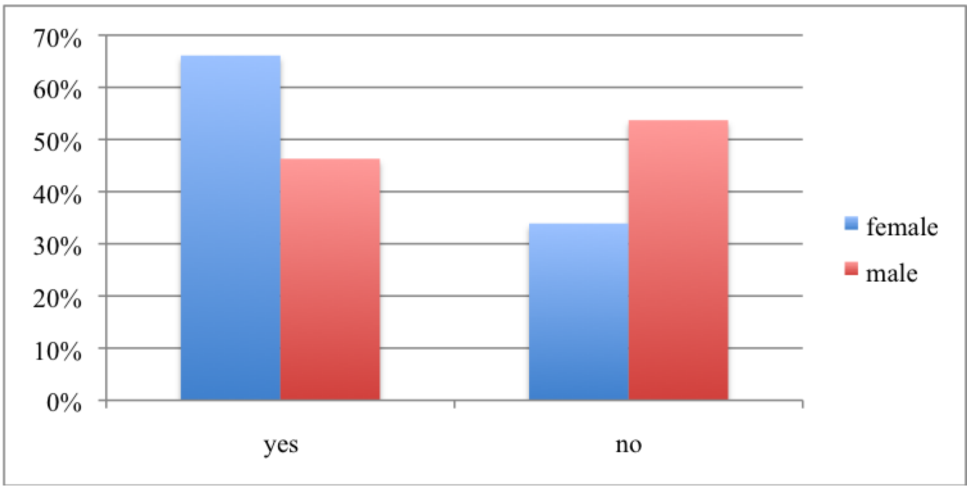

Figure 17. "Gender differences and awareness ” (N=113)

Almost two thirds (63 %, N=172) of the patients thought that lack of time amongst the physicians was the reason for insufficient physician/patient interaction. Figure 18 shows how this is significantly linked (p = 0.029) to gender. More women were aware of this issue than men: 76.1% (35/46) of the female ICD carriers and 57.9 % (73/126) of the male ICD patients perceive time constraints of the physicians as the main reason behind insufficient communication between physicians and patients.

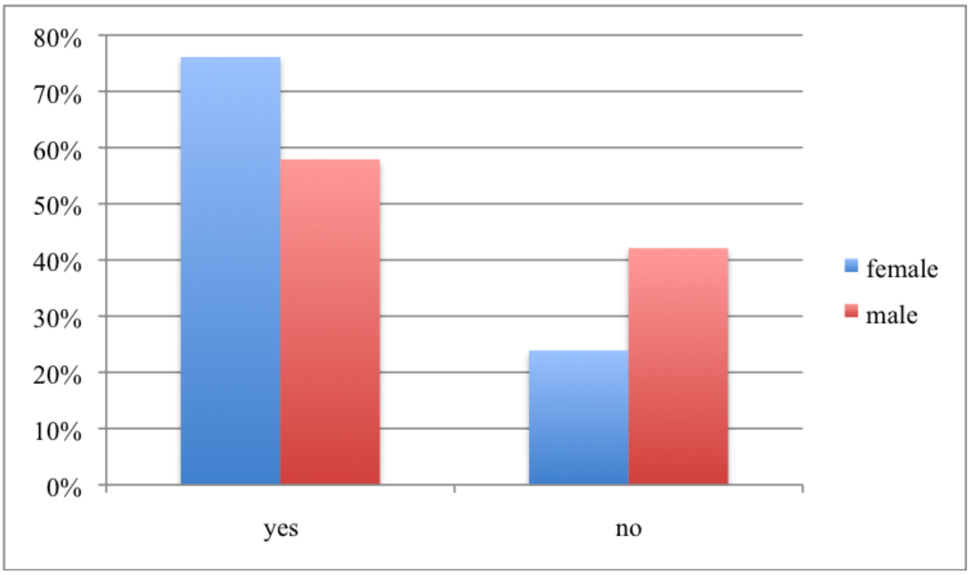

Figure 18. “Gender differences and insufficient communication” (N=172)

The cardiologist appears to be the preferred person the patients want to relate to (60%, N= 129). As Figure 19 shows, this preference is linked (p=0.038) to the patients' gender: 71.4 % (40/56) of the female ICD patients and 55.6 % (89/160) of the male ICD patients preferred to have a discussion with the cardiologist.

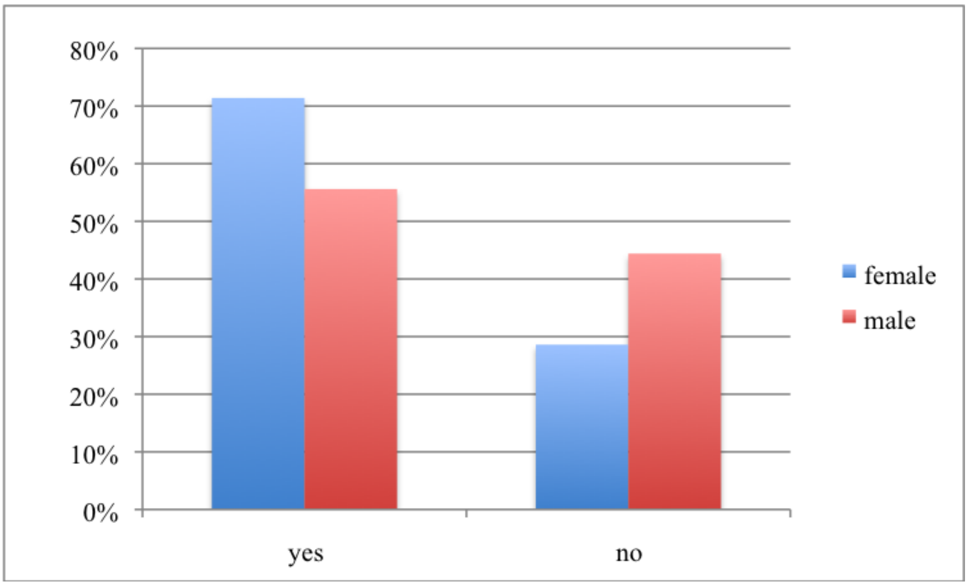

Figure 19. "Gender differences and Cardiologist as conversation partner" (N=216)

Discussion of ICD deactivation related issues with family members or their partner is desired by 53 % of patients (N=115). Figure 20 shows, that 58.1 % (93/160) of the male patients and only 39.3 % (22/56) of the female patients (p = 0.015) preferred to talk with family members or their partner.

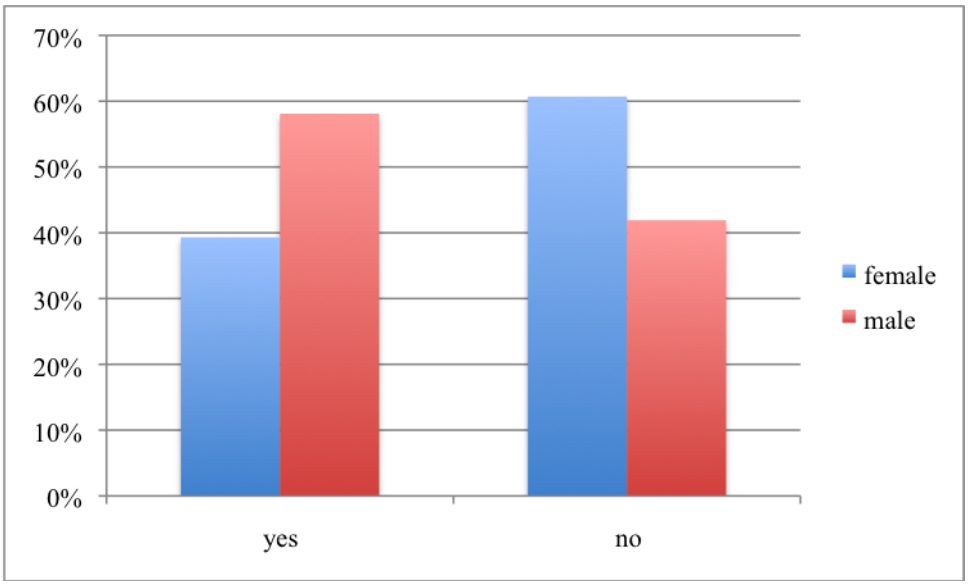

Figure 20. "Gender differences and family conversation partner” (N=216)

About 42 % (N=77) of the patients prefer to assign the decision about ICD deactivation to their partner. This is significantly linked (p=0.005) to patient gender: Figure 21 shows, that 47.2 % (67/142) of the male ICD patients and 23.3 % (10/43) of the female ICD patients prefer to assign the decision about ICD deactivation to their partner.

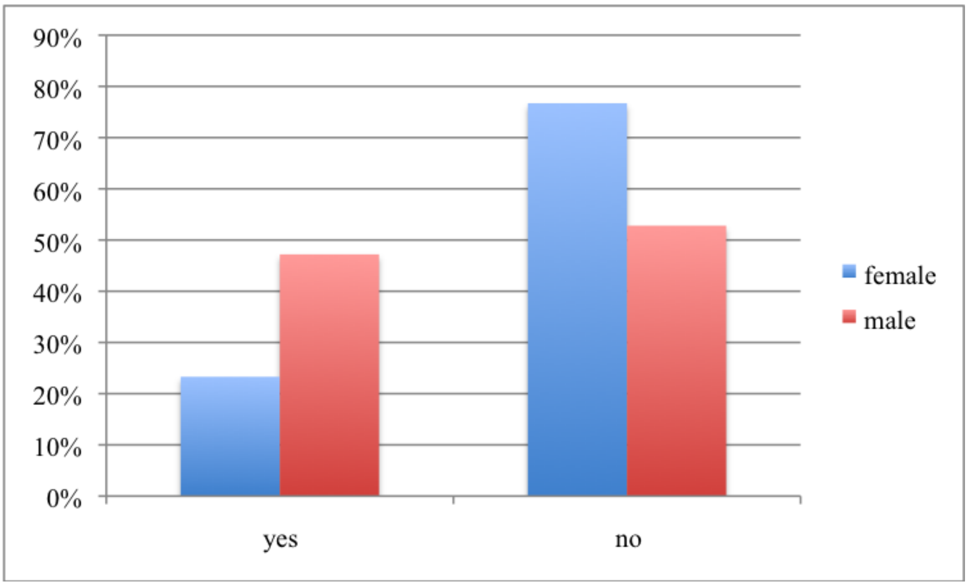

Figure 21. "Gender differences and decision maker" (N=185)

4.3.3 Differences with ICD therapy duration

Issues of dying with their ICD were considered by 51 % (N=113) of the patients. Figure 22 shows that of the patients with an ICD in situ for $\geq$ 4 years only 69.4 % (86/124) had considered issues related to dying with an ICD compared to 85 % (68/80) of the patients with an ICD in situ for < 4 years (p=0.011).

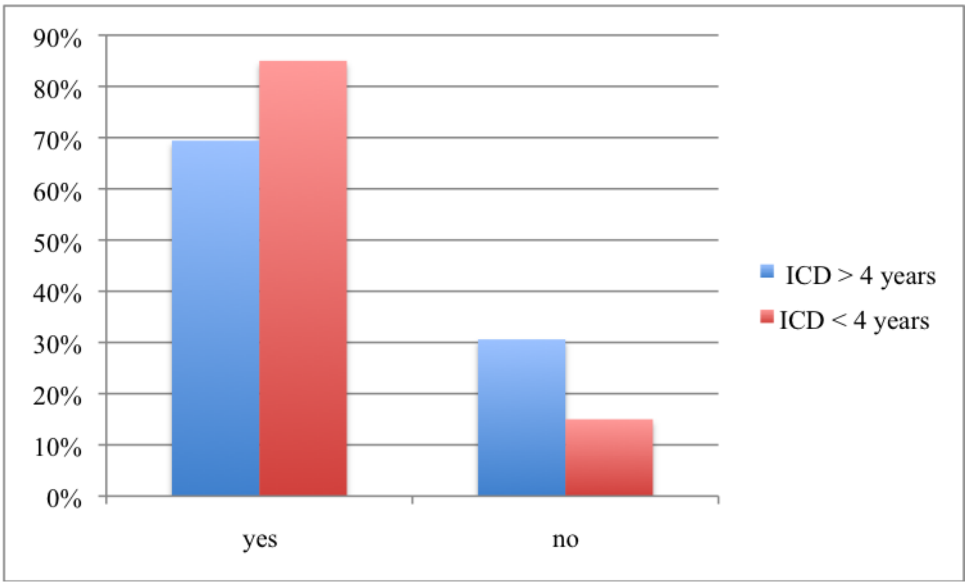

Figure 22. "Therapy duration and awareness" (N=204)

Only about 13 % of the patients (N= 27) had approached their physician or cardiologist regarding end of life issues. This behavior is linked (p = 0.002) to ICD therapy duration: Figure 23 shows that patients with longer duration of ICD therapy were less likely to be proactive in communicating with their physician. 22.8 % (18/79) of the ICD patients with an ICD for less than 4 years and only 7.4 % (9/122) of the patients with an ICD for 4 years and longer took the initiative and approached their physician regarding this topic.

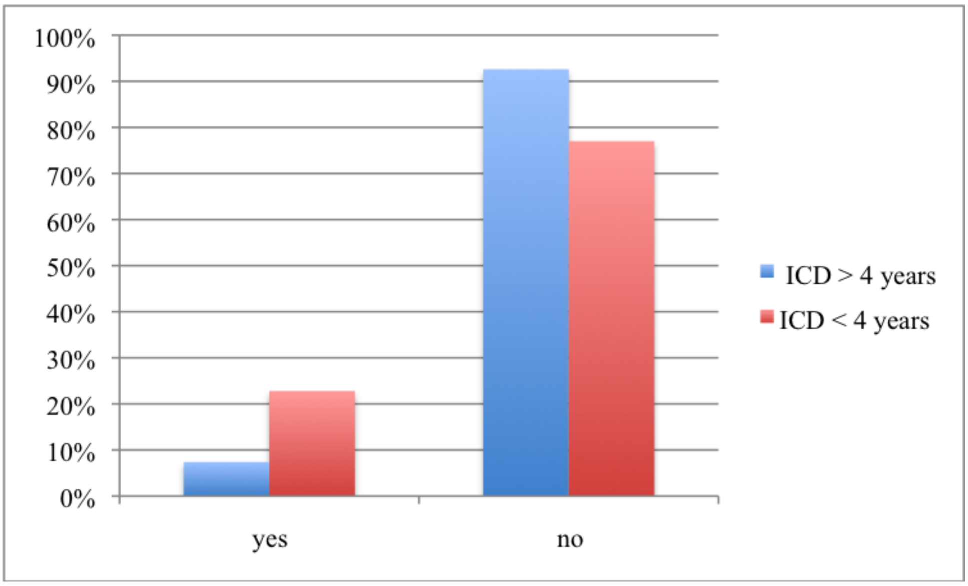

Figure 23. "Therapy duration and patient proactiveness" (N=201)

4.4 Associations

4.4.1 Patient problem awareness, physician/patient communication and patients' attitudes and preferences

Pearson's χ^2-test was used to identify relationships between patient problem awareness, physician/patient communication and patients' attitudes and preferences regarding the management of the ICD at the end-of-life. The most relevant two-group comparisons were calculated. An overview of all significant results can be found in Appendix, 7.6. The following result section was divided in subject areas.

Association between communication and awareness

Table 4 shows that physician/patient interaction and patient problem awareness are related. Pearson's χ^2-test identified those factors associated with positive physician/patient interaction. More specifically, patients who have had a conversation regarding ICD deactivation clearly are aware of the ICD deactivation option (p=0.006) and the issues regarding dying with the ICD (p=0.001). Patients who have had some form of communication with their physicians about ICD deactivation also turn to other available parties for exchange about the issue, including other ICD patients in the same situation (p=0.006), and are interested in receiving more information via the world-wide-web (p=0.021).

Table 4: *Factors associated with communication*

Patients who had a conversation with their physician…	***p-value***
talked to other ICD patients.	0.006
considered further issues related to dying with an ICD.	0.001
are aware of ICD deactivation.	0.006
wish to obtain further information via the internet.	0.021

Associations between awareness and preferences

Being aware of ICD related issues, i.e. knowing of the ICD deactivation option and having considered issues related to dying with the ICD clearly has an impact on patients' preferences as to when decisions about ICD deactivation issue should be considered or made. Table 5 shows that, patients who were aware of the ICD deactivation option agreed to include their decision about ICD deactivation in the Advance Directive (p=0.004). Results on when those patients wanted to discuss this issue disclose that patients see a difference between general discussion and information and the eventual need to make a decision: some patients attempt to avoid any discussion until necessary during a life-threatening situation (p=0.024), whilst some patients clearly see the need to discuss ICD deactivation as early as at the time of establishing the ICD indication (p=0.037).

Table 5: *Factors associated with patient awareness*

Patient who were aware of ICD deactivation and had considered issues related to dying with an ICD…	***p-value***
wanted to include their decision about the issue in the Advance Directive.	0.004
preferred to avoid a discussion until a life-threatening situation occurs.	0.024
wished to talk about the issue as early as indication but before implantation.	0.037

The quality of interaction with physician

The interaction between patient and physician was further analyzed from two perspectives: patients who were proactive in communication and who approached their physicians to discuss ICD management at the end-of-life and those patients, who perceived barriers in conversations.

Patient proactiveness

Table 6 shows the associations with patient proactiveness: Patients who had approached their physician to talk about ICD end-of-life related issues considered their physicians less well informed (p < 0.0001), potentially inadequate as a source of information resulting in a need to discuss with other interested parties, such as other ICD patients (p=0.001), their general practitioner (GP) (p=0.005) and even consulting a psychologist (p=0.022). Further, those patients preferred their physicians to take the initiative in providing the essential information about ICD management at the end-of-life to them (p=0029).

Table 6: *Factors associated with patient proactiveness*

Proactive patients (patients who approached their physician)…	***p-value***
wanted their physician to approach them and teach them (increased pro-activeness).	0.029
believed their physician lacks information.	0.0001
preferred to further talk with a psychologist.	0.022
wished to further discuss issues with their GP.	0.005
wished to further discuss issues with other patients.	0.001

Perceived barriers in conversations

As Table 7 shows, some of those patients, who reported, that it was impossible to initiate discussions with their physician, considered their relationship with the physician insufficiently comfortable (p= 0.04). ICD patients who have barriers in communicating with their physician associated ICD deactivation with suicide (p= 0.001) and voiced the wish to discuss the issue with other ICD patients (p = 0.048).

Table 7: *Factors associated with perceived barriers in conversation*

Patients with barriers in communication…	***p-value***
associated ICD deactivation with suicide.	0.001
did not consider the relationship with their physician sufficiently comfortable.	0.04
wished to communicate with other ICD patients.	0.048

Unmet information need

Results from this study emphasize the high unmet need for information amongst ICD patients. Table 8 confirms, that patients with a need and willingness to be informed wished to discuss the issue consistently throughout the process of ICD therapy ($p < 0.0001$). Interested ICD patients wished to obtain information from their physician ($p < 0.0001$) and further consolidate their knowledge by talking with other ICD patients about the issue during in-group discussions ($p < 0.0001$).

Table 8: *Factors associated with patient information need*

Patients who considered ICD management at the end-of-life important…	***p-value***
wish to discuss the issue throughout the process of ICD therapy.	0.0001
wish to obtain the relevant information from their physician.	0.0001
wish to obtain further information about the issue via in-group discussions with other ICD patients	0.0001

ICD patients with a high information need, i.e. those who would have liked to be informed, stated, that the physicians lacked time to discuss the issues of ICD management at the end-of-life with them ($p = 0.001$).

Another association highlights the importance of physicians being adequately trained about ICD management at the end-of-life: Patients who believed, that their physicians had insufficient information about the issue of ICD management at the end-of-life, were not proactive in initiating a discussion on end-of-life issues and rather engaged in conversations with other ICD patients about the issue ($p = 0.021$).

4.4.2 Relationship between Communication and Awareness

The relationship of “Patient problem awareness” and “communication with the physician” was analyzed using Pearson’s χ^2-test. In order to conduct this analysis, the two constructs were categorized (see 3.6) into two subsets. The result did not reach statistical significance (p=0.059), yet shows a trend which may still be of clinical value: Communication with the physician increased patient problem awareness by 10 %, as shown in Table 9. The vast majority (91 %) of those ICD patients “not aware” of the issue of ICD deactivation had not communicated with their physician at all. Of those patients who were “aware”, 18 % had communicated with their physician (Table 9).

Table 9: *Relationship between awareness and communication*

			Communication		Total
			No	Yes	
Awareness	No	Count	79	8	87
		% within awareness	90.8%	9.2%	100.0%
		% within communication	24.8%	13.6%	23.1%
	Yes	Count	239	51	290
		% within awareness	82.4%	17.6%	100.0%
		% within communication	75.2%	86.4%	76.9%
Total		Count	318	59	377
		% within awareness	84.4%	15.6%	100.0%
		% within communication	100.0%	100.0%	100.0%

4.5 Binary Logistic Regression

Binary logistic regression was used to detect associations in a multivariate analysis. The wish to include a decision about ICD deactivation in the Advance Directive was set as the dependent variable. Patient characteristics and "patient problem awareness" were used as independent values. For the binary variable "no" was coded as 0.

ICD deactivation decision and Advance Directive

Table 10: *Logistic regression for Advance Directive*

Variable	OR	95 % CI for OR		p-value
		Lower Bound	Upper Bound	
Age	**1.045**	**1.005**	**1.087**	**0.029**
Male gender	0.894	0.379	2.110	0.798
Living alone	0.912	0.357	2.332	0.848
Working full-time	**5.913**	**1.083**	**32.277**	**0.040**
ICD therapy duration	1.020	0.930	1.119	0.668
Problem awareness	**2.582**	**1.153**	**5.775**	**0.021**

Note. Bold numbers highlight the associated variables, odds ratios (OR), confidence intervals (CI) and the significant p-values.

With each increasing year of ICD patients' age, the chance of wanting to include the decision about ICD deactivation in an Advance Directive increases (p=0.029, OR=1.045). Thus, older people are more likely to be aware of the option to put down a decision on ICD deactivation in their Advance Directive.

Patients with a full-time job were 5.9 times more likely to include their decision about ICD deactivation in their Advance Directive than patients who were retired (p= 0.040, OR=5.913).

Further, patients considered as “aware” of the ICD deactivation issue were 2.5 times more likely to include a decision about ICD deactivation in their Advance Directive than patients who were “not aware” (p=0.021, OR=2.582). This finding confirms the expected relationship between awareness and patients’ wish to include a decision about ICD deactivation in their Advance Directive

5. Discussion

Issues related to ICD deactivation do not yet form an integral part of ICD therapy, neither during nor early in the ICD treatment process. As trivial as it may sound, patients with an ICD in situ are going to reach end-of-life at some point. In preparation for this, decisions have to be made as to when, how and with whom the decision-making process for potential ICD deactivation should be discussed. A decision should be made before the patient reaches the end of life. The goal of this study was to identify ICD patients' perceptions and attitudes toward end-of-life issues in order to integrate those into the treatment concepts and eventually improve their long-term care and treatment. Other available research in this field has left some gaps: the degree of awareness and the perceptions ICD patients have of the end-of-life and ICD deactivation issues, the degree and quality of communication they have or desire, and the appropriate mode and timing of confronting and informing patients about dying with an ICD. Although the patients' opinions are subjective and perceptual, they are real to them and therefore important for a better understanding of how patients perceive their situation.

5.1 Patient sample

In this questionnaire-based study, 394 patients receiving ICD therapy, either for primary or secondary indication, were included. Registered members (ICD patients) of regional ICD support groups, received the study questionnaire from their support group leader. Although the response rate was rather low with 29 %, the patient sample of this questionnaire-based study is the largest on ICD management at the end-of-life and forms a valid basis for analysis. Five questionnaire-based studies in this field were available at the time (Dodson et al., 2013; Herman et al., 2013; Kramer et al., 2011; Stewart et al., 2010; Pedersen et al., 2013) with sample sizes ranging from 95 patients (Dodson et al., 2103) to 311 patients (Kramer et al., 2011). In this study, 74% of the participants were male. The mean age of the patients was 69 years (±10.4). The distribution of gender and mean age of the participants is comparable to other studies reporting mean ages from 50 years (Kramer et al., 2011) to 71 years (Dodson et al., 2013). There are more males than females among the participants throughout the questionnaire-based studies reported, ranging from 53 % (Kramer et al., 2011) to 84 % (Herman et al., 2013). This reflects the higher overall numbers of male ICD carriers as well as the higher proportion of male patients receiving cardiovascular interventions worldwide. Discussion of the results will be divided in three sections: patient problem awareness, patient/physician communication and patients' preferences and attitudes.

5.2 Patient problem awareness

According to Quill (1994) the patient must be aware of his condition and all therapeutic options, before making a decision about ICD deactivation. This statement emphasizes the necessity that ICD patients be well aware of the full scope of implications of ICD therapy, its benefits and potentially adverse effects, in particular including the downsides of adverse ICD activity during patients' end stage of life.

A small majority of patients (60 %) in this study considered themselves aware of the ICD deactivation option. Yet, only about half (52 %) of the patients had considered issues related to dying with an ICD. This difference may imply that those aware of deactivation are not necessarily following through the fact that death might occur faster after deactivation of the device. In other studies, patient problem awareness regarding ICD management at the end-of-life similarly ranged from 38 % (Raphael et al., 2011) to 68 % (Pedersen et al., 2013). However, lower rates of awareness have been reported earlier: Kirkpatrick et al. (2011) found, that 86 % of the patients had never considered actions in case of terminal illness. Kobza and Erne (2008) reported, that none of the interviewed patients knew of the ICD deactivation option. The increasing general recognition of the clinical and scientific relevance of the subject, as shown by the increasing frequency of publications, is likely to be paralleled also by an increasing level of patient problem awareness of ICD patients.

Analysis of patient characteristics shows that more ICD patients younger than 70 years knew about the ICD deactivation option (64 % versus 46 %), compared to those 71 years and older. An explanation could be, that older patients may have already had these discussions and were able to “park” the issue, or because they had developed a degree of complacency about having such a device. At the same time this finding may also imply, that the preoccupation with ICD management at the end-of-life should begin early in the treatment process, as with increasing age, patients might be dealing with comorbidities and other circumstances occupying their time, mind and energy. The concern about ICD deactivation-related issues was greater amongst female patients (66 % versus 46 %). One reason may be, that women in general are less hesitant to discuss their own health-related issues. Male ICD patients should therefore be motivated towards adopting a more interactive role throughout the therapeutic process. Another notable result: ICD patients were more aware about ICD management at the end-of-life if they were fairly “new” to the ICD situation (ICD < 4 years). Those patients may still be more receptive to information and motivated to learn about the therapy and related issues. Also, their increased awareness will make them more likely to seek further communication on the issue. If the presumably lower rate of ICD shocks in the patients with shorter ICD therapy duration plays a role remains unclear, and cannot be derived from our data.

Patients who were aware and who had considered issues related to dying with the ICD were willing to include their decision about ICD deactivation in their Advance Directive. However, the results mirror insecurity about the adequate timing for discussion of ICD deactivation and related issues. In summary, the analysis of the responses related to awareness and its influencing factors emphasize the importance of an early integration of the end-of-life management issues, in particular, ICD deactivation, into the process of ICD therapy.

5.3 Interaction between patient and physician

The authors of the consensus statements make a case for proactive communication initiated by the clinician to avoid ethical and legal dilemmas as well as unnecessarily stressful and painful situations at the end-of-life (Lampert et al., 2010; Padeletti et al., 2010). Former studies and the present results show, that communication about ICD management at the end-of-life between the physician and the ICD patient is deficient. It may not take place at all or be of insufficient quality. This may be a consequence of the low level of knowledge and problem awareness of both, the physician and the patient. Yet, initiating any end-of-life discussion in seriously ill patients (including ICD patients at the end-of-life) presents a challenging problem, “addressing the elephant in the room” (Quill, 2000). The challenge may be different yet not less, when the patient is not facing imminent death but is at high risk and therefore receiving device treatment (ICD), as is the case with many ICD patients at the time of establishing the indication for ICD therapy.

An astoundingly low percentage (6 %) of the ICD patients reported having discussed the issue of dying with an ICD with their physician, and only a small proportion (18 %) with other ICD carriers. But, as shown in this study, 76.7 % would have liked their physician to teach them about the issue and 76.9 % confirmed the value that this issue had to them. Only a small number of patients (13 %) had proactively approached their physicians about the end-of-life issue and even fewer (7 %) reported that their physician had approached them to discuss ICD management at the end-of-life. These findings confirm the “lack of communication” as mentioned in earlier studies (Goldstein et al., 2004; Goldstein et al., 2007; Kirkpatrick et al., 2011). Recently Herman et al. (2013) found, that of 109 surveyed patients only 7 % had discussed ICD deactivation and related issues. However, in a study

(Kobza & Erne, 2008) conducted with patients diagnosed with a malignant tumor, the option of ICD withdrawal was discussed with 75 %, suggesting that serious comorbidity and the perspective of imminent death might enforce the discussion of ICD deactivation.

No studies have so far investigated the factors that may influence physician/patient communication. More than half (63 %) of the surveyed patients felt that physicians lacked the time to communicate. This opinion is more frequent amongst female ICD carriers. High patient flow and time pressure may not allow “space” for (time consuming) personal discussions on delicate issues like end of life ICD management. Female ICD patients may have a more accurate perception of those circumstances. In this study the female patients were more inclined to talk with their cardiologist than the male patients (71.4 % versus 55.6 %). ICD patients reported their relationship with their physician to be insufficiently comfortable to raise the issue of ICD deactivation. ICD patients believed, that the relationship to their physician was lacking “depth” required for such delicate discussion and, as a result, they preferred to talk with other ICD patients about this issue. ICD patients, who proactively had approached their physicians to discuss ICD management, reported that their physicians were not supplying sufficient information. Again, consequently, patients engaged in communication with other ICD patients and showed interest in talking to their general practitioner or psychologist.

Time constraints, lack of information regarding this topic as well as insecurity about the ethical aspects, were all identified in earlier studies to be reasons for insufficient communication. Physician reticence may be explained by a lack of experience in dealing with ICD deactivation and end stage disease (Hauptman, Swindle, Hussain, Biener & Burroughs, 2008). Another physician survey reported that physicians are willing to discuss Advance Directives and Do Not Resuscitate orders (DNR) with patients who have either progressive incurable or terminal disease, but not for ICD deactivation (Kelley at al., 2009). The lack of legislation or guidelines on introducing such discussions as “standard of care” coupled with lack of experience with this relatively new therapeutic concept as ICD therapy represents (Kelley at al., 2009; Kelley, Eliassen, Stocker & Hnatiuk, 2002; Morrison et al., 2010) are considered reasons for the deficits of physician led discussions regarding end-of-life ICD management (Lipman, 2007). Physicians were found to be more uncomfortable discussing ICD deactivation as compared to life-sustaining therapies (Kramer et al., 2010). In order to eliminate communication barriers of physicians, physician studies may help to better identify the reasons. Educational programs for physicians and standardized processes and structured guidelines will lead to an integration of the ICD management at the end-of-life into the treatment process, thereby facilitating the communication between patient and physician. If necessary, medical coaches or other trained health-care professionals could be installed to initiate personal conversations with the ICD patients tailored to their needs

In this study, patient barriers to communication only existed in 15 % of the ICD patients. Communication barriers of patients have great impact: ICD patients who perceived barriers in communicating with their physician associated ICD deactivation with committing suicide. Patients who did not have access to communication with their physician may have adopted a distorted perception of the justification of ICD deactivation and hence approached other ICD patients or other sources risking false information.

Decision making on ICD deactivation can pose a dilemma to patients and care takers involved, as a number of case studies have shown. The dilemma might be solvable: This is the first study to report a significant relationship between physician/patient communication and patient problem awareness. Patients who had discussed ICD management with their physician were found to be aware of the ICD deactivation option, had considered relevant issues about dying with the device, and had even extended the communication to the circle of their group-members. Further, ICD patients who had received information from their physicians also retrieved information from the world-wide-web. This finding implies that an initial introduction to the topic might be motivation for patients to seek further information to consolidate their understanding of the problem.

Adequate communication about end-of-life issues is fundamental in the management of end- of-life conditions including shared-decision making for patients, families, and caregivers. “Adequate” in this context means thorough engagement with the end-of-life and ICD deactivation issues, yet individualized to patients’ needs and personality. The process of decision making is individual to each patient and can change over time. For this reason the process should be ongoing during the duration of ICD therapy, and patients should receive the time and attention they require. The communication between physicians and patients and their families must include all relevant information to meaningfully assist the joint (shared) decision-making process (Steinhauser et al., 2000). Communication is an integral aspect of shared decision-making (SDM) in patient-centered care. Only recently, greater use of SDM has been encouraged in order to “ensure that medial care better aligns with patients’ preferences and values” (Lee & Emanuel, 2013). SDM is a collaborative ongoing process in which physicians and patients join forces to make choices about the patient’s health and disease management, including end-of-life issues. Taking into consideration patient preferences, psycho-social aspects and the best available evidence, the physicians propose and discuss management options, including the communication of risks and benefits, verifying the patient’s understanding about decisions which have to be made (Allen et al., 2012). Limitations of SDM occur only when patients can no longer actively participate in the decision making process due to cognitive impairment or, in other cases, when patients prefer to leave the decision “in the doctor’s hands”. (Loh, Simon & Kriston, 2007; Allen et al., 2012; Coylewright, Montori & Ting, 2012). In the context of this study, in-depth communication is a prerequisite for SDM, which again is the basis for improved and more patient-centered end-of-life care, thus specifically including ICD patients in the decision making about ICD deactivation.

5.4 Patient preferences on timing and mode of confrontation with end-of-life issues

Patients were asked about their preferences as to when, how and by whom the issues of ICD management at the end-of-life should be communicated. About half (41 %) of the surveyed ICD patients wished to be challenged with the issue before implantation, whilst the other half (42 %) preferred to avoid any discussion about ICD deactivation until the end-of-life situation. This result highlights the potential disconnect between what constitutes “discussion” and what might be preempting the need for making a decision. The choice of the appropriate moment to discuss “dying with the ICD” and making a decision may represent a dilemma. Until patients are facing end-of-life from an underlying irreversible illness, deactivation of the ICD remains too theoretical. Patients need support with this decision. Timely clarification of the possible downsides of the ICD therapy should enhance patients’ understanding. Former patient studies confirm our results: 40 % of patients in a study by Raphael et al. (2011) and 49 % in a recent study by Pedersen et al. (2013) wished discussion to take place before implantation, while more recent studies found that only 21 % wished to raise the issue early and 55 % of the studied patients preferred to postpone the issue to the end-of-life. Although recent recommendations recommend careful and timely communication about ICD deactivation (Dunbar et al., 2012) and emphasize shared decision-making specifically in ICD deactivation (Allen et al., 2012), the ICD patient’s unmet information need was rarely taken into consideration. The information need of patients regarding ICD management at the end-of-life is high and is, to date, not being met: Results of this present study show that 77 % of the participants considered the issues of ICD management at the end-of-life important to them, 76 % wished to receive all relevant information from their physician or cardiologist and discuss ICD deactivation related issues with either of them.

These findings on patient information need corroborate with the literature: Raphael et al. (2011) and Pedersen et al. (2013) showed ICD patients to have high information need: Almost all patients wished to be included in the decision making process and to receive all relevant information about the topic (84 % and 95 %). Further, patients who considered ICD management at the end-of-life important agreed to discuss the issue at some point during the course of care and indicated their preference for receiving all pertinent information from their physician and via in-group discussions with other ICD carriers.

In case of severe illness, patients might have to delegate the decision about ICD deactivation. In this study, 63 % of the participants considered the decision about ICD deactivation to be a personal one. Nevertheless, almost half (41 %) of the patients agreed to assign the decision to their partner, in case of not being able to make it on their own. Male ICD patients are more likely to pass on such a decision to their partner/wife, than female ICD patients. The physician was chosen as the decision maker by 53 % of the patients. Goldstein et al. (2007) found in his study that 20 % of the sample population assigned decision making about ICD deactivation to their treating physician. Assigning such decision making to someone else, more qualified, can be a solution, which is acceptable for the patient and the family. It is a difficult decision to put on a family, unless the patient is unable to take it for him/herself. The questionnaire also tried to identify the patients' preferred conversation partner: The majority of the patients wish to receive information through their cardiologist (64 %). Kirkpatrick et al. (2011) reported similar results: 45% of the patients preferred the cardiologist as conversation partner, 31% the electrophysiologist. This finding was further differentiated by gender: More of the female ICD patients wished to talk with their cardiologist. Men were found to be more likely to talk to members of their family or their partner. Men do not seem to feel comfortable enough to lead a personal discussion about their fears and wishes for the end of their lives with their cardiologist. In general, ICD patients seem to rely on the competence of the physicians and on decisions made by or with family members. Asked about their preferences as to how they wanted to receive information on ICD end-of-life management, group discussions with other ICD patients was identified as the preferred communication channel by almost 70 %, followed by written information materials (55 %) and the internet (15 %). All of the surveyed patients are members of their regional support group program. Hence, educational sessions may be included into group meetings to educate patients about ICD management at the end-of-life. Problem awareness can thus be established, communication ensured and patients' high information need may be met. Pedersen at al. (2013) recently found that 62 % of the patients he had surveyed wished to be informed in written and oral forms. These results confirm that information about ICD deactivation and related issues has to be structured and passed on to the patients in a formal way. Such information should be made available to them early and continuously, by moderated in-group discussions, journals, presentations, at regular control meetings with their physician, or by information from the website of GDA and even computer programs particularly designed for their use and education.

5.5 Selected patient attitudes

The association between ICD deactivation and suicide was made by 42 % of surveyed ICD patients, reflecting a blurred perception of ethically related issues. Goldstein et al. (2007) reported similar findings in one of his early studies. There is insecurity among patients about the distinction of ICD deactivation from physician-assisted suicide, as shown by studies by Kramer et al. (2011) and Kirkpatrick et al. (2011): 17 % and 26 % associated ICD deactivation with induced death (physician-assisted suicide). The insecurities about ethical aspects and the legality of ICD deactivation may inevitably hinder decision making and cause a lack of consensus amongst ICD patients and families involved. The recommendation to patients and families to approach the issue of ICD management at the end-of-life when completing an AD seems appropriate. Not addressing end-of-life ICD management early in the treatment, i.e. prior to or at the time of implantation, or at the time of major changes in clinical status may lead to physically and psychologically more stressful situations in the end-of-life situation of the patient. Patients and physicians are encouraged to complete an AD and specifically address the ICD deactivation at the end-of-life (Lampert et al., 2010). ICD patients in this study approved this recommendation: 75 % of the participants felt ready to include their personal decision on ICD deactivation in an AD. This finding is in line with other results: Kirkpatrick et al. (2011) found that 95 % of the patients were eager to define their personal decision about ICD deactivation in their AD. However, other studies show that only about half of the patients had completed an AD (Tajouri et al., 2012; Kramer et al., 2011). This study also identified the independent associations with the patients' wish to include their decision about ICD deactivation in their AD: Increasing age, a full-time job and a high level of patient awareness were found to be predictors for including a decision about ICD deactivation in the AD. Presumably, younger patients are not yet "ready" to be dealing with end-of-life issues. Patients who are engaged in a full time job might be more receptive to media, such as journals, meetings and conferences and other sources reporting issues concerned with end-of-life care. A regular communication pattern at the work place might enhance their understanding of what is important and preserve the awareness of the issues associated with end-of-life. Psychological and educational aspects have been considered key in ICD management (Dunbar et al., 2012). Patients and their families need to cope with the various phases of the disease process, from diagnosis to various treatments, repeated decision making, device implantation, quality of life issues and psychological aspects, to, eventually, end-of-life decisions, such as ICD deactivation (Sears, Matchett & Conti, 2009). Ensuring awareness and confidence via structured communication and information, both timely and consistently throughout the ICD therapy, increases the chance of a quality of life at the end-of-life (=quality of death) and a bearable end stage of ICD patients.

5.6 Study limitations and strengths

This cross-sectional study has several limitations. No temporal associations can be established as the questionnaire was administered only at one point-in-time. The response rate (29 %) was mediocre. The fact, that this patient group was an “interested group” and not reached via a random public postal survey, shows, that many ICD patients appear to be unable or unwilling to discuss this issue, even anonymously, via a survey. No data on the patient demographics of the total of registered ICD patients in Germany as compared to the study sample are available. So, even though rather unlikely, there may be a selection bias, which could not be avoided.

The study was exploratory in nature, and the questionnaire used was not built on validated constructs. The survey instrument was novel and developed by the investigators for the purpose of this study only. The wording of the questionnaire and respective instructions might have influenced the responses of the participants and need to be revised before applying it again to another patient group. The preliminary actions taken to increase the response rate (oral presentations, visits to support groups, articles) may have influenced the level of awareness of the patients prior to filling out the survey. By the time of completing the questionnaire most patients most likely had heard of the option of ICD deactivation.

A further limitation respective the development of the questionnaire is, that due to the individual character (e.g. older age, severe comorbidities) of this patient group, the questionnaire had to be kept simple in wording and setting. This was also the wish of the CEO of the GDA who participated in the organization of the survey. Patients who carry an ICD for secondary prevention are highly traumatized patients. Therefore the introduction of the issue of ICD management at the end-of-life is delicate, as it may, in some way, contradict the life-sustaining and life-prolonging primary goal (and patients’ expectation)of the ICD therapy. Most of the ICD patients suffer from severe cardiac diseases, but, the participants in this study were not hospitalized or part of a hospice program. Therefore the results may not be representative for all ICD patients. Responses could possibly have been influenced by depression or other psycho-affective disorders and a depression score was not covered in the survey. The study is the largest questionnaire-based study in this field to date. The patient sample is unselected in that patients are not recruited from a single institution. One other strength of this study is the focus on patient problem awareness and factors influencing it, as well as the correlates between awareness, physician/patient communication and patient preferences which, so far, have not been investigated.

5.7 Future research

“Initiative for the improvement of long-term care and treatment of ICD patients” and “End-of-Life ICD management” continued

The data and experiences from this study could feed into the objective of continuing the “Initiative to improve the long-term treatment of ICD patients”. Further research should focus on the perception of ICD patients on their quality of life, the prevalence of depression and anxiety scores possibly influencing patient opinion on end-of-life management issues. The differentiation between the “need to know” and “ the need to act” could also be looked at specifically. The role of partnership and the involvement of the partner in the process of ICD therapy deserve attention. The impact of the “symptom burden” and “illness intrusiveness” of ICD patients on the treatment course and treatment satisfaction also represents a topic of interest for further studies. A fruitful further line of enquiry could be the collection of physicians’ opinion comparing it to those of the patients, thus uncovering the disconnections between the two. The questionnaire designed for this study, was set out to determine patient awareness and patient opinions and attitudes related to ICD management at the end-of-life. Further investigations could investigate the determinants of “ valuable communication” for patients and physicians regarding ICD deactivation. Also, studies should further investigate needs of ICD patients and more specifically, perform a comprehensive evaluation of psychosocial needs of such patients including both qualitative and quantitative methods. As a consequence of this study, appropriate material for patient information should be designed and introduced into routine use with ICD candidates. The impact of such routine information strategy is then to be measured by a questionnaire similar to the present study.

5.8 Conditions for improved ICD care

The dominant prerequisite for improved care is an increased knowledge and problem awareness of patients and physicians, as well as family members. Appropriate education and information of these groups about the issues of ICD management at the end-of-life is required. A relevant factor in improving the treatment of ICD patients is to ensure that communication between physician and patient takes place timely and continuously. Patients do expect to be informed and educated about the possible downsides of the ICD therapy. Physician involvement and their initiative to communicate about end-of-life management of the ICD are insufficient. As results of this study show ICD patients are open and willing to obtain information about ICD management at the end-of-life. Guidelines should be developed and formulated with the goal to not only recommend but also "drive" physicians to timely and appropriately raise the issue of ICD management at the end-of-life and discuss important and related issues with their patients.

Considering the high level of unmet patient information need, clinicians should take responsibility for developing a comprehensive end-of-life care plan as part of shared decision-making. Development of specific counseling programs and improved and standardized concepts for patient information will still require more knowledge on ICD patients' needs.

Timely discussion of ICD deactivation related issues and, if required, specialized consulting could result in an appropriate strategy to deactivate an ICD during the irreversible course of a progressive disease, thereby avoiding unnecessary trauma for the terminally ill ICD patient. The formal character of the Advance Directive offers an opportunity to discuss the issue of deactivation proactively at the time when other preferences surrounding the end-of-life stage are being addressed. If the ability (e.g. for time constraints or lack of patient-physician relationship) or willingness of physicians to cooperate in an initiative for improved patient information is insufficient, other professionals could be installed. Any effort has to be made to ensure a basis for shared decision-making (SDM).

Enhancing problem awareness of patients may be achieved by adjunctive measures: An information leaflet associated with the patient consent for ICD implantation may introduce the issue of end-of-life management at an early stage and trigger further and continuous interest in the topic. Discussions about the end-of-life issues should become an integral part of the in-group meetings offered by the GDA. Brochures and other printed material as well as the GDA website may also direct patients' attention to this most relevant and important issue.

6. Conclusion

Sudden cardiac death (SCD) is an important health issue. ICD therapy is the most effective treatment to prevent SCD. The indications for ICD implantation have expanded and the rate of ICD implantations increases, consequently the number of ICD carriers. This development has not been paralleled by an appropriate and patient-centered care plan before and after device implantation.

ICD patients will eventually reach end-of-life carrying an ICD. The ICD is life-saving in its primary role and commonly seen as a life-sustaining treatment, while it may loose this role at the end stage of life. Rather it may become contraproductive and render an otherwise peaceful dying process in a traumatizing one due to unnecessary shock delivery. Therefore, the option of ICD deactivation becomes important. ICD deactivation at the end-of-life and its associated questions are neglected issues, the relevance of which appears to be underestimated by patients and physicians. Decision about ICD deactivation may pose a dilemma to patients, families and physicians involved with the patient. This is owed to limited knowledge about the ICD therapy, unpreparedness of institutions for ICD patients needing special attention, lack of problem awareness of ICD management at end-of-life with patients and physicians and insecurities about ethical and legal issues.

Not every ICD patient will be confronted with either adequate or inadequate shock therapy during the end stage of life (Carlsson, Paul, Dann, Neuzner & Pfeiffer, 2012). Nevertheless, the issue of ICD deactivation must be introduced into the treatment process. Data on attitudes and knowledge on ICD deactivation at the end-of-life is scarce. Patient awareness regarding the issue of ICD management is generally low, patient information need very high. ICD patients are eager to be involved in the decision making process and only a few perceive barriers in discussing such issues with their physicians.

From this exploratory study it can be concluded, that both patient and physician knowledge and awareness of the issues surrounding ICD deactivation at the end-of-life are insufficient and/or inadequate for informed consent and shared decision-making and have to be markedly improved. Implementing specific guidelines appears mandatory.

Dialogue with ICD patients about the question of ICD deactivation at the end-of-life is warranted and should ideally occur as early as at the time of establishing the indication for ICD implantation. Comprehensive information needs to be given to ICD candidates on the potential trade-off between reduced risk of sudden arrhythmic death and increased risk of hospitalization, risk of prolonged death and decrease in quality of life at the endstage of life.

In order to avoid deactivation-associated dilemmas, patients should be encouraged to engage in advance care or counseling programs including a timely completion of an Advance Directive (AD) with device specific statements. The study shows that ICD patients are willing to complete such an AD.

This study, the largest and most representative questionnaire-based patient survey so far, fills research gaps with respect to patient problem awareness about dying with an ICD and patient information need on this “end-of-life issue”. It adds to the understanding of ICD patients’ attitudes and preferences. The results may be the basis for structuring an improved patient-centered care of ICD patients and specific and more binding practice guidelines.

7. Appendix

7.1 List of abbreviations

AD	Advance Directive (living will)
ICD	Implantable Cardioverter-Defibrillator
CEO	Chief Executive Officer
CRT	Cardiac Resynchronization Therapy
CRT-D	Cardiac Resynchronization Therapy-Defibrillator
DNR	Do-Not-Resuscitate
GDA	German Defibrillator Association of Support Groups
EHRA	European Heart Rhythm Society
GP	General Practitioner
HRS	Heart Rhythm Society
RSG	Regional Support Group
SCD	Sudden Cardiac Death
SD	Standard Deviation
SDM	Shared-Decision Making
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia

7.2 List of figures

7.3 List of tables

7.4 Questionnaires used in this study

Initiative zur Verbesserung der Routineberatung und der langfristigen Betreuung von Defi-Patienten

Patienten-Daten

Gruppennummer: ☐☐☐☐ **Teilnehmernummer:** ☐☐☐

Zu Ihrer Person...	
Bitte geben Sie ihr Geburtsjahr an:	☐☐☐☐
Geschlecht:	☐1 weiblich ☐2 männlich
Sie leben... **(Mehrfachnennungen möglich):**	☐1 alleine ☐2 mit Ihrem Partner zusammen ☐3 in einer sozialen Einrichtung ☐4 mit Ihren Kindern unter einem Dach
Sind Sie berufstätig?	☐1 ja, voll berufstätig ☐2 ja, Teilzeit beschäftigt ☐3 nein, frühberentet ☐4 nein, berentet/pensioniert ☐5 nein, aus sonstigen Gründen

ICD-Gerätedaten

Firma:______________________ Modell:______________________

Implantation: am ☐☐.☐☐.☐☐ Aggregatwechsel: am ☐☐.☐☐.☐☐

Vorhofsonde: ja nein

Risikofaktoren

1= med. behandelt
2= vorhanden
3= nein

	1	2	3
Bluthochdruck	☐	☐	☐
Fettstoffwechselstörung	☐	☐	☐
Diabetes Mellitus	☐	☐	☐
Rauchen	☐	☐	☐
Familiäre Belastung	☐	☐	☐
Übergewicht	☐	☐	☐

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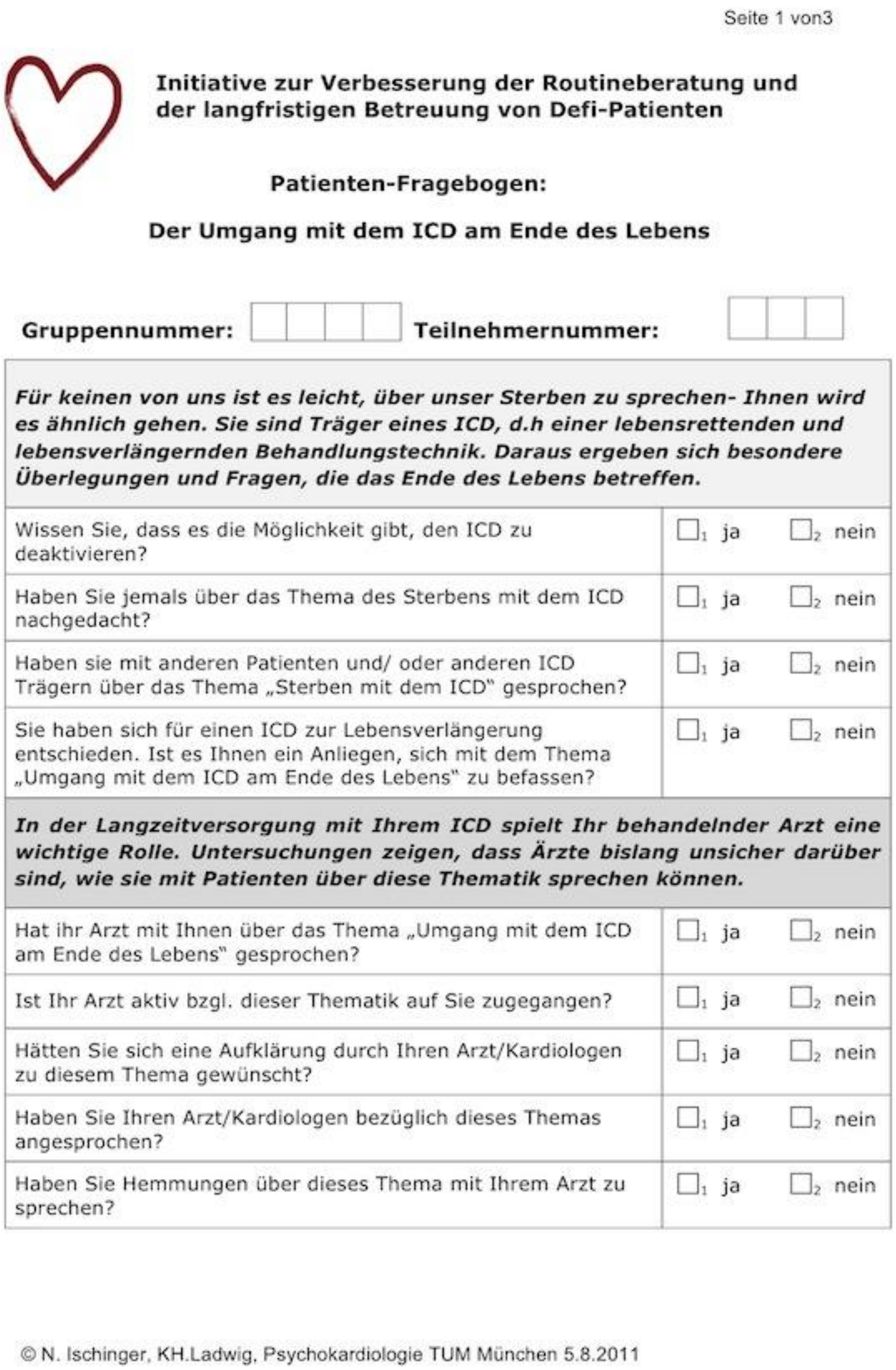

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Initiative zur Verbesserung der Routineberatung und der langfristigen Betreuung von Defi-Patienten

Patienten-Fragebogen:

Der Umgang mit dem ICD am Ende des Lebens

Gruppennummer: ☐☐☐☐ **Teilnehmernummer:** ☐☐☐

Für keinen von uns ist es leicht, über unser Sterben zu sprechen- Ihnen wird es ähnlich gehen. Sie sind Träger eines ICD, d.h einer lebensrettenden und lebensverlängernden Behandlungstechnik. Daraus ergeben sich besondere Überlegungen und Fragen, die das Ende des Lebens betreffen.

Wissen Sie, dass es die Möglichkeit gibt, den ICD zu deaktivieren?	☐$_1$ ja	☐$_2$ nein
Haben Sie jemals über das Thema des Sterbens mit dem ICD nachgedacht?	☐$_1$ ja	☐$_2$ nein
Haben sie mit anderen Patienten und/ oder anderen ICD Trägern über das Thema „Sterben mit dem ICD" gesprochen?	☐$_1$ ja	☐$_2$ nein
Sie haben sich für einen ICD zur Lebensverlängerung entschieden. Ist es Ihnen ein Anliegen, sich mit dem Thema „Umgang mit dem ICD am Ende des Lebens" zu befassen?	☐$_1$ ja	☐$_2$ nein

In der Langzeitversorgung mit Ihrem ICD spielt Ihr behandelnder Arzt eine wichtige Rolle. Untersuchungen zeigen, dass Ärzte bislang unsicher darüber sind, wie sie mit Patienten über diese Thematik sprechen können.

Hat ihr Arzt mit Ihnen über das Thema „Umgang mit dem ICD am Ende des Lebens" gesprochen?	☐$_1$ ja	☐$_2$ nein
Ist Ihr Arzt aktiv bzgl. dieser Thematik auf Sie zugegangen?	☐$_1$ ja	☐$_2$ nein
Hätten Sie sich eine Aufklärung durch Ihren Arzt/Kardiologen zu diesem Thema gewünscht?	☐$_1$ ja	☐$_2$ nein
Haben Sie Ihren Arzt/Kardiologen bezüglich dieses Themas angesprochen?	☐$_1$ ja	☐$_2$ nein
Haben Sie Hemmungen über dieses Thema mit Ihrem Arzt zu sprechen?	☐$_1$ ja	☐$_2$ nein

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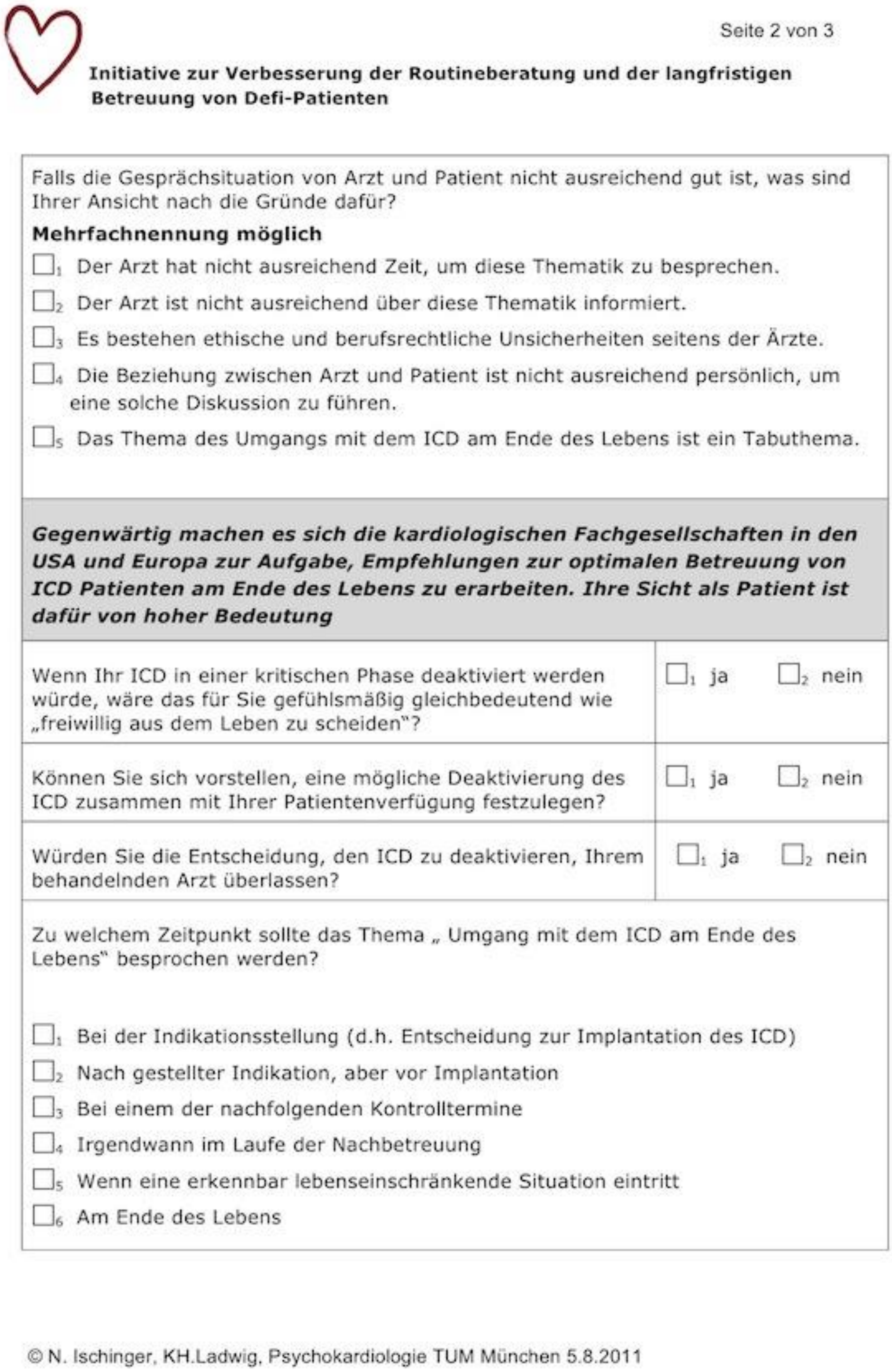

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Initiative zur Verbesserung der Routineberatung und der langfristigen Betreuung von Defi-Patienten

Falls die Gesprächsituation von Arzt und Patient nicht ausreichend gut ist, was sind Ihrer Ansicht nach die Gründe dafür?

Mehrfachnennung möglich

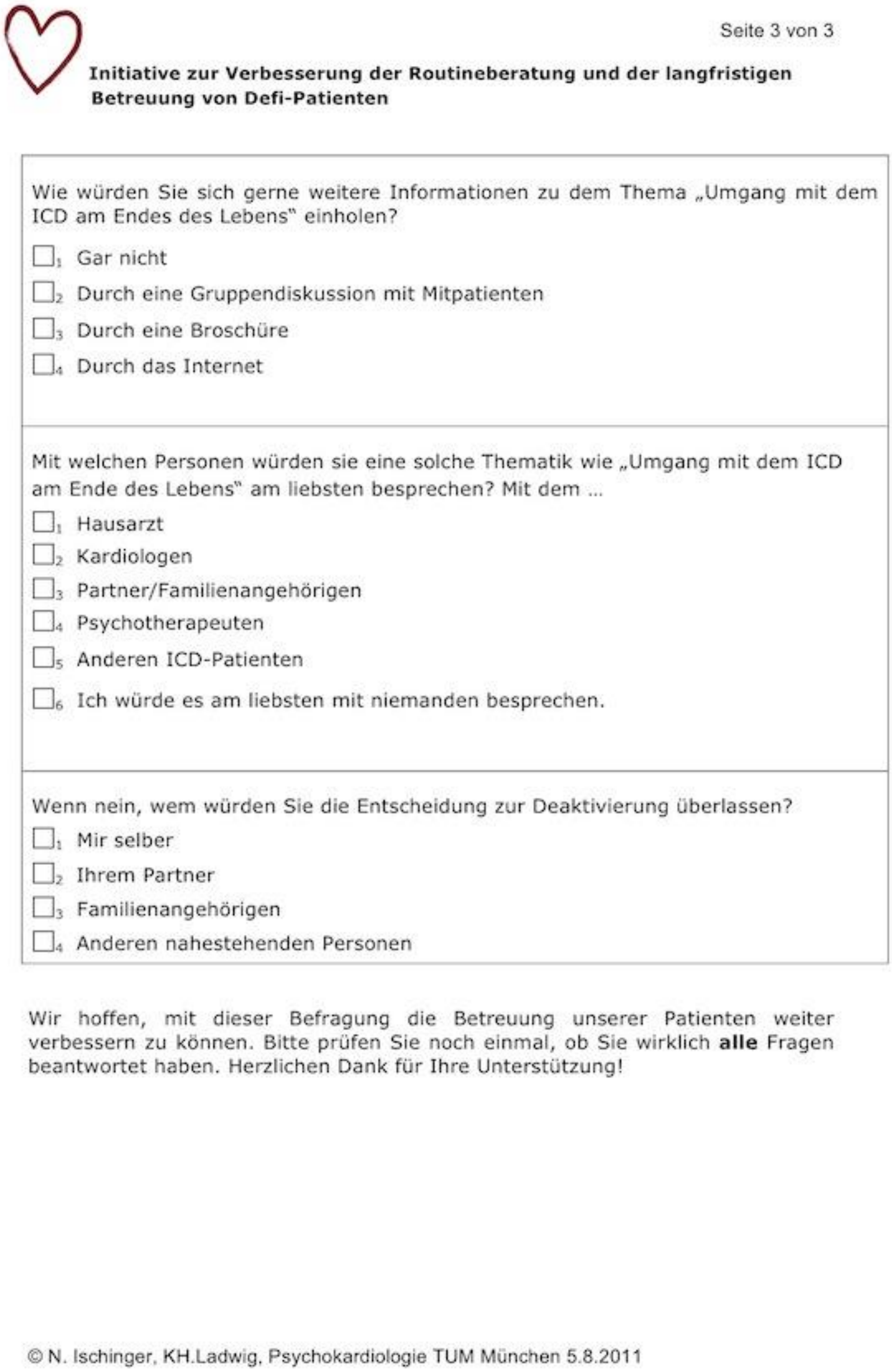
☐$_1$ Der Arzt hat nicht ausreichend Zeit, um diese Thematik zu besprechen.
☐$_2$ Der Arzt ist nicht ausreichend über diese Thematik informiert.
☐$_3$ Es bestehen ethische und berufsrechtliche Unsicherheiten seitens der Ärzte.
☐$_4$ Die Beziehung zwischen Arzt und Patient ist nicht ausreichend persönlich, um eine solche Diskussion zu führen.
☐$_5$ Das Thema des Umgangs mit dem ICD am Ende des Lebens ist ein Tabuthema.

Gegenwärtig machen es sich die kardiologischen Fachgesellschaften in den USA und Europa zur Aufgabe, Empfehlungen zur optimalen Betreuung von ICD Patienten am Ende des Lebens zu erarbeiten. Ihre Sicht als Patient ist dafür von hoher Bedeutung

Wenn Ihr ICD in einer kritischen Phase deaktiviert werden würde, wäre das für Sie gefühlsmäßig gleichbedeutend wie „freiwillig aus dem Leben zu scheiden"?	☐$_1$ ja	☐$_2$ nein
Können Sie sich vorstellen, eine mögliche Deaktivierung des ICD zusammen mit Ihrer Patientenverfügung festzulegen?	☐$_1$ ja	☐$_2$ nein
Würden Sie die Entscheidung, den ICD zu deaktivieren, Ihrem behandelnden Arzt überlassen?	☐$_1$ ja	☐$_2$ nein

Zu welchem Zeitpunkt sollte das Thema „ Umgang mit dem ICD am Ende des Lebens" besprochen werden?

☐$_1$ Bei der Indikationsstellung (d.h. Entscheidung zur Implantation des ICD)
☐$_2$ Nach gestellter Indikation, aber vor Implantation
☐$_3$ Bei einem der nachfolgenden Kontrolltermine
☐$_4$ Irgendwann im Laufe der Nachbetreuung
☐$_5$ Wenn eine erkennbar lebenseinschränkende Situation eintritt
☐$_6$ Am Ende des Lebens



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Initiative zur Verbesserung der Routineberatung und der langfristigen Betreuung von Defi-Patienten

Wie würden Sie sich gerne weitere Informationen zu dem Thema „Umgang mit dem ICD am Endes des Lebens" einholen?

☐1 Gar nicht
☐2 Durch eine Gruppendiskussion mit Mitpatienten
☐3 Durch eine Broschüre
☐4 Durch das Internet

Mit welchen Personen würden sie eine solche Thematik wie „Umgang mit dem ICD am Ende des Lebens" am liebsten besprechen? Mit dem ...

☐1 Hausarzt
☐2 Kardiologen
☐3 Partner/Familienangehörigen
☐4 Psychotherapeuten
☐5 Anderen ICD-Patienten
☐6 Ich würde es am liebsten mit niemanden besprechen.

Wenn nein, wem würden Sie die Entscheidung zur Deaktivierung überlassen?

☐1 Mir selber
☐2 Ihrem Partner
☐3 Familienangehörigen
☐4 Anderen nahestehenden Personen

Wir hoffen, mit dieser Befragung die Betreuung unserer Patienten weiter verbessern zu können. Bitte prüfen Sie noch einmal, ob Sie wirklich **alle** Fragen beantwortet haben. Herzlichen Dank für Ihre Unterstützung!

7.5 Overview of all answers to the “End-of-Life” questionnaire

Frequencies: End of life Questionnaire	
Awareness regarding ICD deactivation	
Knowledge	
Possibility of deactivation of ICD, n/N (%)	384/384 (59.9%)
Have considered issues related to dying with an ICD, n/N (%)	200/386 (51.8%)
Personal perception	
Had conversations with other patients regarding dying with an ICD, n/N (%)	68/383 (17.8 %)
Management of ICD at end of life is important to you, n/N (%)	297/386 (76.9 %)
Physician communication	
Interaction with physician regarding ICD management at EoL	
Had a discussion with physician, n/N (%)	24/388 (6.2 %)
Physician initiated discussion, n/N (%)	28/385 (7.3 %)
Want information from physician/cardiologist, n/N (%)	289/377 (76.7 %)
Approached physician/ cardiologist, n/N (%)	49/388 (12.8 %)
Barriers regarding communication physician regarding ICD management at end of life	

Perceive barriers in communication, n/N (%)	58/388 (14.9 %)
Reasons for insufficient communication with physician regarding ICD management at end of life	
Physician has insufficient time, n/N (%)	206/306 (67.3 %)
Physician has insufficient information, n/N (%)	62/306 (20.4 %)
Physician has issues with ethical and legal insecurities, n/N (%)	28/305 (9.2 %)
Physician relationship isn't comfortable enough, n/N (%)	117/306 (38.2 %)
The topic is considered taboo, n/N (%)	78/305 (25.6 %)
Personal options and readiness regarding ICD deactivation	
ICD deactivation is equivalent to suicide, n/N (%)	149/354 (42.1 %)
Can decide on including ICD deactivation in your advance directive (living will), n/N (%)	275/367 (74.9 %)
Ready to assign the decision of ICD deactivation to the treating physician, n/N (%)	191/358 (53.4 %)
Time of discussion of management of ICD	
At indication, n/N (%)	88/366 (24.0 %)
After indication, but before implantation, n/N (%)	66/366 (18.8 %)
At a control appointment, n/N (%)	85/366 (23.2 %)
Some point during course of care, n/N (%)	102/366 (27.9 %)

During a life threatening situation, n/N (%)	154/367 (42.0 %)
At end of life, n/N (%)	79/367 (21.5 %)
Information regarding management of ICD	
Want information, n/N (%)	
Not at all	31/366 (8.5 %)
Yes (group discussion, brochure, internet)	335/366 (91.5 %)
If yes, Information source preference	
In a group discussion with other ICD patients	230/335 (68.7 %)
In a brochure	183/335 (54.6 %)
Via internet	49/335 (14.6 %)
Personnel preference for discussion of management of ICD	
Not at all	16/369 (4.2 %)
If yes, personnel preference for discussion	
GP, n/N (%)	119/378 (31.5 %)
Cardiologist, n/N (%)	241/378 (63.8 %)
Partner/ family members, n/N (%)	206/378 (54.5 %)
Psychotherapist/ psychologist, n/N (%)	25/378 (6.6 %)
Other ICD patients, n/N (%)	106/378 (28.0 %)

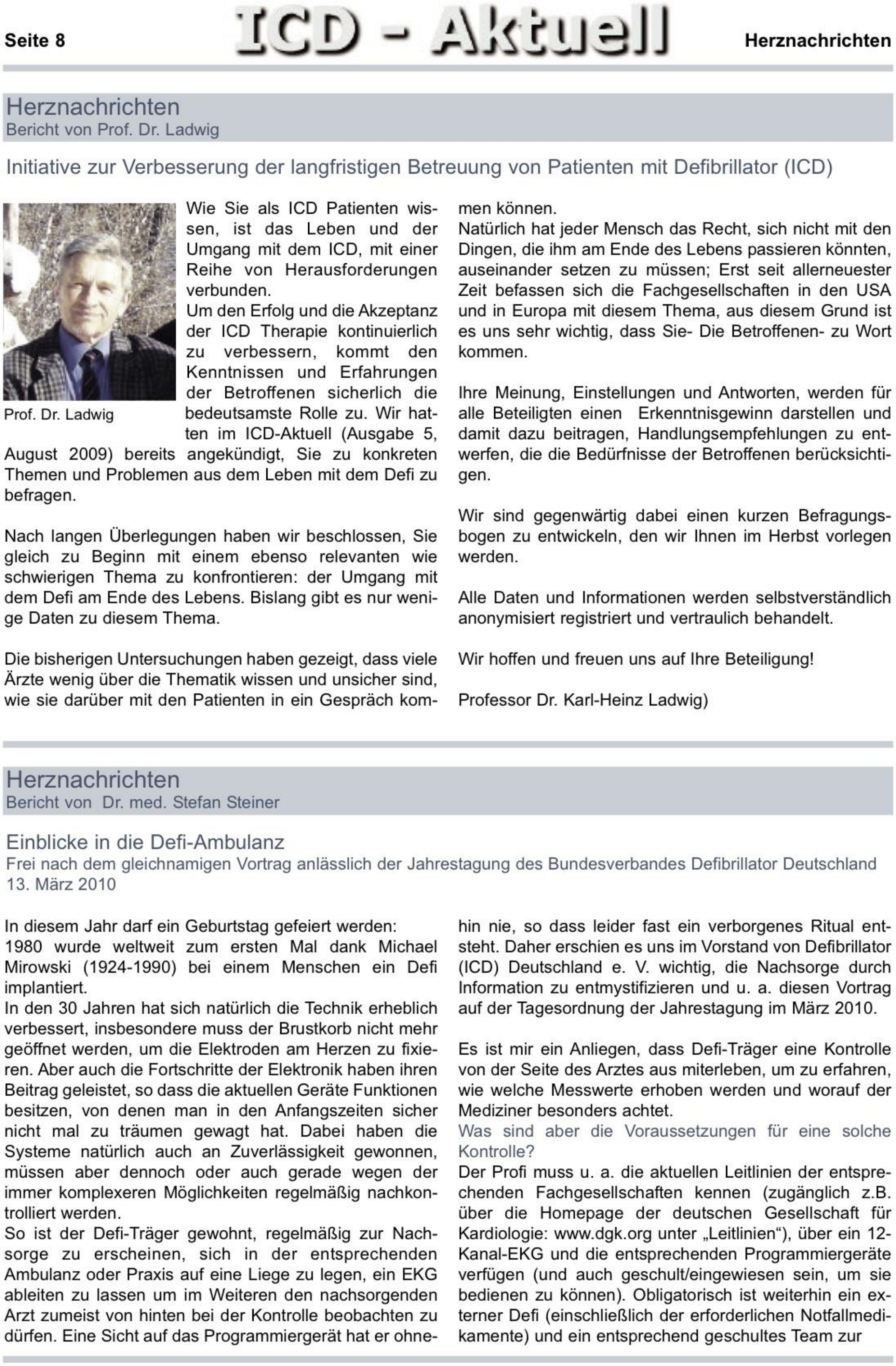
ICD deactivation decision maker	
Solely a personal decision, n/N (%)	194/309 (62.8 %)
Partner, n/N (%)	126/309 (40.8 %)
Family member, n/N (%)	83/309 (26.9 %)
Other close people, n/N (%)	5/189 (1.6 %)

7.6 Overview of significant associations

	Associations	***p-value***
Patients who had a conversation with their physician…	talked to other ICD patients.	0.006
	considered further issues related to dying with an ICD.	0.001
	are aware of ICD deactivation.	0.006
	wish to obtain further information via the internet.	0.021
Patients who were aware of ICD deactivation and had considered issues related to dying with an ICD…	wanted to include their decision about ICD deactivation in the Advance Directive.	0.004
	preferred to avoid a discussion until a life-threatening situation occurs.	0.024
	wished to talk about the issue as early as indication but before implantation.	0.037
Patients who approached their physician…	wanted their physician to approach them and teach them about the issue.	0.029
	believed their physician lacks information.	0.0001
	preferred to talk with a Psychologist.	0.022
	Wished to further discuss issues with their GP.	0.005

Patients who had approached their physician…	Wished to further discuss issues with other patients.	0.001
Patients with barriers in conversation…	associated ICD deactivation with suicide.	0.001
	did not consider the relationship with their physician sufficiently comfortable.	0.040
	wished to communicate with other ICD patients.	0.048
Patients who considered ICD management at the end-of-life important…	wanted their physician to approach them and teach them about the issue.	0.029
	believed their physician lacks information.	0.0001
	preferred to talk with a Psychologist.	0.022
	wished to further discuss issues with their GP.	0.005
Patients who would have liked to be informed…	stated that the physicians lacked time to discuss the issues of ICD management at the end-of-life.	0.001
Patients who believed that their physicians has insufficient information…	were not proactive in initiation of discussion on end-of-life issues and rather talked to other patients.	0.021

7.7 Articles/-Announcements in *"ICD-AKTUELL"*



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Herznachrichten

Bericht von Prof. Dr. Ladwig

Initiative zur Verbesserung der langfristigen Betreuung von Patienten mit Defibrillator (ICD)

Prof. Dr. Ladwig

Wie Sie als ICD Patienten wissen, ist das Leben und der Umgang mit dem ICD, mit einer Reihe von Herausforderungen verbunden.
Um den Erfolg und die Akzeptanz der ICD Therapie kontinuierlich zu verbessern, kommt den Kenntnissen und Erfahrungen der Betroffenen sicherlich die bedeutsamste Rolle zu. Wir hatten im ICD-Aktuell (Ausgabe 5, August 2009) bereits angekündigt, Sie zu konkreten Themen und Problemen aus dem Leben mit dem Defi zu befragen.

Nach langen Überlegungen haben wir beschlossen, Sie gleich zu Beginn mit einem ebenso relevanten wie schwierigen Thema zu konfrontieren: der Umgang mit dem Defi am Ende des Lebens. Bislang gibt es nur wenige Daten zu diesem Thema.

Die bisherigen Untersuchungen haben gezeigt, dass viele Ärzte wenig über die Thematik wissen und unsicher sind, wie sie darüber mit den Patienten in ein Gespräch kommen können.
Natürlich hat jeder Mensch das Recht, sich nicht mit den Dingen, die ihm am Ende des Lebens passieren könnten, auseinander setzen zu müssen; Erst seit allerneuester Zeit befassen sich die Fachgesellschaften in den USA und in Europa mit diesem Thema, aus diesem Grund ist es uns sehr wichtig, dass Sie- Die Betroffenen- zu Wort kommen.

Ihre Meinung, Einstellungen und Antworten, werden für alle Beteiligten einen Erkenntnisgewinn darstellen und damit dazu beitragen, Handlungsempfehlungen zu entwerfen, die die Bedürfnisse der Betroffenen berücksichtigen.

Wir sind gegenwärtig dabei einen kurzen Befragungsbogen zu entwickeln, den wir Ihnen im Herbst vorlegen werden.

Alle Daten und Informationen werden selbstverständlich anonymisiert registriert und vertraulich behandelt.

Wir hoffen und freuen uns auf Ihre Beteiligung!

Professor Dr. Karl-Heinz Ladwig)

Herznachrichten

Bericht von Dr. med. Stefan Steiner

Einblicke in die Defi-Ambulanz

Frei nach dem gleichnamigen Vortrag anlässlich der Jahrestagung des Bundesverbandes Defibrillator Deutschland 13. März 2010

In diesem Jahr darf ein Geburtstag gefeiert werden:
1980 wurde weltweit zum ersten Mal dank Michael Mirowski (1924-1990) bei einem Menschen ein Defi implantiert.
In den 30 Jahren hat sich natürlich die Technik erheblich verbessert, insbesondere muss der Brustkorb nicht mehr geöffnet werden, um die Elektroden am Herzen zu fixieren. Aber auch die Fortschritte der Elektronik haben ihren Beitrag geleistet, so dass die aktuellen Geräte Funktionen besitzen, von denen man in den Anfangszeiten sicher nicht mal zu träumen gewagt hat. Dabei haben die Systeme natürlich auch an Zuverlässigkeit gewonnen, müssen aber dennoch oder auch gerade wegen der immer komplexeren Möglichkeiten regelmäßig nachkontrolliert werden.
So ist der Defi-Träger gewohnt, regelmäßig zur Nachsorge zu erscheinen, sich in der entsprechenden Ambulanz oder Praxis auf eine Liege zu legen, ein EKG ableiten zu lassen um im Weiteren den nachsorgenden Arzt zumeist von hinten bei der Kontrolle beobachten zu dürfen. Eine Sicht auf das Programmiergerät hat er ohnehin nie, so dass leider fast ein verborgenes Ritual entsteht. Daher erschien es uns im Vorstand von Defibrillator (ICD) Deutschland e. V. wichtig, die Nachsorge durch Information zu entmystifizieren und u. a. diesen Vortrag auf der Tagesordnung der Jahrestagung im März 2010.

Es ist mir ein Anliegen, dass Defi-Träger eine Kontrolle von der Seite des Arztes aus miterleben, um zu erfahren, wie welche Messwerte erhoben werden und worauf der Mediziner besonders achtet.

Was sind aber die Voraussetzungen für eine solche Kontrolle?

Der Profi muss u. a. die aktuellen Leitlinien der entsprechenden Fachgesellschaften kennen (zugänglich z.B. über die Homepage der deutschen Gesellschaft für Kardiologie: www.dgk.org unter „Leitlinien"), über ein 12-Kanal-EKG und die entsprechenden Programmiergeräte verfügen (und auch geschult/eingewiesen sein, um sie bedienen zu können). Obligatorisch ist weiterhin ein externer Defi (einschließlich der erforderlichen Notfallmedikamente) und ein entsprechend geschultes Team zur

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so genannte Hypertonie zu Herz-Kreislauf-Erkrankungen und Schlaganfall führen kann, ist es wichtig, hohem Blutdruck entgegenzuwirken.

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Verbesserung der langfristigen Betreuung von Patienten mit einem ICD

Bericht Prof. Dr. Ladwig

Prof. Dr. Ladwig

Startschuss für eine Initiative zur Verbesserung der langfristigen Betreuung von Patienten mit implantierbarem Defibrillator (ICD)

Wie im ICD-Aktuell (Ausgabe 5, August 2009 und Ausgabe 8, September 2010) angekündigt, sind die Vorbereitungen zu der Befragung von Ihnen als Mitglieder der ICD-Selbsthilfegruppen in Deutschland zu konkreten Themen und Problemen aus dem Leben mit dem Defibrillator mittlerweile abgeschlossen.

Das Ziel dieser Initiative ist es, Ihre Meinung und Einstellung und die einer möglichst großen Zahl von weiteren ICD-Trägern systematisch zu erfassen und (so rasch wie möglich) die Auswertung in ICD-Aktuell zu publizieren. Damit erhoffen wir uns, einen Betrag zu der Zielsetzung zu leisten, der Patientenstimme Gehör zu geben und so ein Gegengewicht zu Politik und Industrie zu schaffen. Anders als bei wissenschaftlichen Arbeiten, bei denen es in der Regel oft Jahre dauert, bis eine Auswertung als Manuskript erschienen ist, soll es hier sehr rasch gehen – um auf diese Weise wirkungsvoll zu einer Verbesserung der Versorgung der Patienten beitragen zu können.

Am Anfang wird das noch ein wenig holprig gehen, aber mit der Zeit werden wir sicher so etwas wie eine kleine Routine erreichen. Wir planen daher auch keine ellenlangen Fragebögen, sondern wollen alle paar Monate zu Brennpunktthemen kurz und möglichst bündig Fragen stellen.

Wenn Sie selbst ein kontroverses Thema zur ICD Behandlung (im weitesten Sinne) haben, das Sie gerne diskutiert sehen wollen, wäre es schön, wenn Sie dies innerhalb des Bundesverbandes kommunizieren und der Geschäftsstelle mitteilen würden. Mit einem ersten kurzen Fragebogen zum Thema Behandlungszufriedenheit wollen wir beginnen. Eine weitere Befragung ist für den Monat April geplant. Wir hoffen und freuen uns auf Ihre Beteiligung!

Professor Dr. Ladwig
Helmholtz Zentrum München

Aus den SHGs

Weihnachtsfeier der Defigruppe - Augsburg am 04.12.2010

Alle drei Defigruppen feierten gemeinsam bei unserer Weihnachtsfeier und gleichzeitig das einjährige Bestehen der „Defi-Gruppe Augsburg“. Musikalisch eröffnet und umrahmt wurde der Abend von der „Dinkelscherbener Bläsergruppe“ mit weihnachtlichen Weisen, die an diesem Abend von Frau Colditz aus der Mittwoch-Gruppe unterstützt wurde.

Nach der Begrüßung durch Robert Mayrock wurde auf das vergangene Jahr und das Geschehene noch einmal zurückgeblickt, aber auch ein paar Dankesworte durften nicht fehlen, zum einen an die Stellvertreter Helga Seltmann und Helmut Scholze und natürlich an Walter Schmidtke und an die Ehefrauen, welche die Gruppensprecher immer unterstützen. Ein besonderer Dank ging an die Gruppen-Mitglieder und derer Partner, die immer mit Interesse an den Gruppenabenden und bei Unternehmungen teilnahmen. Mit den Worten „ich möchte mich bei allen, die zu dieser Gemeinschaft und dem guten Miteinander herzlichst bedanken“, wünschte ich einen schönen Abend und alles Gute im neuen Jahr und beendete den Rückblick. Anschließend wurden von unserem Mitglied Herrn Sattelmayer Weihnachtsgeschichten vorgetragen, die sehr amüsant waren. Nach einigen Musikstücken gab Walter Schmidtke einen kurzen Ausblick auf das Jahr 2011. Vorschläge, die von unseren Mitgliedern eingebracht wurden, z.B. Stadtführung in Augsburg/ Patientenverfügung usw., im April oder Mai ist eine Fahrt in den Bayerischen Landtag eingeplant. Wenn wir die Anzahl an Vorschlägen betrachten und das Jahr 2011 bekanntlich nur 52 Wochen hat, wird es problematisch.

Ein Dank ging auch an alle, die uns so tatkräftig unterstützt haben, wie Herrn Esterl/ Fam. Naujocks/ Herrn Rehle/ die Damen vom Gesundheitsamt und viele mehr. Da diese Personen leider nicht anwesend waren, erhalten Sie eine Weihnachtskarte mit einem Dankeschön.

Nach dem gemeinsamen Abendessen und regem Austausch wurde einstimmig beschlossen, nächstes Jahr wieder eine Weihnachtsfeier abzuhalten.

Robert Mayrock und Walter Schmidtke

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Initiative zur Verbesserung der langfristigen Betreuung von Patienten mit implantierbarem Defibrillator (ICD) - Zweite Befragung

Bericht von Prof. Dr. Ladwig und Nina Fleur Ischinger

Prof. Dr. Ladwig

Nina Fleur Ischinger

Zwischen Februar 2011 und Juni 2011 haben Sie an der ersten Befragung unserer Initiative (1.Thema: Behandlungszufriedenheit) teilgenommen.
Wir danken Ihnen für Ihre Teilnahme!
Zur Erinnerung: Das Ziel unserer Befragungen ist, die Meinung einer möglichst grossen Zahl von ICD-Trägern zu konkreten Fragen und Problemen aus dem Leben mit dem Defibrillator zu erfassen, um die langfristige Betreuung von Defi-Patienten zu verbessern.

Ihre Meinung ist wichtig!
Wir arbeiten momentan bereits daran, Ihnen die Ergebnisse der ersten Befragung zur Verfügung zu stellen. Im Rahmen der Ihnen in wenigen Tagen zugehenden zweiten Befragung bearbeiten wir ein schwieriges aber sehr relevantes Thema: der Umgang mit dem Defi am Ende des Lebens.
Wissenschaftliche Untersuchungen haben gezeigt, dass sowohl der Kenntnisstand von Ärzten und Patienten über den Umgang mit dem ICD am Ende des Lebens als auch die Versorgung von ICD-Trägern am Ende des Lebens mangelhaft sind.

Alle Daten und Informationen werden vertraulich behandelt!
Wir hoffen sehr auf Ihre Beteiligung und bitten Sie auch in Ihrem Interesse dringend, den Fragebogen zu beantworten. Nur bei einer sehr hohen Rücklaufquote können unsere Bemühungen erfolgreich sein und therapeutische Verbesserungen erreicht werden!

Ihre
Professor Dr. Ladwig, Helmholtz Zentrum München
und Nina Fleur Ischinger

Informationen zum Thema Defibrillator (ICD)

auf unserer Internetseite www.defibrillator-deutschland.de
oder unter
www.defi-forum.de
finden Sie häufig gestellte Fragen und Antworten zum Thema Defi

Aus den SHGs

Defi-Gruppe Nürnberg Martha-Maria. Was macht die Gruppe?

Die Gruppe Nürnberg verdankt Ihre Entstehung einer Initiative der Kardiologie des Krankenhauses aus dem Jahre 2009. Sie hat sich dafür, dass es in Nürnberg noch eine zweite schon länger existierende Gruppe gibt, recht ordentlich entwickelt. In Zahlen: es gibt etwa 20 ernsthafte Interessenten, der harte Kern der Gruppe –also die, die regelmäßig kommen – besteht aus 10 bis 15 Personen. Die Gruppe tagt 6 mal im Jahr in einem sehr komfortablen Konferenzraum auf dem Gelände Martha Maria in Nürnberg-Erlenstegen, den die Diakonie kostenlos zur Verfügung stellt.
Weitere Einzelheiten sind unserer Homepage www.icd-selbsthilfegruppe.de zu entnehmen.

Das Diakoniekrankenhaus Martha Maria unterstützt uns nach Kräften. Seine Kardiologinnen und Kardiologen halten bei uns nicht nur Vorträge über von uns gewünschte Themen, sondern eine/einer von ihnen nimmt an jeder der 2-stündigen Gruppensitzungen teil, hört sich alle Sorgen an und geht auf jede Frage ausführlich ein – wo hat man so etwas sonst im normalen Medizinalltag?

Natürlich gestalten wir die Treffen auch selbst. Wir laden Psychologen, Apotheker, Defi-Hersteller usw. zu Vorträgen oder Präsentationen ein oder machen einfach einen Abend des Informations- oder Erfahrungsaustausches unter den Gruppenmitgliedern. Wir reden aber auch über Patientenverfügung oder Einschränkungen beim Autofahren.

Angehörige und Interessenten am Defi sind uns stets willkommen.

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9. Acknowledgement

My special thanks go to Professor Dr. Karl-Heinz Ladwig for introducing me to this relevant topic and encouraging me to engage in this research. His invaluable advice and professional guidance throughout the organization and conductance of this study were indispensable for the completion of this dissertation. I am indepted to Professor Dr. Jürgen Beckmann for accepting to be my doctoral thesis supervisor and for his advice and availability. I also extend my gratitude to Mr. Peter Esterl, at the time President of the German Defibrillator Association and Mr. Udo Naujocks (deceased) for the fruitful cooperation, and the ICD patients who were willing to participate in this study and without whom the research would not have become reality. I thank Mr. Bernhard Ulm for his consultation during the statistical analysis. I highly appreciate the exchange with Mrs. Tricia Henry on the subject. Special thanks go to my family, to my father, Professor Dr. med Thomas Ischinger, for the stimulating and critical professional advice and to my mother, Jeannette Ischinger, for her continued and extremely helpful moral support, as well as for her constant availability to take care of my daughter. I further thank Marianne Joiser and Regina Harl for their often very spontaneous readiness to babysit and thus permit me to work on this project.

Last but not least I thank my partner, Gernot Harl, for his motivation and patience and the confidence he had in me.