A Qualitative Study of Decision-Making about Implantation of Cardioverter Defibrillators (ICDs) and Deactivation during End of Life Care

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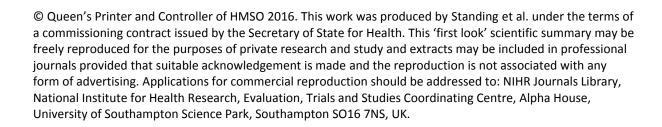
A final version (which has undergone a rigorous copy-edit and proofreading) will publish as part of a fuller account of the research in a forthcoming issue of the Health Services and Delivery Research journal.

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The research reported in this 'first look' scientific summary was funded by the HS&DR programme or one of its predecessor programmes (NIHR Service Delivery and Organisation programme, or Health Services Research programme) as project number 11/2004/29. For more information visit http://www.nets.nihr.ac.uk/projects/hsdr/11200429

The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HS&DR editors have tried to ensure the accuracy of the authors' work and would like to thank the reviewers for their constructive comments however; they do not accept liability for damages or losses arising from material published in this scientific summary.

This 'first look' scientific summary presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health.

SCIENTIFIC SUMMARY

Background

In the UK there are 100,000 sudden cardiac deaths per year. Implantable cardioverter defibrillators (ICDs) are recommended for patients at high risk of sudden cardiac death (primary prevention) and for survivors of cardiac arrest (secondary prevention). All ICDs combine both a shock function (to treat fast heart rhythms) with a pacing function (to treat slow heart rhythms). In some cases the pacing function may be very sophisticated, and can provide so called cardiac resynchronisation therapy (CRT) for the treatment of heart failure. CRT itself may be provided by a pacemaker (CRT-P) or in conjunction with an ICD (CRT-D). The great majority of ICDs are used for primary prevention and in people with chronic heart failure. They increase life expectancy, but may be associated with adverse effects (unnecessary or inappropriate shocks, device complications, increased hospitalisation, and anxiety and depression). Consequently, decision-making about an ICD for individual should consider the benefit of averting sudden death, alongside possible future harms, including adverse effects and the potential need for deactivation towards end of life. We aimed to critically explore patient/relative and professional views about, and experiences of, ICD implantation and deactivation, and to examine how this information could support better shared decision-making (SDM).

Objectives

Our objectives were to explore patients', relatives' and clinicians' views and experiences of decision making about ICD implantation and deactivation; establish how and when ICD risks, benefits and consequences (including deactivation) are communicated to patients; determine patients'/relatives' and clinicians' information and decision support needs in the context of SDM; and identify the individual and organisational facilitators and barriers to discussions about implantation and timely decision making about deactivation.

Methods

Qualitative methods – observations, interviews and workshops – were used. To reflect a diversity of patients' experiences we recruited people before and after ICD implantation, as well as those who declined ICD therapy, those considering prospective deactivation, and bereaved relatives. Phase I involved observation of 37 consultations with patients being considered for ICD at three different settings: one specialist implanting centre, and two District General Hospitals. These observations facilitated 'context setting' (the nature of ICD consultations and decision making interactions, including the patient's journey through different referral and care pathways) to inform our purposive sampling strategy and the content of interview guides for in-depth interviews with patients, relatives and clinicians (Phase II). Patient participants in Phase II were recruited following an initial approach by a member of the clinical team. Bereaved relatives (up to 18 months post-bereavement) were identified via the physiologists at one tertiary care centre, and contacted via letter. Following return of a consent form, they were contacted by the research team. Observations were recorded in field notes and all interviews were audio-recorded and transcribed verbatim.

Data collection and analysis occurred concurrently. Interactive workshops with clinicians and patients/relatives were used to validate our findings and to explore their ideas on how the findings could be used to support better SDM.

Findings

In total 37 consultations were observed across three sites (July 2013 to January 2015); 80 interviews were conducted with 44 patients/relatives (35 men, 11 women, aged 47-85 years), 7 bereaved relatives of ICD patients and 29 clinicians (implanting and non-implanting cardiologists, palliative care clinicians, physiologists, psychologists and specialist nurses). Workshops with 11 clinicians and 11 patients/relatives were subsequently facilitated

Patients and relatives want to be offered a choice and to be given balanced information about the available options, in particular the potential impact on psychological well-being and quality of life in the short and long-term [deactivation]). There was a lack of standardised methods used to convey information about the nature of ICDs (and other options), and associated risks, benefits and consequences, including a lack of tools to support understanding of information on benefits and adverse events in the short- and long-term. Clinicians' values about patients' preferences for information and involvement in decision making were often discordant with those of patients.

Patients and relatives want to know about deactivation in advance of implantation and be actively involved in decision-making. We found a lack of consensus/ownership among clinicians about who should take responsibility for discussing deactivation with patients and relatives and when that should happen. Potential trigger points for deactivation discussions within the care pathway were suggested, aligned with the need for regular monitoring and review over time in terms of effectiveness and appropriateness of continued ICD therapy.

Limitations

It was only possible to recruit two patients who were prospectively considering deactivation and seven bereaved relatives. Consequently, the views and experiences of these groups may be under-represented. With regard to bereaved relatives, the length of time post-bereavement may have compromised accurate recollection. This study also lacks the perspectives of primary care clinicians.

Conclusions

Patients/relatives want information about the surgical procedure to implant ICDs, balanced information on the benefits, risks and consequences of ICD therapy, including involvement in decision-making about implantation and deactivation with a preference that these were addressed at the time of implantation. In particular they want to know about the risk of adverse effects (including potential psychological problems and negative effects of ICDs on

body image) which is often not conveyed to patients and may inhibit informed values-based decisions about ICD therapy.

The clinical rationale for offering ICD therapy should be clearly communicated to patients and their relatives as early as possible in the patient pathway, potentially using co-designed information and tools, including live demonstration and manipulation of devices. There is a need for increased access, and a greater role for psychological support from appropriately qualified mental health professionals, including signposting to peer support groups. Patient/family member preparation for SDM with cardiologists provided by clinicians with frequent patient contact (e.g. heart failure nurses) may be of value.

The issue of deactivation should be introduced early in the pathway and raised later at subsequent specific trigger points for more detailed and timely discussions with patients and relatives throughout the pathway. There is a pressing need for evidence-based strategies to foster inter-professional learning and collaboration between cardiology and palliative care teams in the context of ICD therapy.

Future Work

Multi-faceted SDM interventions are warranted that also include a focus on skills development for SDM (patients/relatives and clinicians); appropriate use of updated/revised decision support tools; exploration of a central role of heart failure nurses and physiologists in supporting patients/relatives; and defining the role of primary care clinicians in providing ongoing care and initiating deactivation issues.