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Restoring Normalcy: The Experiences of Five Women Living with an Implantable Cardioverter Defibrillator

April Manuel, RN, PhD, and Gina Colbourne, BN, MD

Abstract

Background: *Women in Newfoundland and Labrador (NL) have the second highest rate of deaths related to cardiovascular disease in Canada. The implantable cardioverter defibrillator (ICD) is one of the treatment options for cardiovascular disease.*

Objective: *The objective of this study was to gain a fuller understanding of the experiences of five women in the province of NL who are living with an ICD.*

Methods: *A phenomenological approach (van Manen, 1997) was used to capture the essence of what it is like for five women to live with an ICD.*

Results: *Three reccurring themes evolved from the women's narratives: 1) living with the decision to have an ICD, (2) creating modes of self-surveillance, and (3) finding a new normal. Collectively these themes captured the essence of this phenomenon as restoring normalcy.*

Conclusions: *Education and counselling programs that address the psychosocial needs of women living with an ICD are needed. Multidisciplinary clinical practice guidelines that address the psychosocial aspects of living with an ICD are imperative to help this cohort cope. Nurses can play an important leadership role in advocating for the development, implementation and evaluation of these resources.*

Key terms: nurses, implantable cardioverter defibrillator, cardiovascular disease, phenomenology, women

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Approximately 1.6 million Canadians have cardiovascular disease (CVD) and it is the leading cause of death for women over the age of 55 (Public Health Agency of Canada [PHAC], 2009). This is of particular concern for women in the province of Newfoundland and Labrador (NL), Canada because that population has the second highest rate of deaths related to CVD in Canada at 201.6 deaths per 100,000 (PHAC, 2009). The implantable cardioverter defibrillator (ICD) is one of the primary treatment options for CVD (Eckert & Jones, 2002; Setoguchi, Nohria, Rassen, Stevenson, & Schneeweiss, 2009). Roughly 4,000 patients in NL living with CVD have an ICD (D. Rideout, personal communication, March 7, 2012). NL has one of the oldest populations in Canada, with 41.5% (215,725) of people over the age of 50 years (Statistics Canada, 2016), thus it is anticipated that the rates of CVD and subsequent number of ICDs will continue to rise in the province of NL, as well as across the country.

An ICD is an electric pulse generator implanted under the patient's skin that is connected to the heart by a series of wires. On detection of a specific arrhythmia the ICD generates an electric impulse or shock to correct the problem. Despite the large body of research that examines issues and trends, as well as the risk factors for CVD in Canada (Lee et al., 2009), there is a dearth of literature that focuses exclusively on the psychosocial issues faced by women living with an ICD. Existing literature on the experience of living with an ICD tends to juxtapose the experiences of women against men (Carroll & Hamilton, 2005; Flemme, Hallberg, Johansson, & Stromberg, 2011; Friedmann et al., 2006), using small sample sizes and cross-sectional designs, which limits causality (Starrenburg et al., 2014). As a result, psychosocial issues faced by women living with an ICD are under-explored. For example, while some studies have found that women experience a poorer quality of life (QOL) post ICD implant, as compared to men (Lauck et al., 2015; Miller, Thylén, & Moser, 2016), other studies have found the opposite results (Gopinathannair et al., 2017; Starrenburg et al., 2014). In fact, some studies report no significant association between gender and QOL post ICD implant (Brouwers, van den Broek, Denollet, & Pedersen, 2011; Habibović et al., 2011).

The research on the relationship between gender and psychosocial distress post ICD implant (e.g., anxiety, depression, worry) is not conclusive. Research shows that women experience increased levels of anxiety post ICD implant (Bilge et al., 2006; Spindler, Johansen, Andersen, Mortensen, & Pedersen, 2009), but levels of anxiety and depression post ICD are not significantly different between men and women (Habibović et al., 2011; Miller et al., 2016; Spindler et al., 2009; Starrenburg et al., 2014). Rahmawati et al. (2013) found that women had higher depression, worry and stress

scores than men post ICD, but there was no statistical difference on the anxiety scores. In fact, ICD-specific psychosocial distress for women was no different than the general population post ICD implant (Gopinathannair et al., 2017). These findings suggest that the post ICD experience is multifactorial and contextual in nature and can result in different health trajectories for men versus women (Habibović et al., 2011; Lauck et al., 2015).

Saliently threaded throughout the literature is the fact that women's responses to living with an ICD can be substantially different from men. That is, women experience a variety of concerns (e.g., body image, personal relationships, role within the family, shock-related worry) differently than men, which can lead to a significant period of adjustment post ICD implant (Marshall, Ketchell, & Maclean, 2012; Palacios-Ceña et al., 2011; Starrenburg et al., 2014). While both men and women seem to adjust to having the ICD over time (Marshall et al., 2012), what remains unclear are the migrating factors that collectively influence how women adjust to living with an ICD. It is this lack of understanding that Brouwers et al. (2011) cautions healthcare practitioners to explore if they are to meet the unique needs of women living with an ICD.

Given the high rates of CVD, the aging population, and the lack of conclusive research on the specific experiences of women living with an ICD, it is important to conduct research that contributes to our understanding of the unique healthcare needs of this population. Further research is warranted to highlight and address the specific needs of women living with an ICD in light of the lack of existing research (Palacios-Ceña et al., 2011). The aim of this study was to gain a fuller understanding of the experiences of five women in the province of NL who are living with an ICD.

Methodology

A phenomenological approach (van Manen, 1997) was used to capture the essence of what it is like for these women to live with an ICD. The essence uncovers and describes the internal meaning structures of a lived experience in order to gain a deeper understanding of the phenomenon under investigation (e.g., living with an ICD). The essence represents the core of the phenomenon and without it the experience would remain fragmented. The researcher gains insights into the essence of the experience by reflecting on participants' narratives individually and within the context of the entire experience. Throughout this process, themes that illustrate the phenomenon are constructed (van Manen, 1997).

Sample and Recruitment

Five women between the ages of 39 and 72 years participated in this study. Eligibility criteria included: (1) able to communicate fluently in English; (2) mentally competent in order to understand the purpose of the study, give informed consent, and participate actively in an interview; (3) 19 years of age or older; (4) female; and (5) a recipient of an ICD as a treatment for cardiac disease. All five women had a strong family history of cardiovascular disease (e.g., high cholesterol, hypertension, atrial fibrillation, myocardial infarction or a genetic heart condition). Three women received an ICD as the primary management for arrhythmogenic right ventricular cardiomyopathy, a fatal genetic linked heart condition. Two women had the ICD implanted as part of a treatment plan to address the complications of congestive heart failure such as fluid overload and arrhythmias. Of these five women, three had experienced an ICD shock. Four women had a pacemaker/ICD combination; only one had a stand-alone ICD. The length of time of ICD implant ranged from one year to 20 years. Three women were retired and two of the women work outside the home.

Ethical approval was obtained from both the Health Research Ethics Authority and the Research Proposals Approval Committee, Eastern Health, prior to start of the study. Recruitment was done through the Cardiac/Critical Care Program at Eastern Health. A registered nurse working in the ICD clinic approached patients who met the criteria to participate in the study. Individuals who expressed interest provided their contact information and a member of the research team contacted the individual to request an interview. Prior to the interview, the study was explained to participants, any questions were answered, and informed written consent obtained.

Data Collection

Participants engaged in semi-structured interviews lasting approximately one hour in duration. Follow-up questions were asked to clarify spoken ideas, thoughts, and feelings in order to gain a clearer understanding of what life is like to live with an ICD. Four interviews were conducted face to face and one interview was conducted by telephone.

Data Analysis

Two members of the research team analyzed the data. Interviews were audiotaped and transcribed into written verbatim for analysis. Using the selective highlighting approach, important phrases and themes that reflected the lived experience of women with an ICD were underlined. Similar statements were grouped together in order to develop themes. Narratives were then reviewed collectively in order to capture the essence of the experience of living with an ICD. An audit trail was used to describe the decisions made throughout data collection and analysis. Any preconceived notions or ideas about the data and knowledge about the ICD experience were documented in a journal prior to confirming the analysis with the participants. According to van Manen (1997), findings of a phenomenology study are only credible when they are confirmed with the study participants to ensure the researcher has accurately interpreted the data. As such, interpretative summaries were provided to participants to confirm that the summaries accurately reflected their experiences.

Results

The experiences of five women living with an ICD are described within the following three themes (1) living with the decision to have an ICD, (2) creating modes of self-surveillance, and (3) finding a new normal. Collectively these themes captured the essence of this phenomenon as restoring normalcy.

Living with the Decision to have an ICD

All five women in this study spent considerable time rethinking the path that led them to make the decision to have the ICD. This reflection provided an opportunity for the women not only to identify the factors that helped them make this decision, but also to regain a sense of confidence and comfort that the decision to have the ICD was the right choice. It was this awareness that helped them adjust to having the ICD.

For most participants, the decision to have an ICD was considered a non-event; it was based on the advice of the healthcare provider (e.g., cardiologist), required little deliberation, and did not cause a lot of psychosocial distress, *"Well the doctor sort of indicated that it would help me and I went along with this decision and I am glad that I did."* The women put a lot of trust in the knowledge of the cardiologist to do what was in their best interests. In fact, once the women perceived that they had a cardiac condition that could be treated with the ICD they wanted it. *"For me it was not an issue to make up my mind. I just knew right from the start getting the ICD was what I was going to do."* One woman spoke of the nurse as playing a significant role in informing her decision. *"I remember speaking to the nurse at the hospital and she went through a lot of information with me about the ICD and showed me a sample of one and what they would do."*

The decision to have the ICD was influenced by the realization that there was no other option for them if they wanted to live a good quality of life. *"I felt like I did not have an option, well the option was to drop dead."* Many spoke of the ICD as being an *"insurance policy"* that in the event of a cardiac episode they had *"faith"* that the ICD would discharge and save their lives. For these women, living became synonymous with having the ICD, thus the ICD was seen as a means to cope with their heart disease. For the women, it was the recognition that they had a potential life-threatening cardiac condition that was more difficult to deal with than making the decision to have the ICD. *"Accepting that I had this heart condition was hard. Making the decision to have the ICD was not."* Similar sentiments were echoed by another participant. *"[Cardiologist] said you could drop dead at any time… So now I am going for an ICD and pacemaker and good, cannot wait to get it."* For these women having the ICD was like having a second chance at life and this opportunity was something they felt they could not pass up. *"Sometimes you are not going to get a second chance."*

The support of family members was critical for the women, as they weighed the benefits and risks associated with making the decision to have the ICD. Conversations were held with others who had an ICD and this helped them make their decision. *"I had two aunts that had the ICD and we would talk about it."* The experiential knowledge of relatives who themselves had an ICD helped the women to contextualize the experience and provided advise on how to manage living with the ICD. These discussions often extended to include other members of the family (e.g., spouse) and were often based on concern for the children. *"I discussed it with my husband and said what choice I have. I am not prepared to leave this earth with you and two small kids."*

Creating Modes of Self-Surveillance

Living with an ICD for all participants meant they were in a constant state of self-surveillance. That is, participants were always cognizant of their bodily functions and looking for any physical signs of failing health that would put them at risk for the ICD to discharge (e.g., increase in pulse or palpitations). Being able to recognize the signs of an impending ICD discharge was seen as providing an opportunity to prepare for the outcome and a means of regaining some sense of control over one's body. *"You have to be aware of your own self… because I know that's the only thing that I have control over. I just have to control how I react to it."* This state of constant self-surveillance put women in a conundrum, as they contemplated driving or not. That is, while driving was considered essential to performing everyday life activities such as getting groceries and socializing, they had difficulty with actually getting behind the wheel. Many were afraid that the ICD would fire and cause an accident. *"We all need our cars for work and for our social activities, but you got to get the big picture. You are saving somebody's life by not getting behind the wheel."*

Having to continuously monitor one's body was stressful because the women were unsure how visible signs of illness would be manifested and how much time they had to respond before the ICD would discharge. *"I spent a lot of time watching and waiting… Breathing heavy puts me in a panic."* What was particularly stressful was knowing that the ICD could fire without any warning and essentially there was nothing they could do about it. *"There is no warning. It has happened in my sleep, when I am out by the door. I was shoveling snow and I got shocked. I was cutting grass and I got shocked. I was lifting laundry when I got shocked. I have not driven since 2006. I have lost my independence because now I have to have somebody with me all the time."* This lack of control related to when, where, and how many times the ICD fired not only left participants feeling restricted in their level of daily activities, but also contributed to a sense of social isolation and powerlessness. *"It's so powerless, I cannot stop this from happening."* For one person, the psychosocial distress associated with having the ICD fire was so traumatic that she had counselling to help cope with this experience.

A significant part of this self- surveillance was trying to decipher what would constitute an appropriate or inappropriate shock. *"So that's on my mind too, you know, when it fires, is it really a shock or is it the machine that malfunctioned."* Identification of factors that could lead to an ICD shock were collected as a repertoire of things to avoid (e.g., physical activity). In some respects, knowing the potential factors that could lead to a shock decreased participants stress and helped them cope. For the women who have not experienced an ICD shock, knowing that this could happen made them nervous. *"I will be scared. But hopefully I will be able to handle it."* Adding to this was the concern that having a shock meant their condition was deteriorating. *"Yes, [ICD firing] my heart would be probably getting worse."*

Finding a New Normal

Despite the challenges experienced by these women, they gradually began to accept the ICD as part of their everyday lives. *"It has just become a part of me and that's it. I don't really think about the fact that I have an ICD in my chest other than when I look in the mirror."* Part of accepting the ICD was coming to terms with the fact that the device was something they needed to survive. *"You got two choices. You can accept it, and keep going, and keep a positive attitude and thank God when you get up in the morning. Or you can sit there in the corner and say poor pitiful me, I got an ICD, I can't do things. There are many things that you can do."* These sentiments are also captured in another woman's narrative. *"I can honestly say it [ICD] does not really affect me. I don't think about it right now. You can't dwell on it, you have just got to accept it and move on."*

All women agreed that key to living with an ICD is maintaining a positive attitude. *"I get to go to work and have fun with my friends, and I feel like I am contributing, so that is all that really matters to me now."* Part of sustaining this positive attitude was having faith in the capabilities of the ICD. *"When I am shocked, it sort of gives me the feeling that it's working."* Some women were of the frame of mind that if the ICD fired it was simply doing what it was designed to do. *"Now I think okay it shocked, it did its job, and I can carry on as normal. I feel really safe [when ICD fires]."* Similar thoughts were shared by another woman who stated: *"I just feel if the time comes and I need it, it's there and it works."* For these women, the ICD provided a sense of solace and comfort that many had not felt for a long time. *"It is making me feel better and I just feel more secure because of it being there and maybe I will have a better chance."* This newfound sense of security helped the women focus on the positive aspects of their lives. They spoke of having more energy, and re-introducing activities such as housework. *"I carry on and do what I can and watch what I do with regards to doing things that I am not supposed to do."* For one woman reintroducing physical activity was particularly challenging, as she described in this narrative: *"I pushed myself to do it [physical activity] … But it is a struggle… If I was not so persistent or have such strong will I would have given up long ago… "*

Part of adjusting to living with the ICD was an awareness that the mediating factors causing the ICD to fire were often out of their control. *"I was afraid if I did something it would set off the defibrillator, but once I got more comfortable and realized nothing that I would do personally would set it off, I became more comfortable with it and I found afterwards I just got used to it. Right now, I don't even think about that I got it."* Unfortunately, despite the women's efforts to maintain a positive outlook, each firing of the ICD was a reminder of their illness. "It is like every time this happens how do I get through this and what is it that I do to go back to normal? And feel normal and not let the fear of losing my life take over the beautiful days that I have got right now."

Formal (e.g., healthcare providers) and informal supports (e.g., family, friends, and co-workers) were essential to helping participants adjust to their new normal. While participants appreciated the fact that nurses in the ICD clinic were accessible and provided much-needed reassurance, one participant felt that nurses could help more with the psychological aspects of living with an ICD. *"The nurses are fantastic and excellent… they are there to listen, but they don't have the tools to help you get through the psychological trauma."* Family and friends also provided support in that they were seen as a resource to help them manage their everyday daily life activities such as doing laundry, driving to physician appointments and being prepared in the event of an emergency. *"He [husband] knows where I got everything put if anything happens to me and where he could call."*

The Essence: Restoring Normalcy

The five women in this study provided a vivid description of their efforts to restore a sense of normalcy to their lives after receiving an ICD implant. Critical to achieving what many participants considered as a *"new norm"* was having the confidence to make the initial decision to have the ICD implanted. Restoring a sense of normalcy also meant having a watchful eye over their bodies in an effort to ascertain the factors that would predispose the ICD to fire and how to manage that event. This constant surveillance on one level helped to decrease participants' anxiety, while on another level caused them the most distress. Overtime all of the women reported that they accepted and needed the ICD to live. Hence, they reported that they developed strategies (e.g., drawing on social supports, being prepared for cardiac event, self-surveillance) to deal with living with the ICD and tended to focus on the positive aspects of their lives.

Discussion

For the women in this study it was a quick and easy decision to have the ICD implanted. They did not report any lengthy contemplation or significant distress, and they made the decision in consultation with the cardiologist. Despite this the women did spend considerable time reflecting on the migrating factors influencing their decision to have the ICD.

This reflection provided a venue to instill the confidence that they had, indeed, made a decision that was warranted and justified. This reflection and confirmation helped the women to accept that the ICD helped them maintain a good quality of life and, hence, was a normal part of their everyday lives.

Knowing that reflection can help patients accept the ICD as a normal part of their lives, it is important that the healthcare team collaborates with the patients during the initial decision and plans interventions that engage the patient in periods of reflection about the decision. As reported by these five women, reflection and discussion of concerns can help to facilitate coping with and accepting of the ICD. Such interventions are within the scope of practice for registered nurses and can be provided through individual counselling/education sessions or in small support group sessions. Nurses, however, must be prepared to provide this counselling or refer the patient to another appropriate member of the healthcare team (e.g., mental health nurse practitioner, social worker, psychologist).

Analogous to other studies (Bolse, Hamilton, Flanagan, Caroll, & Frilund, 2005; Cesarino, Beccaria, Aroni, Rodriques, & Pacheco, 2011; Conelius, 2015; Dickerson, 2002; Etchegary et al., 2017; Magnusson, Jonsson, Morner, & Fredriksson, 2017; Manuel & Brunger, 2016; Morken, Severinsson, & Karlsen, 2010; Palacios-Cena et al., 2011; Zeigler & Nelms, 2009) the experiences of these five women living with an ICD included a sense of comfort and security that in the case of a cardiac event the ICD would fire and save their lives. Even with this newfound sense of safety, the women in this study still described having similar accounts of psychological distress related to anticipating and having an ICD shock, as is seen threaded throughout the literature (Conelius, 2015, Humphreys, Lowe, & Rance, 2016; Manuel & Brunger, 2016; Morken et al., 2010; Versteeg et al., 2012; Zeigler & Nelms, 2009).

In effort to decrease their anxiety, the women in this study engaged in constant surveillance of their bodies that required them to be vigilant in observing for issues with the device, which is consistent with the findings by Dickerson (2002). Surveillance included watching their own bodies for any signs of deterioration that would predispose them to having an ICD shock. Participants reported awareness of the activities thought to trigger the firing of the ICD (e.g., lack of sleep, physical activity) and that they either restricted or modified those activities, again similar to the findings in the literature (Bolse et al., 2005; Eckert & Jones, 2002; Flemme et al., 2011; Hallas, Burke, White, & Connelly, 2010; Manuel & Brunger, 2016; Ooi, He, Dong, & Wang, 2016; Williams, Young, Nikoletti, & McRae, 2007). The healthcare team caring for patients living with an ICD must recognize that it is important to prepare these patients to be able to identify the unique, individual factors that might cause an ICD shock, how to anticipate a shock, and how to manage the firing of the ICD. In particular, nurses can play a critical role on the team by providing the patient education, and psychological support and counselling that are needed by this population, as they start to reintroduce activities into their lives.

These women's narratives revealed that living with an ICD was not something that happens in a silo, but as found in other studies, requires the constant support of family and friends (Manuel & Brunger, 2016; Morken et al., 2010; Ooi et al., 2016). Family and friends were deemed essential to helping the women maintain their normal daily routines such as grocery shopping and driving. When developing a plan of care for this population it is important for the healthcare team to take into consideration the broader context of the family. It is critical to involve family members in developing interventions that reflect the unique healthcare needs of the patient and the family and support participants to maintain their new sense of normalcy.

Restoring normalcy for these women also meant coming to terms with a feeling of dependence on the ICD and restoring the sense of loss of control, as cited in the literature (Kamphius et al., 2004; Morken et al., 2010). The women reported that over time they had more faith in their abilities to handle the ICD, which is similar to the findings of Kamphius et al. (2004). Similar to other research, all of the women eventually accepted having the ICD and started to focus on the positive aspects of their lives (Manuel & Brunger, 2016; Marshall et al., 2012; Ooi et al., 2016; Versteeg et al., 2012; Williams et al., 2007) within the context of a new normal. However, several women noted that the firing of the ICD was a constant reminder of their illness. Being cognizant of the fact that women living with an ICD can experience a loss of independence post ICD insertion, which makes them vulnerable, the healthcare team needs to collaborate with a variety of professionals such as psychologists, social workers, and physicians to help patients develop the skills they need to cope with having an ICD. This study shows there is a need for the development of clinical practice guidelines that not only address the education needs of women living with an ICD, but also address the psychological concerns of this patient population.

The women in this study reported that they experienced psychosocial distress and anxiety post ICD insertion similar to that described in the literature by men (Habibović et al., 2011, Miller et al., 2016; Rahmawati et al., 2013; Splinder et al., 2009, Starrenburg et al., 2014). Similar to their male counterparts, all of the women in this study slowly began to accept the fact that the ICD was something they needed to have in order to live. Women in this study also described similar challenges as men including social isolation, loss of independence and trying to understand the factors that predisposes the ICD to discharge a shock. What is not clear is if there is a difference between how women and men come to accept the ICD as a new norm. Longitudinal studies are needed to address this gap.

Implications for Practice

A well-planned education program that informs ICD recipients and their families as to the working and management of the ICD could help women adjust to having an ICD. Nurses can play an important role in developing and implementing such a program. The healthcare team must also be prepared to plan and implement counselling and psychological interventions for this population beginning at the initial decision about the ICD. When discussing ICD implants with patients it is important to convey a realistic picture as to what life with an ICD might entail. Psychological services that facilitate women to restore a sense of normalcy, as they move along the continuum from making the decision to actually living with the ICD, are needed.

Multidisciplinary clinical practice guidelines that address the psychosocial aspects of living with an ICD are imperative to help this cohort cope. Nurses can play an important leadership role in advocating for the development, implementation and evaluation of these clinical practice guidelines to help to provide the best possible care for women living with an ICD.

Limitations

This study had several limitations. The length of time that the women had an ICD implanted varied from one to 20 years, hence the experiences of the women may differ in relation to their life experiences. Although the women in this study received an ICD implant to treat the complications of cardiovascular disease, each condition can have different physical manifestations and outcomes. Thus, the experiences of the women may be influenced by the disease manifestations, prognosis, and available treatment options. Finally, being that only three of the women had an ICD shock, the findings of this study may not fully capture what this experience is like for these women.

Conclusions

This study captures the experiences of five women, as they tried to restore a sense of normalcy that was disrupted because they had a cardiac condition that warranted an ICD implant. Imperative to accepting a new sense of normalcy was the confidence that having the ICD was the correct decision. The findings of this study support other research in that efforts to identify, anticipate, and prevent the ICD from firing causes significant psychosocial distress and disrupts one's sense of normalcy. Restoring normalcy is contingent on accepting the ICD as something needed to survive, having a good social support network, developing modes to cope with the firing of the ICD, and one's ability to manage everyday challenges. Helping women to build the confidence and the skills needed to manage the ICD is imperative to restoring their state of normalcy. The women in this study reported that although it took time, they eventually assimilated the ICD into their everyday lives, as part of a new normal. It is this integration that helped the women to take a positive outlook on life and to adjust to living with an ICD.

Clinical Highlights

- Clinical practice guidelines that address the physical and psychosocial implications of having an ICD are needed.
- Nurses must develop the requisite skills to provide counselling and education to women living with an ICD.
- Further research is needed to examine if the experiences of women living with an ICD are significantly different from men. ♥

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The Predictive Value of Cardiac Prodromal Symptoms on Major Adverse Cardiac Events: A Systematic Review Protocol

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Abstract

Cardiac warning signs (prodromal symptoms) are symptoms experienced by individuals as a result of encroaching development of obstructive heart disease, years, months, weeks, or days prior to a seminal cardiac event. Prodromal symptoms (PS) are defined as intermittent, vague, singular sensations or a constellation of cardiac-related symptoms felt in tandem with varying levels of intensity and frequency before a major cardiac ischemic event. The variable nature of the PS presentation poses a problem for patients and clinicians to recognize PS as related to ischemic heart disease and, thus, effective and immediate treatment is delayed causing increased negative cardiac morbidity and mortality outcomes. Typically, PS occur up until the time of myocardial tissue injury or death and dissipate once the event has occurred. Effective awareness, screening and timely recognition of individuals who suffer with PS in Canada is urgently needed.

Purpose: *This systematic review protocol will examine the predictive value of prodromal symptoms on acute coronary syndrome-related acute symptom presentation and major adverse cardiac events (MACE).*

Methods: *We will identify, select and critically appraise the quantitative evidence and extract, analyse and summarize the results following methods of the Cochrane Handbook (Higgins & Green, 2011). Search strategy: MEDLINE, Embase, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Proquest Nursing and Allied Health, Education Source, Web of Science, and other relevant subject databases will be searched.*

Potential Significance: *Understanding the predictive value of PS in individuals will help further explain the relationship between PS and MACE. Understanding the similarities and differences in prodromal symptom presentation between men and women will assist in development and provision of pre-emptive assessment and management strategies, individualization of risk factor modification and timely educational and treatment interventions for individuals afflicted with IHD.*

Key words: cardiac prodromal symptoms, ischemic heart disease, systematic review protocol

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Background

Utilization of a cardiovascular health approach in the care and treatment of individuals with ischemic heart disease (IHD), focuses on promotion of heart healthy lifestyle behaviours and modification of risk factor profiles in order to stave off development of disease and provide management of those at risk for IHD (Mozaffarian et al., 2015). Although maximum efforts by healthcare professionals (HCPs) have targeted these areas, the global burden of cardiovascular disease (CVD) remains significant in terms of morbidity and mortality (GBD 2015 Disease and Injury Incidence and Prevalence Collaborators, 2016; Mathers & Loncar, 2006). IHD impacts more than 110 million individuals globally and the incidence is expected to rise over the next decades (GBD 2015 Disease and Injury Incidence and Prevalence Collaborators, 2016; Mathers & Loncar, 2006). CVD worldwide is the number one cause of death in men and women (World Health Organization, 2017). Although there is evidence of a decrease in the incidence of myocardial infarction in recent years (Mozaffarian et al., 2015), escalating levels of diabetes and obesity across many countries makes attention to cardiac health an area of major concern for global health (Balakumar, Maung-U, & Jagadeesh, 2016). Increased attention is needed in terms of incorporation of proactive approaches to effectively screen people for the warning signs—prodromal symptoms—of the development of IHD.

Early recognition of cardiac-specific prodromal symptoms (PS) of an impending cardiac event (unstable angina [UA] or myocardial infarction [AMI]) is critical to circumvent death, provide immediate reperfusion therapies and cardiac risk factor modification for individuals at risk for development of IHD. Symptoms associated with IHD are identified as belonging to the acute coronary syndrome spectrum (ACS). ACS includes unstable angina, AMI, and sudden death (Mozaffarian et al., 2015). Millions of individuals seek emergency care for ACS-related cardiac pain. Of these,

a considerable number fail to recognize warning PS and delay seeking immediate medical attention (Canto et al., 2000; Graham, Westerhout, Kaul, Norris, & Armstrong, 2008).

PS experienced by men and women are typically individual in nature with an array of varied patterns and distributions. Hence, PS are often described as transient and vague symptoms that have included symptoms of chest pain, discomfort in the jaw/teeth/arms, unusual fatigue, anxiety, headaches, shortness of breath and nausea, indigestion and vomiting experienced days, weeks or months prior to an ACS (McSweeney et al., 2003; O'Keefe-McCarthy, 2008; O'Keefe-McCarthy, McGillion, Victor, Jones, & McFetridge-Durdle, 2016; O'Keefe-McCarthy & Ready, 2016). The incidence of PS ranges from 49% to 92% (O'Keefe-McCarthy & Ready, 2016). Little evidence exists that examines the predictive value of PS on acute ischemic symptom presentation or the occurrence of major adverse cardiac events (MACE).

Knowledge to Date

Observations from clinical practice indicate that individuals who report PS prior to their cardiac event will typically experience similar symptoms during the acute cardiac event. For instance, Løvlien et al., reported among 533 ACS patients, women with acute chest pain/discomfort were five times more likely to have had prodromal chest pain (adjusted OR =5.11; 95% CI, 1.38–18.88) (Løvlien, Johansson, Hole, & Schei, 2009). This was almost three times more likely in men (OR=2.80; 95% CI, 1.17–6.70) (Løvlien et al., 2009). McSweeney et al. (2014) reported women (n=1097) with prodromal jaw/teeth pain (HR=1.14; 95% CI, 1.07–1.21) and fatigue (HR=1.08; CI, 1.05–1.11) were more likely to report similar acute symptoms compared with those with no reported PS.

Few studies report the association of PS and MACE. Graham et al. (2008) examined the association of PS and one-year mortality in 2,266 individuals and found that PS were associated with a reduction in one-year mortality for women (HR, 0.74; 95% CI, 0.58–9.95), but not for men (HR, 0.92; 95% CI, 0.76–1.12). McSweeney et al. (2014) examined the association of PS on MACE in 1,097 women; 7% of women experienced a MACE. PS associated with increased risk of MACE were chest discomfort (HR, 1.09; 95% CI, 1.03–1.16), unusual fatigue (HR 1.05; 95% CI, 1.01–1.08) and SOB (HR 1.07; 95% CI, 1.03–1.11).

Prodromal Symptom Presentation

Men and women may experience PS differently in terms of frequency, duration and intensity (Canto et al., 2000; Graham et al., 2008; Løvlien et al., 2009; McSweeney et al., 2003, 2014; Norris et al., 2008; O'Keefe-McCarthy, 2008; O'Keefe-McCarthy et al., 2016; O'Keefe-McCarthy & Ready, 2016). Women report a greater number of PS compared to men (Canto et al., 2000, 2007, 2012; Canto, Canto, & Goldberg, 2014; Graham et al., 2008; McSweeney, Cody, & Crane, 2001; McSweeney & Crane 2000; McSweeney et al., 2010). However, men may present with more prodromal chest pain, whereas women experience greater prodromal fatigue, sleep disturbances, anxiety and headaches (Canto et al., 2007, 2012, 2014; Cole et al., 2012; Hofgren, Karlson, & Herlitz, 1995; Løvlien et al., 2009).

The Alberta Provincial Project for Outcome Assessment in Coronary Artery Disease (CAD) registry examined patients for sex differences; age was associated with PS (Norris et al., 2008). Premenopausal women reported a greater number of PS compared to men of the same age (Norris et al., 2008). Despite the evidence accrued through single studies, no comprehensive systematic reviews were found that provide an in-depth evaluation of the predictive value of PS on acute ACS symptom presentation and MACE. Knowledge from this systematic review will attempt to address this knowledge gap, inform clinical practice and provide research-informed information for patients to base decisions on whether to seek immediate medical advice for cardiac-specific PS to mitigate an untoward, catastrophic cardiac event.

Objectives

This systematic review will identify, select and critically appraise the quantitative evidence and extract, analyse and summarize the results following methods of the Cochrane Handbook (Higgins & Green, 2011) to examine the predictive value of prodromal symptoms (PS) on acute coronary syndrome-related acute symptom presentation and major adverse cardiac events (MACE).

Primary Objective

To examine the predictive value of PS on MACE, specifically unstable angina, acute myocardial infarction (AMI), hospitalizations and all-cause mortality.

Secondary Objective

To investigate whether PS are a significant predictor of acute symptom presentation, adjusting for important and commonly reported confounders (e.g., age, sex, co-morbid conditions such as hypertension, diabetes).

Definitions

Prodromal symptoms. An early symptom (sign or cluster of two or more symptoms occurring together) that is an indication of developing obstructive or ischemic cardiac disease; symptoms occur sporadically and increase in frequency until the cardiac event, then dissipate after the event occurs (McSweeney et al., 2003; O'Keefe-McCarthy, 2008; O'Keefe-McCarthy et al., 2016; O'Keefe-McCarthy & Ready, 2016).

Major adverse cardiac event (MACE). Is defined as all-cause mortality, or hospital admission for ACS, reperfusion therapy (percutaneous coronary intervention), revascularization (coronary artery bypass grafting).

Unstable angina. Sudden onset of unprovoked cardiac chest pain that increasingly becomes worse; occurs at rest or while asleep (Mozaffarian et al., 2015).

Acute myocardial infarction. Death of myocyte (cardiac cells) from ischemia related to an imbalance between supply (blood perfusion) and demand (Thygesen et al., 2012).

Population Inclusion/Exclusion Criteria

The studies for review will include adult men and women (aged 18 years or older) with report of acute symptoms of cardiac chest pain and/or those with confirmed ACS (either unstable angina or AMI [non-ST-elevation myocardial infarction/ST-elevated myocardial infarction]) exhibiting PS.

Phenomena of Interest. Cardiac prodromal symptoms are the area of interest and will include, although will not be limited to chest/arm/jaw pain intensity (pain/discomfort/pressure), SOB, anxiety (fear/worry/restlessness), fatigue, headache, nausea/vomiting, sleep disturbance, chest sensations or palpitations and dizziness or weakness.

Outcomes. The review outcomes of interest will include ACS-related acute symptoms presentation, all-cause mortality and cardiac-related hospitalizations for ACS, reperfusion therapies and revascularization procedures.

Comparator/Controls. There is no control or comparator group.

Study Selection. We will consider randomized controlled trials, quasi-randomized studies, cohort studies, case-control studies and cross-sectional studies as eligible for inclusion into the review. Only studies published in the English language will be considered for inclusion in this review.

Search Strategy

The information specialist will develop a peer-reviewed search strategy and conduct the search of subject literature databases, from their inception to current date, including MEDLINE, Embase, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Proquest Nursing and Allied Health, Education Source, Web of Science and other relevant subject databases. Relevant medical subject heading (MeSH) terms will be used in combination with key word searching: preliminary search strategy is provided in Table 1. To access additional peer-reviewed and grey literature we will hand search the reference lists of key studies and pertinent cardiovascular journals and conference programs. Additionally, we will contact corresponding authors and experts in the field for additional details of published/unpublished work, as required.

Study Selection. The web-based application Zotero will be used to manage all of the references and organize the study selection process (Zotero, n.d.). All unique citations will be screened with a pre-designed screening tool listing inclusion

Table 1: Search Strategy-Predictive Value of Cardiac Prodromal Symptoms on Major Adverse Cardiac Events

Search concept	Search terms: keywords, related terms and/or subject headings (Joined with OR search operator)		
Population			
MACE	"Major Adverse Cardiac Event" MACE "acute coronary syndrome" angina "myocardial infarction" "heart attack" death mortality reperfusion "percutaneous coronary intervention" revascularization "coronary artery bypass graft*"		
AND			
Phenomena of interest			
Cardiac prodromal symptoms	Prodrom* Warning Predict*	AND	(Chest OR arm OR jaw OR teeth) AND (pain OR discomfort OR pressure) "shortness of breath" Anxiety Fatigue Headache* Nausea Vomit* Sleep* Palpitation Dizziness Weakness

and exclusion criteria by two team members, independently. We will document the results in a flow chart, as recommended in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher, Liberati, Tetzlaff, Altman, & PRISMA Group, 2009) showing the total numbers of retrieved references and the numbers of included and excluded studies.

First, titles and abstracts will be screened as "include", "exclude" and "unsure". Second, for citations deemed as either "included" or "unsure" the full text citations will be retrieved and screened as "include" or "exclude". A third reviewer will review any disagreements that are not resolved through discussion among reviewers undertaking screening and reach a consensus on the final rating.

Critical Appraisal of Studies. Again, two members of the team will independently assess all included studies for risk of bias. Unresolved disagreements between reviewers will be resolved by a third reviewer. As this synthesis is addressing prognosis, all randomized, quasi-randomized studies, cohort and case control studies will be assessed using Quality In Prognosis Studies (QUIPS) checklists (Hayden, van der Windt, Cartwright, Côté, & Bombardier, 2013; Moons et al., 2014) to examine the quality of reporting and use of methods that influence the quality of the studies, as recommended in the Cochrane Handbook (Higgins & Green, 2011). Randomized and quasi-randomized studies will be treated as two single arm observational studies, one arm being the intervention group and the other control group (Iorio et al., 2015).

Data Extraction. Relevant data will be extracted independently by two team members using a form that is reviewed and revised with input from all team members. Extracted data will be entered into RevMan (Review Manager [RevMan], 2014).

Synthesizing the Findings. The characteristics of the included studies and their risk of bias assessments will be summarized, as well as quantitative findings using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach (Guyatt et al., 2008).

Characteristics. A narrative summary will provide an overview of the relevant studies. A summary table will be generated and will include information on purpose, study design, sample size, setting, year of publication, country, PS and outcome/measurement tool(s) and limitations identified by authors and reviewers.

Risk of Bias. Risk of bias within and across studies will be narratively summarized and graph figures and summary figures generated using the Cochrane Collaboration format (Higgins & Green, 2011).

Predictive Value of Prodromal Symptoms

A summary of findings table using the GRADE approach will summarize the results (Guyatt et al., 2008). Following data extraction from all included studies will, where possible, be pooled statistically for meta-analysis. Subsequently, heterogeneity between studies will be evaluated using chi-square tests for the tau-squared statistic, quantified using the I2 statistic (Turkeltaub, Eden, Jones, & Zeffiro, 2002). If the studies are clinically heterogeneous we will summarize the results using a narrative synthesis approach to describe the impact that PS have on MACE and acute symptom presentation. If there is statistical and clinical homogeneity, the primary and secondary objectives will be evaluated using random effects binary meta-regression to determine effect sizes (DerSimonian & Laird, 1986; Westfall & Young, 1989) to 1) establish whether acute symptom presentation and MACE are associated with the presence of PS (PS [dichotomous] will be modelled onto acute symptoms, unstable angina, AMI death, reperfusion, revascularization), and 2) evaluate the predictive weight of PS on acute symptom presentation, adjusting for confounders (e.g., age, sex, co-morbid conditions such as diabetes). An inverse-variance random effects model (using Hedges and Vevea's estimator) will be used when studies can be combined (Turkeltaub et al., 2002). To account for type I error, p-values will be adjusted using bootstrap re-sampling (DerSimonian & Laird, 1986) to control for family wise error rate. Potential publication bias will be visualized with funnel plots. Given the possibility of age- and sex-related differences in the occurrence, frequency, intensity and duration of PS, where possible, an exploratory gender analysis will be conducted controlling for all confounders.

Potential Significance

For cardiovascular nurses, having access to knowledge generated from this systematic review, where we examine the predictive value of PS in individuals, adjusting for differences in age, sex, co-morbidity and risk factors, will increase clinician understanding of the relationship between PS and MACE. Recognition of the similarities and differences in prodromal symptom presentation between men and women will assist in individualized and targeted PS assessment in clinical practice. Further, this knowledge will provide nurses the evidence to support, develop and provide pre-emptive risk factor modification and timely educational and treatment interventions for individuals afflicted with IHD. At present, public messaging by government and healthcare agencies on PS is non-existent and non-gender-specific. Research-informed messaging and information identified through this systematic review will support the early recognition of pre-clinical, cardiac-specific PS that is long overdue. Synthesizing research to identify the predictive value of PS is the critical next step in preventative care for those at risk or currently suffering with ischemic heart disease. ♥

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