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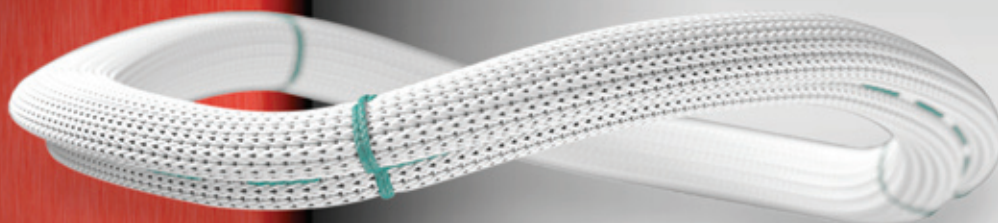
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Canadian Journal of Cardiovascular Nursing

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Nurse Practitioners in Postoperative Cardiac Surgery: Are They Effective?

Catherine L. Goldie, MSc, RN, Natasha Prodan-Bhalla, MN, NP(A), CCN(C), and Martha Mackay, PhD, RN, CCN(C)

Abstract

Background: High demand for acute care nurse practitioners (ACNPs) in Canadian postoperative cardiac surgery settings has outpaced methodologically rigorous research to support the role.

Purpose: To compare the effectiveness of ACNP-led care to hospitalist-led care in a postoperative cardiac surgery unit in a Canadian, university-affiliated, tertiary care hospital.

Methods: Patients scheduled for urgent or elective coronary artery bypass and/or valvular surgery were randomly assigned to either ACNP-led ($n = 22$) or hospitalist-led ($n = 81$) postoperative care. Both ACNPs and hospitalists worked in collaboration with a cardiac surgeon. Outcome variables included length of hospital stay, hospital readmission rate, postoperative complications, adherence to follow-up appointments, attendance at cardiac rehabilitation and both patient and health care team satisfaction.

Results: Baseline demographic characteristics were similar between groups except more patients in the ACNP-led group had had surgery on an urgent basis ($p \leq 0.01$), and had undergone

more complicated surgical procedures ($p \leq 0.01$). After discharge, more patients in the hospitalist-led group had visited their family doctor within a week ($p \leq 0.02$) and measures of satisfaction relating to teaching, answering questions, listening and pain management were higher in the ACNP-led group.

Conclusion/implications: Although challenges in recruitment yielded a lower than anticipated sample size, this study contributes to our knowledge of the ACNP role in postoperative cardiac surgery. Our findings provide support for the ACNP role in this setting as patients who received care from an ACNP had similar outcomes to hospitalist-led care and reported greater satisfaction in some measures of care.

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Key words: nurse practitioners, role, acute care, thoracic surgery, evaluation studies

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Est-ce que les infirmières praticiennes en soins post-opératoires de chirurgie cardiaque sont efficaces?

Introduction : Au Canada, les fortes demandes concernant les besoins en infirmières praticiennes spécialisées (IPS) dans les unités de soins post-opératoires de chirurgie cardiaque ont dépassées les recherches scientifiques rigoureuses supportant ce rôle.

But : Comparer l'efficacité des soins post-opératoires de chirurgie cardiaque prodigués par l'IPS aux soins prodigués par les hospitalist-led dans une unité de soins d'un centre hospitalier tertiaire affilié universitaire.

Méthodes : Les patients en attente d'une chirurgie cardiaque électorale ou urgente (pontages coronariens ou chirurgie valvulaire) ont été aléatoirement divisés dans l'un des deux groupes : celui de l'IPS ($n = 22$) ou de hospitalist-led ($n = 81$) pour le suivi post-opératoire. L'IPS et l'hospitalists ont travaillé en collaboration avec le chirurgien cardiaque. Voici les variables qui ont été mesurées : la durée du séjour hospitalier, le taux de réadmission à l'hôpital, les complications post-opératoires, l'observance aux rendez-vous de suivis, la fréquentation du centre de réadaptation cardiaque ainsi que la satisfaction des patients et de l'équipe de soins.

Résultats : Les caractéristiques démographiques initiales se sont révélées similaires entre les deux groupes sauf sur ces aspects : plus de patients suivis par l'IPS ont eu des interventions chirurgicales urgentes ($p \leq 0.01$) et ont vécu davantage de complications chirurgicales ($p \leq 0.01$). Lors du congé médical, plus de patients dans le groupe de l'hospitalist-led ont eu un rendez-vous avec leur médecin de famille durant la semaine suivant leur congé ($p \leq 0.02$). Les mesures de satisfaction concernant l'enseignement, la réponse aux questions, l'écoute et la gestion de la douleur ont été plus élevées dans le groupe de l'IPS.

Conclusion/Implications : Cette étude a contribué à optimiser l'importance du rôle de l'IPS auprès des patients en soins post-opératoires de chirurgie cardiaque. Malgré une participation moindre qu'escomptée initialement, nos découvertes permettent de supporter que le rôle de l'IPS dans le contexte où les patients ayant bénéficiés des soins de l'IPS en post-opératoire de chirurgie cardiaque ont présentés des résultats similaires aux patients recevant des soins de l'hospitalist-led en regard des variables à l'étude et même un niveau de satisfaction supérieure pour quelques mesures de soins.

The emergence of the nurse practitioner (NP) role in Canadian health care settings has improved access to high-quality, cost-effective patient care (DiCenso & Bryant-Lukosius, 2010; Kilpatrick et al., 2010; Martin-Misener, Downe-Wamboldt, Cain, & Girouard, 2009; McAiney et al., 2008). The Canadian Nurses Association (2009) defines NPs as “registered nurses with additional educational preparation and experience who possess and demonstrate the competencies to autonomously diagnose, order and interpret diagnostic tests, prescribe pharmaceuticals, and perform specific procedures within their legislated scope of practice” (2009). The NP role is firmly established in primary care settings as its effectiveness has been evaluated and proven through systematic reviews of existing literature (Horrocks, Anderson, & Salisbury, 2002; Laurant et al., 2005). However, changes in health care environments, such as increased patient acuity levels and pressure to both reduce inpatient length of stay and contain costs have created a demand for NPs in acute care settings (Rosenthal, Guerrasio, & Bell, 2009; Sidani & Irvine, 1999). Acute care nurse practitioners (ACNPs) provide acute care services for adult and pediatric patients who are acutely, critically, or chronically ill (DiCenso & Bryant-Lukosius, 2010). There is an especially high demand for ACNPs in postoperative cardiac surgery, as decreased numbers of medical residents and staff physicians (Grover et al., 2009), coupled with pressures to respond to long waiting lists by increasing the number of surgeries performed (Levy et al., 2005), have created a bottleneck in the flow of care. ACNPs are uniquely situated to address these systemic gaps in postoperative cardiac surgery, as they have the knowledge and skills to deliver care in this setting and are not simply replacements for their physician counterparts. ACNPs provide comprehensive care for patients through enhanced education and communication between health care providers and family members. Further, the need for ACNPs in this setting has outpaced methodologically rigorous research to support their role (Jensen & Scherr, 2004). In this paper, we present findings from a prospective study that evaluated the ACNP role on a postoperative cardiac surgery unit at a large, tertiary-care Canadian hospital.

Literature Review

ACNPs in cardiac surgery. Despite significant advances made in the implementation of the ACNP role since the inception of the first Canadian ACNP program offered in neonatology at McMaster University in 1986 (Mitchell et al., 1995), considerable opportunity still exists to define ACNPs' contributions to Canadian health care teams and to measure outcomes associated with their care in cardiac surgery settings. In a recent review of published randomized controlled trials (RCTs) ($n = 18$) that compared the effectiveness of ACNP- versus physician-led care in various acute care settings, no differences in patient outcomes such as morbidity, mortality or length of hospital stay were identified (DiCenso

& Bryant-Lukosius, 2010). However, only one of these studies was conducted in Canada (Mitchell-DiCenso et al., 1996) and only two studies were situated in a cardiac surgery context (Allen et al., 2002; Stables et al., 2004). In the study conducted by Stables et al. (2004), the researchers compared the performance of ACNPs trained to prepare patients for diagnostic cardiac catheterization to junior medical staff in the United Kingdom. They found that the incidence of major adverse clinical events and patients' preparation for the procedure, as measured by cardiologists' assessments, were equivalent. However, patient satisfaction was found to be greater in the ACNP group ($p \leq 0.04$), even though they spent significantly less time than the junior medical staff (165 min versus 185 min, $p = 0.01$) preparing patients for surgery. Other RCTs that have indicated that ACNP-led care versus usual care among discharged cardiac surgery patients have demonstrated comparable outcomes (Tranmer & Perry, 2004) and highlighted benefits of ACNP-led interventions to assist patients to achieve cardiovascular risk reduction targets (Allen et al., 2002).

ACNP-provided care in conjunction with cardiovascular surgeons or cardiologists has also proved to be advantageous for patients and the health care system. Meyer and Miers (2005) conducted a retrospective comparison study in the United States to examine patient and economic outcomes of cardiovascular care delivered by either cardiovascular surgeons alone or cardiovascular surgeons in collaboration with ACNPs. They found that when cardiovascular surgeons directed postoperative care in collaboration with ACNPs, the average length of hospital stay decreased by 1.91 days and average total cost decreased by \$5,038.91 (U.S.) per patient, compared to surgeon-only care. Similarly, Broers et al. (2005) evaluated the safety and efficacy of ACNP-led care provided to post-coronary artery bypass graft (CABG) patients in the Netherlands, compared to care by a medical resident. The investigators found that, although both groups were supervised by an attending cardiologist, ACNP-treated patients were discharged significantly sooner than those treated by medical residents (11.5 versus 14.8 days; $p \leq 0.001$). Thirty-day mortality did not differ between groups.

In Canada, there has been little research to support ACNP roles in cardiac surgery settings and the research that has been conducted has had methodological limitations. For example, Jensen and Scherr (2004) surveyed health care providers who worked with an ACNP in a cardiothoracic intensive care unit at a large tertiary care hospital, and found that processes and outcomes of care were positively affected following implementation of the ACNP role. However, this study had a low ($n = 34/90$) response rate that may introduce potential bias in the findings. Sidani et al. (2006) used a cross-sectional design to compare the health outcomes of hospital in-patients who received care from either ACNPs ($n = 320$) or medical residents ($n = 46$)

in various medical and surgical settings. Although this study was not specifically designed to evaluate care in the cardiac surgery setting, 46% of the sample was cardiac surgery patients and half of the providers ($n = 20$) were recruited from cardiovascular surgery units. The investigators found that patients who received ACNP-led care reported higher ($p \leq 0.0001$) levels of satisfaction with care coordination, participation in care, counselling and education, as compared with those who received care from medical residents. This finding contributes to the rationale of the current study as it highlights a need for further inquiry into ACNP-led care in cardiac surgery settings.

Important barriers and facilitators have also been identified that have an impact on ACNP roles in the Canadian health care system. Previous research has identified these barriers as a lack of full utilization of their role components, limitations placed on their scope of practice, inconsistent acceptance from other health care providers, and issues related to funding ACNP positions. Facilitators for ACNP role implementation include clear communication about the role, support from healthcare managers and reliable funding for ACNP positions (Kilpatrick et al., 2010).

Conceptualization of the ACNP role. The conceptual framework that was used to guide this study was developed by Sidani and Irvine (1999) and patterned after Donabedian's (1988) structure-process-outcome model of care. This framework represents the complex system of interrelated factors that are known to influence ACNP role effectiveness. Two components of the model are hypothesized to influence the quality of patient care and cost outcomes. The first, the structure component, includes the patient, the ACNP and organizational variables. The second is the process component, which consists of ACNP role components and role enactment. These components informed the design of this study and were particularly useful for selecting measures to evaluate the ACNP role in a postoperative cardiac surgery setting.

Rationale. While ACNPs practise in cardiac surgery programs across the United States and Europe, the effectiveness of the role in a Canadian setting has not been thoroughly investigated. The purpose of this prospective study was to compare the effectiveness of ACNP-led-care to hospitalist-led-care in our postoperative cardiac surgery unit, which is situated in a Canadian tertiary-care hospital. Patients who received care from hospitalists were characterized as belonging to the control group, because this was the care delivery model in place before introduction of ACNPs on our unit, and patients who received care from ACNPs were categorized as the experimental group. Based on our literature review, we hypothesized that patient outcomes associated with the ACNP role would be as or more favourable than care provided by hospitalists.

Research questions. The study was guided by the following research questions:

1. Is there a difference in ACNP-led versus hospitalist-led postoperative cardiac surgical care with respect to the following patient outcomes:
 - a. hospital length-of-stay
 - b. rates of re-admission to hospital
 - c. selected postoperative complications
 - d. adherence to follow-up with family physician and cardiologist
 - e. cardiac rehabilitation attendance
2. Is there a difference in patient or health care team satisfaction with ACNP versus hospitalist-led care in a postoperative cardiac surgery program?

Methods

Setting and participants. We employed a prospective, randomized design. This study was conducted at a 450-bed, university-affiliated tertiary care hospital where the postoperative cardiac surgery unit is 25 beds, 15 of which have telemetry capability. Complex patients from throughout the province of British Columbia are routinely transferred to this centre for specialized cardiac surgical care. As a result, the patients have highly variable demographic and ethno-cultural characteristics, multiple co-morbidities, and are from both urban and rural areas.

Patients over the age of 18 years, who had been scheduled for either urgent or elective CABG and/or valvular surgery between May 2004 and February 2005 and could read and understand English were approached to participate in the study. Patients who were unable to provide informed consent or who had had emergency cardiac surgery were excluded from the study. The sample size was calculated based on the length of stay endpoint. By setting the power (beta) at 80%, alpha at 5%, and assigning three controls for each case, the sample size was set to detect a mean difference of two days between the ACNP and hospitalist-led groups. This calculation determined that 75 patients in the ACNP arm and 225 patients in the hospitalist arm were needed. As 600 patients underwent CABG +/- valve surgery at the study site annually at the time of the study, we expected that our recruitment strategy would meet this target.

ACNP role. The ACNP role was introduced to the postoperative cardiac surgery unit a year before this study began. Before this role was implemented, patients were cared for by hospitalists, who were physicians trained in general practice, in collaboration with a cardiac surgeon. After implementation of the ACNP role, patients were assigned to either ACNP-led or hospitalist-led postoperative care. Cardiac surgeons were available postoperatively to assist both the ACNP and hospitalists with urgent issues and were present daily at rounds. Care provided by the ACNP and the hospitalists was guided by a previously established clinical pathway, and

individualized on a case-by-case basis. The pathway included guidelines for care of postoperative patients and directed use of pain and prophylactic medications, telemetry and frequency of dressing changes.

The ACNP in this study had a caseload of approximately eight to 10 patients per day and functioned solely as a clinician, without administration or research responsibilities. The ACNP developed individualized plans of care for her patients to augment established clinical pathways, by performing focused physical assessments and comprehensive health histories and reviewing her patients' medications and diagnostic tests. Upon discharge, patients' family physicians were sent a letter with a summary of the hospital stay and recommendations. If the ACNP anticipated that the patient would experience complications after discharge, the family physician was contacted over the telephone and his or her plan of care was discussed.

Procedure for data collection. Ethics approval was obtained from the affiliated hospital and university research ethics boards. Potential participants were identified from the elective surgery list five to seven days before their scheduled procedure and urgent list at least one day before their scheduled procedure. Identified individuals were approached to participate by a research assistant before their surgery. Patients who were not from the immediate geographical catchment area were approached the day before surgery. Once written informed consent was obtained, participants were randomly assigned by the cardiac surgery triage coordinator at a planned ratio of 3:1 to either ACNP-led or hospitalist-led postoperative care using a randomization procedure. The coordinator then informed the ACNP and the hospitalists which patients were assigned to their care. This randomization procedure was selected because there was one ACNP providing care in our study on a part-time basis and two hospitalists, which limited the number of patients who could be assigned to ACNP-led care.

Clinical data were collected at three time points: admission, discharge and six-to-eight weeks after discharge. At admission, a research assistant, who was blinded to group assignment, collected demographic characteristics, clinical and procedural data from the participants' health records. At discharge, patients completed a questionnaire measuring satisfaction with care. This 23-item Likert measure was developed by our research team using the Picker-Commonwealth dimensions and it was further tailored to the cardiac surgery setting. It included questions relating to patients' satisfaction with information and education provided to them, coordination of care, physical comfort, emotional support, respect for their preferences, involvement of family and friends, continuity of care and overall impression of quality of care. The Picker-Commonwealth dimensions have previously demonstrated consistent reliability estimates >0.8 and have exhibited high internal construct validity when used in

five countries including the United States, United Kingdom, Germany, Sweden and Switzerland (Jenkinson, Coulter, & Bruster, 2002).

After six to eight weeks, participants were contacted by a research assistant to determine whether they had followed discharge recommendations (enrolling in a cardiac rehabilitation program, attending follow-up visits with their family physician and cardiologist), or had been readmitted to the hospital since their surgery. Other patient outcome data collected included length-of-stay and postoperative complications, as recorded on the hospital discharge summary. Members of the health care team (including nurses, allied health professionals and surgeons) also completed questionnaires measuring team satisfaction with ACNP and hospitalist care. This seven-item questionnaire, developed by our research team, used the Picker-Commonwealth dimensions. Respondents were asked to rate the ACNP and hospitalist on their written and verbal communication, attentiveness and quality of care provided to their patients, as well as their ability to cooperate with other health care providers (e.g., nurses and cardiac surgeons).

Data analysis. Descriptive statistics were used to profile the samples' demographic and baseline clinical characteristics, as well as details of the surgical procedures performed in each group. Independent t-tests (for continuous variables) and chi-square analysis (for categorical variables) were used to compare participants in the ACNP-led group with those in the hospitalist-led group on key outcomes. Patient and team satisfaction scores were summed and compared by independent t-tests. Group differences in patient satisfaction responses were explored using multiple regression analysis. The groups' engagement in follow-up care was compared using chi-square analysis. Statistical significance was set at ≤ 0.05 .

Results

Sample characteristics. After the initial screening, 103 patients were enrolled in the study; 22 in the experimental group and 81 in the control group. Twenty-six patients in the hospitalist-led group and five patients in the ACNP-led group were lost to follow-up, leaving 55 people in the hospitalist and 17 people in the ACNP group for follow-up. Patients who were lost to follow-up did not return telephone calls from the research team or provided unreliable telephone numbers and could not be reached. See Figure 1 for a flow diagram of study participants. There were no appreciable differences between participants who were lost to follow-up and those who completed the study. Challenges to recruitment were met in this study because it was conducted in a highly active research environment where there were competing research priorities. Because of this, the targeted sample size of 300 participants was not reached before study funding had been exhausted. This limited our ability to conduct meaningful sub-group analysis.

Participants' pre-operative clinical and demographic data are provided in Table 1. Participants were primarily men (86%) with a mean age of 67 (SD = 10) years in the ACNP-led group and 65 (SD = 11, p , NS) years in the hospitalist-led group. The majority in both groups had not completed postsecondary education. The groups had an equal number of co-morbid medical diagnoses at admission. However, other clinical characteristics between groups differed significantly. In the ACNP-led group, the majority of patients had undergone urgent procedures, whereas most patients in the hospitalist-led group had received procedures on an elective basis. Further, procedures differed between groups: three-quarters of participants in the ACNP-led group had had coronary artery bypass (CABG) surgery and one-quarter had received CABG and valve surgery, whereas, in the hospitalist-led group, more than half of participants had had CABG surgery, one-quarter valve-only surgery, and a small percentage of participants had had both CABG and valve surgery.

Clinical outcomes. Clinical outcomes by group are provided in Table 2. The ACNP- and hospitalist-led groups did not differ significantly in length of hospital stay, hospital re-admission within 60 days, number of postoperative complications and attendance at cardiology or cardiac rehabilitation appointments. However, significantly more individuals in the hospitalist-led group attended their family physician follow-up appointment within a week of discharge ($p = 0.02$).

Patient and team satisfaction. Overall patient and team satisfaction scores did not significantly differ between groups (see Table 3). However, multiple linear regression analysis revealed significant differences between groups on certain patient satisfaction items (see Table 4). After controlling for clinical characteristics such as urgency of procedure and type of procedure performed, participants in the ACNP-led group had significantly higher satisfaction scores for items related to teaching, answering questions, listening skills, and pain management. Cronbach's alpha for

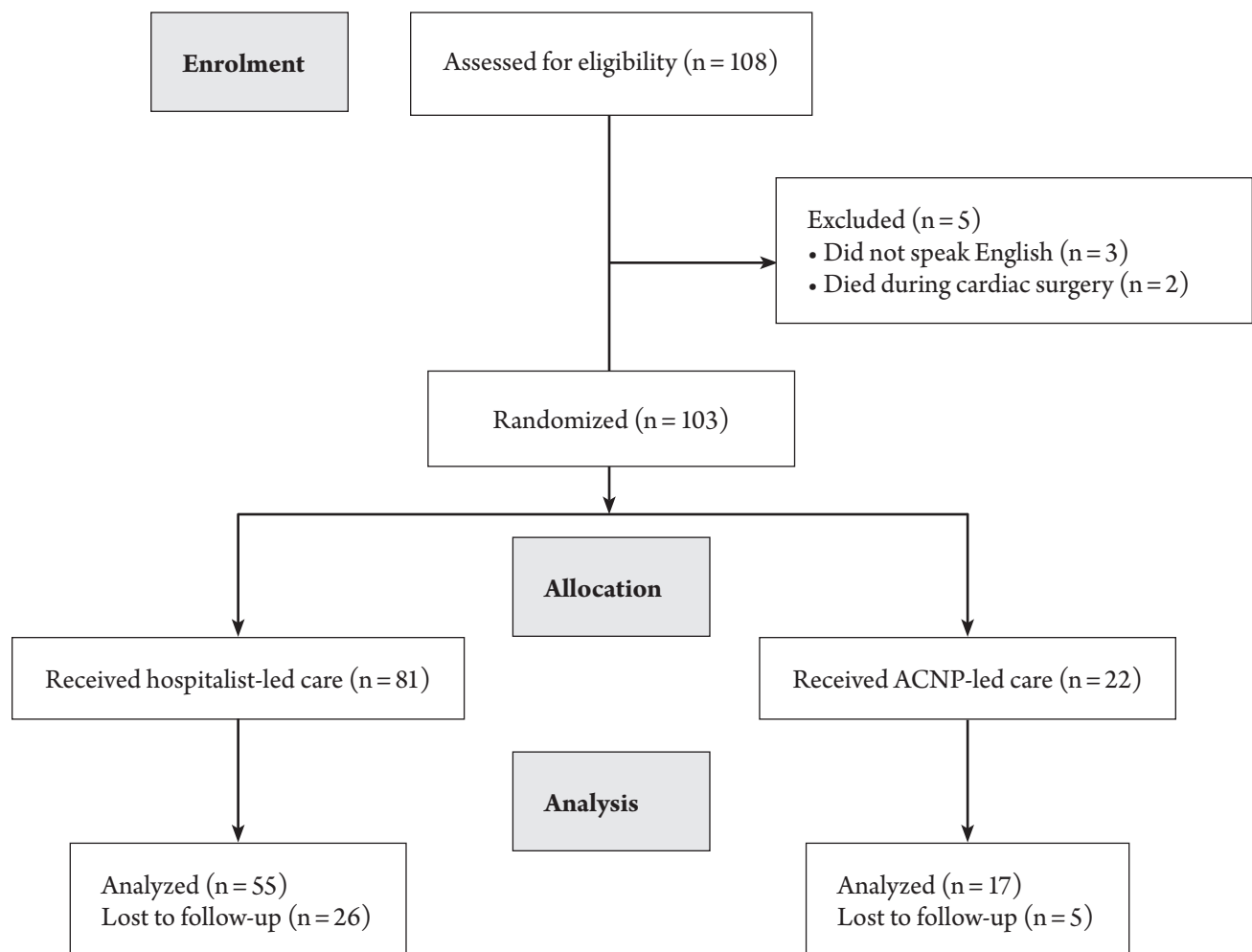


Figure 1: Patient Flow Diagram

the patient satisfaction score was 0.95 and positive item correlations ranged from 0.2-0.8. Cronbach's alpha for the team satisfaction score was 0.90 and positive item correlations ranged from 0.3-0.8, indicating that both questionnaires have satisfactory internal validity.

Discussion

The aim of this study was to evaluate the effectiveness of the ACNP role in a Canadian postoperative cardiac surgery unit using an established framework. Although we were not able to recruit the desired sample size, we believe our study findings illuminated useful patterns related to the ACNP role in this setting that could be explored in future research. We found no differences in hospital length of stay, hospital re-admission rates, number of postoperative complications, adherence to cardiologist follow-up and cardiac rehabilitation between ACNP-led versus hospitalist-led care. We also noted a disproportionately high number of men in our sample, which raises questions about system level factors that

Table 1: Pre-operative patient clinical and demographic data for ACNP- and hospitalist-led care

Characteristic	Group		p
	ACNP (n=22)	Hospitalist (n=81)	
Age, mean (SD) (n = 103)	67 (10)	65 (11)	0.30
Sex, N (%) (n = 103)			
Female	3 (14)	15 (19)	
Male	19 (86)	66 (81)	0.58
Education Level, n (%) (n = 74)			
Secondary or less	11 (61)	28 (50)	
Started or completed university or college	5 (28)	20 (36)	
Post graduate	2 (11)	8 (14)	0.71
Co-morbid diagnoses, mean (SD) (n=98)	2 (1)	2 (1)	0.36
Urgency of procedure, n (%) (n = 87)			
Elective	3 (15)	38 (57)	
Urgent	17 (85)	29 (43)	<0.01
Procedure, n (%) (n = 98)			
CABG	15 (71)	48 (62)	
Valve	0	19 (25)	
CABG and valve	6 (29)	10 (13)	<0.01
Note: n variable due to varying amounts of missing data; ACNP (acute care nurse practitioner); CABG (coronary artery bypass graft)			

Table 2: Clinical outcomes for patients who received ACNP-led versus hospitalist-led care

Outcome	Group		p
	ACNP (n = 22)	Hospitalist (n = 81)	
Length of hospital stay, days (SD) (n = 103)	9 (6)	9 (14)	0.87
Hospital readmission within 60 days, n (%) (n = 47)	3 (38%)	11 (28%)	0.61
Postoperative complications, mean (SD) (n = 70)	3 (18)	9 (17)	0.95
Attended family physician follow-up appointment, n (%) (n = 50)	5 (63%)	40 (95%)	0.02
Attended cardiology follow-up appointment, n (%) (n = 50)	7 (88%)	36 (86%)	0.89
Attended cardiac rehabilitation, n (%) (n = 50)	2 (25%)	13 (31%)	0.73
Note: n variable due to varying amounts of missing data; ACNP (acute care nurse practitioner)			

Table 3: Overall patient and team satisfaction scores for ACNP-led and hospitalist-led care

Outcome	Group		p
	ACNP	Hospitalist	
Overall patient satisfaction, mean (SD) (n = 72)	103 (11)	97 (14)	0.10
Overall team satisfaction, mean (SD) (n = 29)	32 (3)	30 (3)	0.07
Note: varying amounts of missing data			

Table 4: Group differences between patient satisfaction items

Question	Group		p
	ACNP (n = 17)	Hospitalist (n = 55)	
The way you were taught by the ACNP/Hospitalist helped you understand better	4.56 (.69)	3.70 (1.1)	< 0.01
Your ACNP/Hospitalist listened to you	4.76 (.42)	4.23 (.85)	0.01
Your questions were answered	4.76 (.48)	4.31 (.80)	0.02
Your pain was acceptable during your hospital stay	4.71 (.48)	4.28 (.77)	0.04
The care by ACNP/Hospitalist was excellent	4.82 (.38)	4.33 (.74)	0.02
Note: Scores are reported as mean (SD); ACNP (acute care nurse practitioner)			

may privilege men in our cardiac surgery program, or the willingness of women versus men to participate in research studies. Overall patient and team satisfaction did not differ significantly between groups, as has been previously reported in similar studies (Jensen & Scherr, 2004; Sidani et al., 2006; Stables et al., 2004). However, ACNP-led care was rated significantly higher on several patient satisfaction items (relating to teaching, answering questions, listening and pain management). These areas of strength align with ACNP goals and education, which are grounded in nursing. ACNPs prioritize effective pain management, and it appears as if this skill translates well to the postoperative cardiac surgery setting. The overall patient satisfaction score was slightly higher, but not statistically more significant in the ACNP group than the hospitalists' group (103 versus 97, $p = 0.1$). It is possible that this represents a Type II error, and that a larger sample size would have yielded statistically significant differences in this outcome. It is also possible that the instruments we used to measure satisfaction had inherently more random error than we anticipated.

It is also interesting that, although patients in the ACNP group were more complex (a higher proportion were characterized as "urgent", and a higher percentage underwent more complicated surgical procedures) than patients in the hospitalist-led group, the groups did not differ in their clinical outcomes. This patient assignment pattern contrasts with previously reported practice patterns in which physicians typically care for higher acuity patients than do ACNPs (Rudy et al., 1998). We suggest that our findings indicate that ACNP-led care holds promise for the care of postoperative cardiac surgery patients. Our data analyses suggest that patients who were cared for by hospitalists were more likely to visit their family doctor within a week of discharge. Perhaps patients assigned to the ACNP did not understand the need for follow-up with their family physician, or the participants in the ACNP-led group did not feel the need to seek follow-up after discharge because of the care that they received in hospital. Further qualitative and quantitative research is required to confirm and interpret this finding.

Several barriers and facilitators to enactment of the ACNP role were encountered in our cardiac surgery setting. Barriers to the ACNP role included initial lack of awareness of the role by other health care professionals and administrators, the initially limited scope of practice when the role was introduced and the unknown benefits to patient care. Administrators, as well as cardiac surgeons, had to become familiar with these issues before they could support and facilitate the implementation of the role. Facilitating factors for the ACNP role included support from all levels of nursing (staff nurses, other advanced practice nurse colleagues and nursing administration) and medical staff. The willingness of senior hospital administrators to support this new ACNP role was key to its implementation in this setting.

The conceptual framework that we used allowed us to identify and anticipate these factors in the design phase of this study and avoid overlooking important aspects associated with implementing and evaluating the effectiveness of the ACNP role.

Some limitations of the current study are important to note when interpreting the findings. First, our recruitment strategy lacked resources and this yielded a smaller than desired sample size. This limits the generalizability of the study findings and our ability to conduct sub-group analyses. Second, although many attempts were made to obtain complete post-discharge data on all participants, a sizable number were lost to follow-up, which introduced the potential for bias in the study findings. Third, the patient and team satisfaction measures for this study were newly developed, and require further psychometric testing.

Conclusion

The findings of this evaluation of the ACNP practice in a postoperative cardiac surgery unit indicate that the ACNP role is effective in this setting and patients are satisfied with ACNP-led care. Further research is required to replicate these findings in other postoperative cardiac surgery units with larger sample sizes and validated measures. Larger studies will increase our understanding of ACNP practice in Canadian acute care settings. ♥

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A Pilot Randomized Trial of a Smoking Cessation Nursing Intervention in Cardiac Patients after Hospital Discharge

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Abstract

Background: One fifth of Canadians are smokers despite the availability of community-based smoking cessation programs. It was hypothesized that offering a post-discharge smoking cessation program to cardiac patients would decrease smoking rates at six months.

Method: This pilot randomized study explored the feasibility, acceptability and preliminary efficacy of a smoking cessation intervention delivered by a Smoking Cessation Nurse Specialist (SCNS) to cardiac patients after hospital discharge.

Sample: Participants (N = 40) were randomized to either a post-discharge telephone intervention delivered weekly for the first month and then monthly until the third month (experimental group [EG]), or referral to usual community care (control group [CG]).

Findings: The researchers confirmed the feasibility of recruitment and acceptability of the intervention, but difficulty with follow-up. The intention-to-treat analysis showed similar smoking cessation rates in both groups at six months (25% EG versus 30% CG; $p = 0.72$).

Conclusion: An intensified follow-up protocol, or a more intensive, comprehensive and multidisciplinary intervention might be required, given the characteristics of the smokers.

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Key words: smoking cessation, nursing intervention, motivational interviewing, stages of change, randomized pilot trial, cardiovascular care

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Étude clinique randomisée évaluant les effets d'un programme d'interventions infirmières en cessation tabagique chez des patients cardiaques suivant leur congé de l'hôpital

Introduction : Un Canadien sur cinq est fumeur malgré l'accessibilité et la disponibilité des interventions visant à favoriser la cessation tabagique au sein de la communauté. Une hypothèse a été émise : l'application d'un programme d'interventions en cessation tabagique chez des patients cardiaques suivant leur congé de l'hôpital aidera à diminuer le taux de fumeurs 6 mois post-intervention.

Méthodes : Cette étude pilote randomisée a exploré la faisabilité, l'acceptation et l'efficacité préliminaire d'un programme d'interventions en cessation tabagique prodigué par une infirmière spécialisée en cessation tabagique chez des patients cardiaques suivant leur congé de l'hôpital.

Échantillon : Lors de leur congé de l'hôpital, les participants (N=40) ont été aléatoirement attribué à une intervention téléphonique à raison d'un appel par semaine durant le premier mois suivant le congé de l'hôpital puis un appel à chaque mois jusqu'au 3^e mois (Groupe expérimental [GE]), ou référé aux soins habituellement offerts en communauté (Groupe contrôle [GC]).

Résultats : Les chercheurs confirment la faisabilité du recrutement et l'acceptation de l'intervention mais le suivi est difficile. Cette analyse intention-to-treat a démontré des taux de cessation tabagique similaire entre les deux groupes à 6 mois (25 % GE vs 30 % GC; $p = 0.72$).

Conclusion : Un protocole de suivi intensif, ou encore un programme d'interventions multidisciplinaires plus intensif et adapté aux fumeurs semble nécessaire, compte tenue de leurs caractéristiques.

Smoking is a major risk factor for cardiovascular disease (CVD) morbidity and mortality, and is associated with significant health care costs due to hospitalizations and disability (Baliunas, Patra, Rehm, Popova, & Taylor, 2007; Centers for Disease Control and Prevention, 2008). Smoking cessation can reduce CVD mortality by more than one-third, outperforming other CVD prevention treatments (Critchley

& Capewell, 2004). A large number of clinical trials have been designed to evaluate smoking cessation interventions. These interventions have included a variety of counselling approaches and delivery methods (e.g., individual face-to-face, telephone, group format, or web-based formats) at varying intensities that have been combined with a variety of pharmacological approaches in diverse populations,

including hospitalized smokers. Despite the extensive body of literature supporting smoking cessation interventions, one-fifth of adults in North America and Western Europe still smoke (Health Canada, 2010; Pleis, Lucas, & Ward, 2010). In light of this troubling fact, efforts towards knowledge generation and transfer must persist in order to make further progress in reducing tobacco use (Fiore et al., 2004).

When smokers are hospitalized for an acute smoking-related problem such as CVD, they may be more open to receiving smoking cessation interventions than prior to hospitalization (McBride, Emmons, & Lipkus, 2003). Nurses are well positioned to provide these interventions because of their access to smokers during hospitalization (Rice & Stead, 2008). However, there is a gap in smoking cessation interventions after hospitalization, since most smokers do not use the community-based smoking cessation services available to them (Edwards, McElduff, Jenner, Heller, & Langley, 2007; Kairouz et al., 2007; Stead & Lancaster, 2009; Stoltzfus et al., 2011).

One meta-analysis that included smoking cessation interventions beginning in hospital and continuing after discharge found a dose-response relationship between the intensity of the intervention and smoking cessation rates (Rigotti, Munafo, & Stead, 2008). The authors found that only the highest dosage of intervention—beginning during the hospital stay and continuing with supportive contacts for at least one month after discharge—was successful in terms of decreasing smoking rates. Cessation rates following less-intensive interventions, for instance those with shorter post-discharge follow-up, were not as high as those of longer duration. Therefore, it was hypothesized that extending a usual care in-hospital smoking cessation intervention beyond discharge would improve cessation rates beyond those of the in-hospital intervention alone.

Smoking cessation intervention trials involve methodological challenges including validation of smoking status, and description of participation rates—the latter being rarely reported (Rigotti et al., 2008). Individual characteristics such as smoking history and habits, including degree of nicotine dependence (Heatherton, Kozlowski, Frecker, & Fagerström, 1991), along with well-known barriers to smoking cessation such as depression (Hughes, Stead, & Lancaster, 2007), fear of weight gain (Parsons, Shraim, Inglis, Aveyard, & Hajek, 2009), living with a smoker, and social isolation (Stead & Lancaster, 2009) are potential confounding variables. Since weight gain is common in smoking cessation, but can be minimized by diet and exercise counselling, these variables should also be evaluated in smoking cessation programs (Audrain-McGovern, & Benowitz, 2011). Therefore, before proposing a full-scale smoking cessation intervention trial, we decided to undertake a pilot study to evaluate the feasibility and acceptability of an intervention, as well as the influence of the above variables on the outcome.

Theoretical Orientation of the Intervention

Most smoking cessation counselling interventions have been derived from two main theoretical sources—the Stages of Change model (Prochaska & DiClemente, 1983), and motivational interviewing (Rollnick, Miller, & Butler, 2007). Prochaska and DiClemente's (1983) model of behaviour change includes five stages: pre-contemplation, contemplation, preparation, action, and maintenance. Smokers in the pre-contemplation stage have no intention of quitting for at least the next six months, while those in the contemplation stage intend to quit within the next six months, but not the next month, and those in the preparation stage intend to quit within the next month. The action stage begins immediately after smoking cessation, and the maintenance stage takes effect after six months of smoking abstinence. Despite the popularity of the Stages of Change model as a basis for stage-matched smoking cessation interventions, some authors have argued that smokers who are classified within a particular stage of change can have heterogeneous levels of motivation, making it difficult to tailor interventions (Etter & Perneger, 1999; West, 2005).

Therefore, to better adapt the intervention to each smoker's motivation, the present study superimposed the clinical approach of motivational interviewing (Rollnick et al., 2007) over all five stages of change. Motivational interviewing is effective in assisting people to change behaviour, particularly related to cardiac risk factors (Thompson et al., 2011). With this approach, smokers' motivation towards smoking cessation can be evaluated by both their perceived level of conviction to quit smoking, as well as their perceived level of confidence in being able to quit. A high level of perceived conviction to quit smoking represents a smoker's firm belief that the reasons to quit outweigh the reasons to continue. Perceived confidence in being able to quit smoking represents the smoker's belief in being able to overcome potential obstacles to smoking cessation. Studies testing the effect of motivational interviewing on behavioural change often include interventions that draw on the Stages of Change model (Tomlin & Richardson, 2004). For example, recent nursing intervention studies that used similar combinations of these two models showed significant improvements in health perceptions and sense of social isolation among cardiac patients (Beckie & Beckstead, 2010) and increased confidence in performing self-care behaviours among heart failure patients (Paradis, Cossette, Frasure-Smith, Heppell, & Guertin, 2010).

Goal of the Study

The goal of this randomized pilot study was twofold: to evaluate the feasibility and acceptability to participants of a nurse-led smoking cessation intervention in post-discharge cardiac patients, and to evaluate the preliminary efficacy of the intervention on smoking cessation (primary outcome) and progression through stages of change and other cardiac risk factors (secondary outcomes).

The feasibility of the study was evaluated by examining recruitment and retention of participants at follow-up. The acceptability of the intervention was evaluated by examining participants' acceptance of the intervention (i.e., the six telephone calls and the delivery of the experimental intervention). As recommended by the Consolidated Standards of Reporting Trials (CONSORT) group, details on the actual delivery of the interventions are provided (Zwarenstein et al., 2008).

The preliminary efficacy of the intervention was evaluated by comparing the rate of smoking between the experimental and control groups at six months. Comparison of the two groups was also made on secondary outcomes including other cardiac risk factors, such as diet and physical exercise, as they may be modified by smoking cessation interventions, and progression through the stages of change, which is one theoretical component of the intervention tested (Cargill, Emmons, Kahler, & Brown, 2001; Heaton & Frede, 2006; Holme, Haaheim, Tonstad, & Hjermann, 2006; Perez, Nicolau, Romano, & Laranjeira, 2008; Thorndike et al., 2008).

Methods

Design. This prospective, controlled, experimental, randomized pilot study included both an experimental (EG) and control group (CG). It was authorized by the hospital's institutional review board, and was registered in a randomized clinical register (Current Controlled Trials Registration number: ISRCTN26884027; <http://www.controlled-trials.com/ISRCTN26884027>).

Sample. The sample was drawn from patients who were hospitalized for any diagnosis in an adult acute-care cardiovascular centre in Montreal, Canada. To be eligible, patients had to: a) report daily cigarette smoking prior to hospital admission, b) have the cognitive and physical capacity to answer a questionnaire and provide informed consent, c) be able to communicate by telephone, d) be able to communicate in French or English, and e) have received "usual care" smoking cessation nursing support during hospitalization.

Procedures. While hospitalized, all patients who reported smoking received usual care smoking cessation support (described in detail below) from the smoking cessation nurse specialist (SCNS) until discharge. The SCNS was master's prepared with significant experience in the field of smoking prevention and cessation.

After delivering this support, the SCNS assessed patients' eligibility for the study and, if they were interested in participating, obtained their written consent. Approximately one week after discharge, she telephoned all participants to inform them of their random assignment to either the EG or the CG. Randomization was performed using opaque, sealed envelopes prepared by an independent coordinating centre. The SCNS then proceeded with the telephone smoking cessation intervention among EG patients, while the CG patients were referred instead to community smoking cessation programs.

In-hospital smoking support: Both groups. All smokers in the present study received usual care in-hospital smoking cessation support derived from the Stages of Change model and the principles of motivational interviewing. For smokers in the pre-contemplation stage, the intervention was focused on raising doubts about the smokers' intentions to maintain their smoking behaviour; for those in the contemplation stage the focus was on helping them resolve their ambivalence toward smoking cessation. The intervention for participants in both of these stages of change entailed a collaborative exploration of the disadvantages of continued smoking, the advantages of smoking cessation, and possible strategies for a future smoking cessation attempt. Smokers in the preparation stage were encouraged to fix a quit date, and the SCNS focused on relapse prevention through a collaborative discussion of strategies, identifying high-risk situations, and providing information about nicotine withdrawal symptoms, and the benefits of social support. For patients who had stopped smoking and were in the action stage, the intervention was focused on preventing any relapse. Maintenance stage interventions consisted of encouraging the patient to stay vigilant and determined to remain smoke-free.

Across all these stage-matched interventions the SCNS superimposed additional interventions guided by her assessment of the patient's level of conviction and confidence. Interventions to increase conviction helped patients focus on their personal and affect-related motives for smoking cessation. To this end, the nurse used communication strategies such as reframing, and reinforcing the patient's own speech in favour of smoking cessation. Additionally, the patient's confidence was reinforced and enhanced by focusing on past successes and affirming the patient's determination to quit smoking. The number of in-hospital encounters are reported in the results section and depended on each patient's individual needs and length of stay. In addition to counselling, all patients in the preparation or action stages were offered pharmacotherapies for smoking cessation (e.g., nicotine replacement therapies [NRT], bupropion, or varenicline) in hospital and on discharge. Usual care also included motivational letters up to six months after hospital discharge.

Post-discharge usual group. After randomization, at the beginning of the first post-discharge telephone call, those randomized to usual care were automatically referred to the community smoking cessation program, which contacted them in the following days. This program includes a free, interactive web site, a telephone help line, and smoking cessation centres located in all regions of the province of Quebec (<http://www.iquitnow.qc.ca>). Participants were also encouraged to call the program themselves, as soon as possible. No other contact was offered by the SCNS, since usual care at the study hospital does not involve post-discharge interventions.

Post-discharge experimental group interventions. For the EG, the SCNS's post-discharge telephone call intervention was based on the same theoretical model as the in-hospital intervention. It included a weekly telephone call for the first month, and one call at the end of the second and third months. The SCNS was also available to receive calls from study subjects during months three to six. At each telephone call, the SCNS evaluated the participant's stage of change, and level of motivation and conviction, and intervened accordingly, as in the in-hospital intervention. These evaluations served only to guide the intervention, and were not used as outcome measures of efficacy of the intervention. The outcome measures were collected by an independent interviewer and are described below.

Measures. Feasibility measures included the ability to recruit the desired sample in a reasonable timeframe, the proportion of patients who consented, and the proportion of those consenting who could be reached at the six-month follow-up call. The researchers also examined the feasibility of performing urinary or salivary cotinine tests at six months during a home visit by the research assistant for patients who lived within 50 kilometres of the study hospital. Cotinine levels were measured using the NicAlert™ system. Scores range from zero (0–10 ng/ml cotinine concentration [C]) to six (> 1000 ng/ml cotinine C), with a level of one or greater (10–30 ng/ml cotinine C) indicating tobacco use.

Two components of intervention acceptability were assessed: the patients' acceptance of the nurse's telephone calls, and the actual delivery of the intervention. Acceptance of the telephone call was assessed by the number of telephone interventions actually delivered in comparison with the six telephone calls planned in the protocol. The intervention delivery was measured using an intervention grid (Table 1), which was developed from clinical expertise and theoretical literature, and was validated by experts in the clinical or research field of smoking cessation. The grid includes 42 potential nursing interventions classified into the five stages of change, and two motivational concepts (conviction and confidence). Because the experimental intervention was tailored to each individual's stage of change and level of motivation, the protocol encouraged use of the most relevant intervention for each patient. Therefore, while a range of interventions is proposed in the grid, not all of them were expected to be retained. The description of the actual delivery of the intervention served to document the "treatment fidelity", as is recommended for standardized interventions (Sidani & Braden, 2011).

To assess the preliminary efficacy of the intervention, the primary outcome, point-prevalence smoking status, was measured through self-report at six months post-randomization. A call was made by a research assistant blinded to the group assignment, and participants were asked if they were smoking (yes or no), and if "no", the date they had quit.

Secondary outcomes included diet, physical activity and progression through the stages of change with respect to smoking cessation. The latter was measured using questions based on Chouinard and Robichaud-Ekstrand's instrument (2005). These questions assessed smoking status, intention to quit within the next 30 days or the next six months, past attempts to quit, and past success in quitting. For instance, current smokers who are not planning to quit are classified in the pre-contemplation stage. Smokers who are thinking of quitting in the next six months are in the contemplation stage. Among smokers who are thinking of quitting within the next 30 days, those who have not attempted to quit in the past year are in the contemplation stage, whereas those who have made at least one 24-hour attempt to quit in the past year are in the preparation stage. Because current smoking was required for eligibility, no participants were in the action or maintenance phases at study entry. Progression was treated as a dichotomous variable: the participant either progressed or did not.

Diet was measured using the scale, "Are you eating healthy?" (Acti-Menu Health Program, 2005). This scale includes 20 questions with a total score ranging from 0 to 100: the higher the score, the healthier the diet. It asks about fat consumption, e.g., How often are you eating fast food or fried food? (Occasionally = 5, about two times a week = 2, at least three times a week = 0), as well as intake of healthy foods, vitamins and minerals. Cronbach's alpha in the present study were 0.72 at baseline and 0.67 at six months. No previous studies have yet established the validity of the scale, which was created for clinical purposes.

Physical activity was measured using one question from the "Do you have a healthy heart?" scale (Acti-Menu Health Program, 2004). The question was, "In general, how many days per week are you physically active for at least 30 minutes (walking, dancing, sports, workout, etc.; does not have to be a continuous 30 minutes)". The three possible answers are: less than once a week, one to two days per week, or three to four days per week. For the present study, data were dichotomized (0 = less than once a week and 1 = once or more a week) to avoid small cell size due to the small sample size.

Baseline data that were collected with self-report scales included an assessment of nicotine dependence and depression/anxiety. Nicotine dependence was assessed using the *Fagerström Test for Nicotine Dependence* (Heatherton et al., 1991). This test is composed of six questions related to nicotine dependence, and the level of dependence is classified into three categories: low dependence (scores of 0 to 3), moderate (scores of 4 to 6), or high (scores of 7 to 10). The alpha coefficient was 0.61 in Heatherton et al. (1991) and 0.45 in the present study. Higher scores predict lower smoking cessation rates.

	<i>Nursing interventions</i>	T2a	T2b	T2c	T2d	T2e	T2f
Pre-contemplation	1. Increase negative perceptions of continued smoking	0	0	0	0	0	0
	2. Increase doubt	0	0	0	0	0	0
	3. Explore what the smoker likes and does not like about his smoking	0	0	0	0	0	0
	4. Discuss the concerns the smoker has about his smoking	0	0	0	0	0	0
	5. Discuss the benefits of smoking cessation	0	0	0	0	0	0
	6. Discuss the different possibilities the smoker may try to facilitate smoking cessation	0	0	0	0	0	0
Contemplation	7. Explore ambivalence (increase the negative perceptions of smoking and decrease the positive perceptions of smoking)	0	0	0	1	0	3
	8. Help the smoker to express the reasons in favour of change	0	0	0	1	0	3
	9. Help the smoker express the consequences of not changing	0	0	0	1	0	3
	10. Increase the smoker's confidence in his ability to quit smoking	0	0	0	1	0	3
Preparation	11. Offer a menu of strategies for change	4	4	4	4	9	6
	12. Fix a quit date	3	3	2	3	4	6
	13. Respond to questions regarding the benefits of smoking cessation	3	3	2	3	6	5
	14. Discuss the importance of thinking about situations that trigger the craving to smoke	0	3	4	4	7	6
	15. Discuss alternative ways to cope (elaborate strategies for relapse prevention)	2	3	3	4	7	6
	16. Inform about nicotine withdrawal symptoms; medication for smoking cessation; stress management; and weight gain	5	4	3	4	9	5
	17. Inform about the benefits of social support from friends and family	3	3	2	2	5	3
Action	18. Provide support in the smoker's process of behaviour change	12	10	7	9	3	5
	19. Ask the smoker if there are any particular problems with regards to the level of withdrawal symptoms or if he experiences the craving to smoke	15	16	16	15	9	10
	20. Reinforce his new behaviour changes	15	15	14	13	10	10
	21. Provide encouragement	15	16	16	15	11	11
	22. Affirm all current behaviour changes in relation to smoking cessation	15	16	16	14	11	11
Maintenance	23. Propose strategies for relapse prevention	0	0	0	0	0	0
	24. Re-explore ambivalence	0	0	0	0	0	0
	25. Normalize the situation if the smoker relapsed	0	0	0	0	0	0
	26. Build motivation to re-engage in the process of contemplation, preparation, and action	0	0	0	0	0	0
	27. Inform about what brought him back to smoking	0	0	0	0	0	0
	28. Remind him of the reasons why he decided to quit smoking	0	0	0	0	0	0
	29. Discuss the importance of quitting smoking again in the near future	0	0	0	0	0	0
	30. Offer possible strategies to resist the craving to smoke	0	0	0	0	0	0
Level of conviction	31. Help increase the perceived advantages of a smoke-free life	12	10	9	8	9	9
	32. Help increase the perceived benefits of smoking cessation	11	8	7	8	8	8
	33. Reframe, and reinforce the client's own speech in favour of smoking cessation	18	14	13	12	13	10
	34. Help the client elaborate on his personal, and affect-related motives towards smoking cessation	3	6	2	6	5	8
	35. Detect the presence of affect-related motives for smoking cessation	1	3	2	4	4	7
	36. Provide personalized information about the advantages of smoking cessation	17	14	13	14	15	15
	37. Affirm and reinforce the advantages perceived by the client	19	18	0	19	20	18
Level of confidence	38. Help the client verbalize barriers and doubts about the client's ability to quit smoking as well as arguments against smoking cessation	7	8	10	8	10	10
	39. Increase client's confidence by referring to past successes achieved to this date in smoking cessation-related behaviour changes	14	13	13	11	12	9
	40. Help the client find his own solutions to his perceived barriers	9	9	8	8	9	8
	41. Arrive at a negotiated plan that the client agrees to implement until the next consultation	6	7	7	8	11	9
	42. Affirm and congratulate the client for his determination to quit smoking	19	18	19	19	19	17
Key: T2a: Telephone call first week; T2b: second week; T2c: third week; T2d: fourth week; T2e: end of second month; T2f: end of third month							

Depressive symptoms and anxiety were assessed using the *Hospital Anxiety and Depression Scale* (HADS) (Herrmann, 1997). Fourteen items with an ordinal scale from 0 to 3 enabled the computation of two scores: anxiety and depressive symptoms. A higher score for each sub-scale (possible range of 0 to 21) indicated a more severe level of symptoms. The alpha coefficients reported by Herrmann vary from 0.81 and 0.90 for the depression subscale and from 0.80 to 0.93 for the anxiety subscale. In the present study, the alpha coefficients were 0.67 and 0.15 for the anxiety and depression subscales respectively. The depression subscore was not retained in the analysis because of the low alpha coefficient, partially due to a lack of variability.

Baseline sociodemographic and clinical variables were abstracted from the medical chart (e.g., diagnosis, comorbidities, height, weight, body mass index [BMI]) or were self-reported (e.g., employment status, education, marital status, living with a smoker, number of cigarettes per day).

	Experimental group n = 20	Control group n = 20
Age: mean years \pm SD	59.8 \pm 12.6	54.4 \pm 7.1
Sex: Male	13 (65%)	11 (55%)
Employment: Active worker	8 (40%)	14 (70%)
Education: \geq high school	16 (80%)	15 (75%)
Marital status: Married/common law	12 (60%)	13 (65%)
Living with smoker: yes	10 (56%) ^a	13 (65%)
Hospitalized for an acute coronary syndrome (ACS): yes	2 (10%)	9 (45%)
Surgery during hospitalization (bypass or valve replacement or angioplasty): yes	8 (40%)	8 (40%)
Previous myocardial infarction: yes	8 (40%)	4 (20%)
Diabetes: yes	7 (35%)	3 (15%)
Hypertension: yes	14 (70%)	8 (40%)
Dyslipidemia: yes	14 (70%)	10 (50%)
Body mass index: \geq 30	11 (58%)	4 (20%)
Exercise: \geq 1–2 days a week	9 (50%) ^a	12 (63%) ^c
Diet mean score \pm SD	54.4 \pm 15.6 ^b	53.0 \pm 15.0 ^d
Anxiety mean score \pm SD	9.2 \pm 3.8 ^c	9.1 \pm 3.9 ^c
Depressive symptoms mean score \pm SD	5.5 \pm 2.2 ^c	5.3 \pm 2.6 ^c
Mean length of hospitalization in days \pm SD	8.3 \pm 5.0	7.9 \pm 7.3
Note. Data are means \pm standard deviations, or numbers and percentages (%). ^a (n = 18). ^b (n = 15). ^c (n = 19). ^d (n = 17).		

Sample size and analyses. A sample size of 20 patients per group was chosen a priori because this was a pilot study, intended only to provide a preliminary assessment of effect size and trend and, therefore, did not require adequate statistical power (National Institute of Health, 2004).

Sociodemographic and clinical variables were summarized as mean \pm SD for continuous variables and as count and percentage for categorical variables. As recommended by the CONSORT statement (Moher et al., 2010), no statistical tests were performed to evaluate differences between groups at baseline. Chi-square tests using SPSS version 17 software were used to test group differences for the primary outcome (smoking status at six months) and stages of change (progression versus no progression). The assumption of the chi-square analysis (expected count in each cell \geq 5) was verified. Consistent with an intention-to-treat (ITT) analysis, patients who could not be contacted at six months were designated as smokers (Barnes, Larsen, Schroeder, Hanson, & Decker, 2010). A “complete case analysis” was also performed with a chi-square test, to test group differences in those for whom primary outcome data were available (Altman, 2009). Logistic regression was used to model predictors of six-month smoking, adjusting for selected clinical and sociodemographic variables (one variable at a time). These variables included imbalances between groups that were judged to be large enough to have potential clinical significance, and smoking-related factors that have been described in the literature (e.g., nicotine dependence test, depressive symptoms). The secondary outcome of “diet”, expressed as a continuous score, was evaluated using analysis of covariance (ANCOVA), and “physical activity”, expressed as categorical variable, was evaluated using logistic regression models. In these latter analyses, the corresponding baseline score was used as a covariate in the statistical models.

Results

Feasibility of recruitment and follow-up. During the three-month recruitment period between September and November 2008, 115 patients were assessed for eligibility, of whom 11 did not meet the inclusion criteria, 44 refused to participate (13 were reluctant to stop smoking and the remainder provided no explanation), and 18 were excluded for logistical reasons (nurse’s schedule, late discharge or weekend hours). This resulted in a sample of 40 participants. At the end of the study, six months after-randomization, seven of the 20 EG patients and 10 of the 20 CG patients were lost to follow-up (14 were unreachable by telephone despite a mean of three attempts, and three refused to answer questions when contacted).

Sample characteristics. Compared to the EG, the CG patients were younger, more likely to be employed and more likely to be hospitalized for an acute coronary syndrome (ACS, i.e., myocardial infarction or unstable angina)

in comparison to other illnesses such as arrhythmias or heart failure (Table 2). Compared to the CG, more patients in the EG had experienced a previous myocardial infarction (MI) and had diagnoses of diabetes, hypertension, dyslipidemia and obesity (BMI ≥ 30). Regarding baseline smoking characteristics (Table 3), more participants in the CG were heavier smokers (> 20 cigarettes per day) compared to the EG, and fewer patients had previously attempted to stop smoking for longer than six months. All participants in both groups were in the preparation stage of change except for one CG patient who was in the contemplation stage. Nicotine dependence was similar in the two groups. The number and duration of

encounters for the usual care in-hospital support was similar between groups, with the majority of patients having met with the SCNS two or three times during their hospitalization for a mean duration of 41 to 42 minutes. None of the CG patients contacted the SCNS after randomization. However, five of the 10 CG patients who were reached at six months reported contacting community smoking cessation resources after discharge. Additionally, one EG patient contacted community resources after discharge.

Acceptability of the experimental intervention. After randomization, all patients from the EG accepted the six planned telephone calls, which ranged from 7.9 minutes to 12.2 minutes in duration (Figure 1). Table 1 provides details on the number of patients who received each nursing intervention in each of the six post-hospitalization telephone calls. No participant received interventions for the pre-contemplation stage, as none was in that stage at any time point. Similarly, because of the inclusion criteria and study duration no patients reached the maintenance stage (defined as having quit for more than six months) because the study ended at six months. The interventions used most commonly related to the action stage of change. Interventions targeting conviction and confidence were frequently used and some of them were applied with almost all (95%) patients. For example, the intervention focusing on affirmation and reinforcement of the client-perceived advantages of smoking cessation was used for 18 to 20 patients in the EG in each of the six phone calls. Overall, interventions that were delivered during each of the six phone calls to at least 10 EG patients consisted of “Reinforce new behaviour changes”, “Provide encouragement”, “Affirm all current behaviour changes in relation to smoking cessation”, “Reframe, and reinforce the client’s own speech in favour of smoking cessation”, “Provide personalized information about the advantages of smoking cessation”, “Affirm and reinforce the advantages perceived by the client” and “Affirm and congratulate the client’s determination to quit smoking”.

Efficacy of the Intervention: Preliminary Analysis

Primary outcome: Smoking status at six months. Twenty-three patients were reached at the six-month telephone call and provided data on their smoking status (13 from the EG and 10 from the CG). For the ITT analysis, the remaining 17 patients, for whom there was no six-month smoking data, were categorized as smokers. Based on this classification, the ITT results indicated that 25% (5/20) of EG patients were non-smokers at six months compared to 30% (6/20) of CG patients (Chi-square 0.125, $p = 0.72$, odds ratio [OR] 0.78, 95% confidence interval (CI) [0.19–3.13]). Similar results were found after logistic regression analysis controlling for baseline imbalances between the groups that were judged to be large enough to have potential clinical significance. Values for group effect after controlling for each covariate

	Experimental group (n=20)	Control group (n=20)
Mean number of years smoked	38.7 \pm 12.8	39.0 \pm 14.3
Number of cigarettes smoked per day	19.6 \pm 12.6	25.3 \pm 14.3
10 or less	6 (30%)	2 (10%)
11 to 20	6 (30%)	4 (20%)
> 20	8 (40%)	14 (70%)
Ever stopped smoking for ≥ 6 months	6 (33%)	2 (11%)
Perceived cause of smoking relapse		
Withdrawal symptoms	10 (50%)	8 (40%)
Social pressures	4 (20%)	3 (15%)
Major life event (death, divorce)	2 (10%)	3 (15%)
Intolerance to nicotine replacement therapy	1 (5%)	5 (25%)
Nicotine replacement therapy		
None	9 (45%)	7 (35%)
Bupropion, Varenicline	4 (20%)	2 (10%)
Patch, gum, other	7 (35%)	11 (55%)
Stage of change		
Contemplation	0	1 (5%)
Preparation	20 (100%)	19 (95%)
Nicotine dependence Fagerström		
Mean score	6.2 \pm 1.3 ^a	6.5 \pm 1.1
Clinical score		
Low (0 to 3)	1 (5.3%)	0
Moderate (4 to 6)	10 (53%)	11 (56%)
High (7 to 10)	8 (42%)	9 (45%)
Number of encounters with the SCNS during hospitalization		
1	4 (20%)	2 (10%)
2–3	16 (80%)	18 (90%)
Mean number of contact minutes during hospitalization	42.5 \pm 15.6	41.0 \pm 11.4
<i>Note.</i> Data are means \pm standard deviations, or numbers and percentages (%).		
^a (n = 19)		

were: age ($p = 0.67$, OR 0.73, 95% CI [0.17–3.12]), working status ($p = 0.87$ OR 0.89, 95% CI [0.21–3.84]), diagnosis of ACS versus other illnesses ($p = 0.77$, OR 1.28, 95% CI [0.26–6.38]), previous MI ($p = 0.89$, OR 0.90, 95% CI [0.22–3.79]), diabetes ($p = 0.68$, OR 0.74, 95% CI [0.18–3.11]), hypertension ($p = 0.89$, OR 0.90, 95% CI [0.21–3.92]), dyslipidemia ($p = 0.90$, OR 0.91, 95% CI [0.22–3.87]), BMI ($p = 0.31$, OR 0.42, 95% CI [0.08–2.22]). Similar results were found after controlling for smoking-related factors described in the literature: nicotine dependence test ($p = 0.82$, OR 0.88, 95% CI [0.21–3.60]), ever stopped in the past ($p = 0.51$, OR 0.57, 95% CI [0.11–2.96]), smoking cessation medication at hospital discharge ($p = 0.69$, OR 0.75, 95% CI [0.18–3.06]), living with a smoker ($p = 0.89$, OR 1.12, 95% CI [0.20–6.43]), and anxiety symptoms ($p = 0.99$, OR 1.01, 95% CI [0.24–4.29]). Chi-square “complete case analysis” was performed retaining only the 23 patients who provided data on their smoking status at six months and, similarly, no differences were found in smoking status between the groups ($p = 0.31$, OR 0.42, 95% CI [0.08–2.25]).

For the cotinine assessment, only eight of the 23 patients reached at six months were living within a 50-km area, and only two of these reported not smoking (for whom a validation cotinine test is relevant). One of these two participants agreed to provide a sample for cotinine assessment and the other refused. These data were not further considered in the analysis.

Secondary outcomes: Stages of change, diet and physical activity. Data on stability or regression within the stages of change from baseline to six months did not provide more information than the smoking status per se at six months. This is because all participants (except one) began the study in the preparation stage. Therefore, any progress in the stages of change also meant they had stopped smoking. Similarly, lack of progress or regression in stages of change also meant they were still smokers at six months. Stages of change can vary more than smoking status when the starting point begins in the pre-contemplation stage and then moves to contemplation or preparation.

There were no significant differences between groups ($p = 0.99$) on the diet outcome (EG [$n = 12$], end of study mean, adjusted for baseline, $57.5 \pm \text{SE } 3.9$, versus CG [$n = 7$], end-of-study mean, adjusted for baseline, $57.6 \pm \text{SE } 5.3$). More patients in the EG reported having exercised at least once a week at six months, although statistical significance was not reached (EG 61.5% versus CG 33.3%; OR 2.84, 95% CI [0.46–17.61], $p = 0.26$).

Discussion

This pilot experimental study aimed to assess the feasibility, acceptability and preliminary efficacy of a smoking cessation intervention in a sample of previously hospitalized cardiac patients. It was found feasible to recruit the target sample size in a reasonable timeframe. However, we encountered a 44% refusal rate, which

may limit the generalizability of the results, as well as the feasibility of a large-scale study. As reported by Rigotti et al. (2008) participation rates are rarely reported in smoking cessation trials. In the present study, 13 of the 46 who refused to participate reported not wishing to quit, whereas the rest did not provide a reason for not participating. Therefore, it was not possible to determine whether non-participation was due to a desire to continue smoking or the burden associated with participating in a trial, or both, thus introducing an important selection bias. This highlights the additional challenges of carrying out studies in this particular population.

The attempt to corroborate self-report smoking status with the cotinine test proved

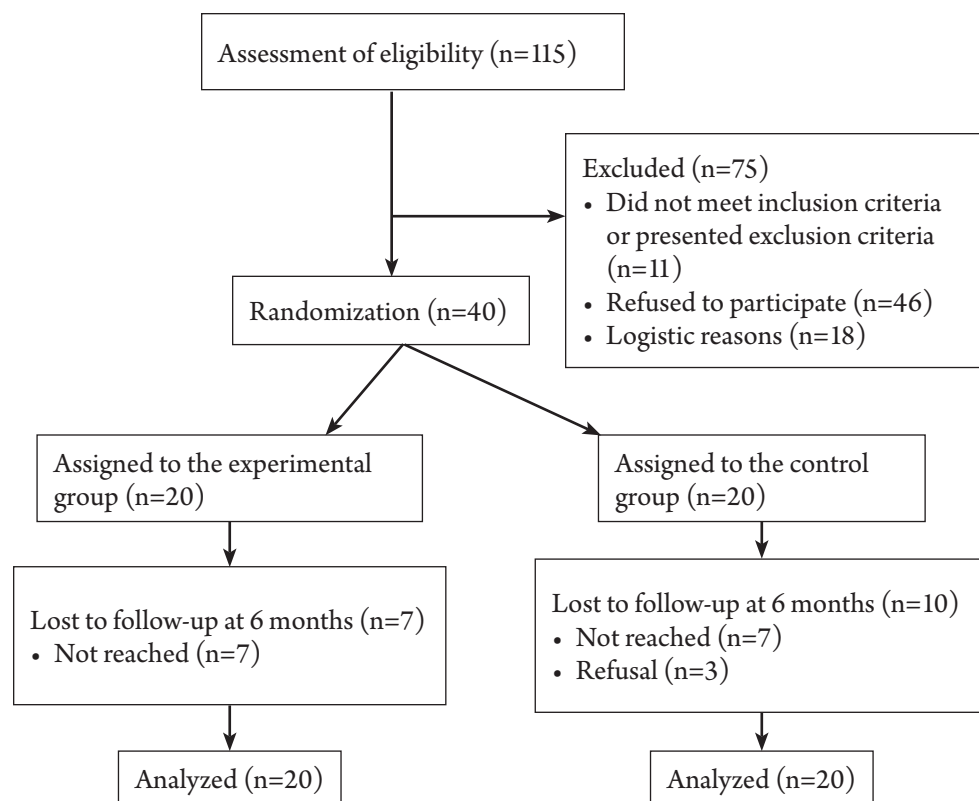


Figure 1: Consort flow diagram

not feasible owing to the fact that only two patients lived close enough to be eligible for the test and only one patient agreed to having a cotinine measurement taken. This problem could be addressed in a future study by recruiting only patients living within a reasonable distance from the study hospital, although this strategy would reduce the generalizability of the sample and lengthen the duration of the recruitment period.

The low response rate for the six-month follow-up telephone call (23/40) and self-reported smoking status may have been due to patient anxiety about a judgmental reaction from an unknown independent interviewer (even though the interviewer was experienced with sensitive topics and had conducted hundreds of follow-up telephone assessments in other trials). Offering compensation to participants who complete the six-month interview is an avenue to explore in future studies.

All patients from the EG accepted the six telephone calls from the SCNS, as intended in the protocol, demonstrating the acceptability of providing continuity of care for smoking cessation through the hospital-based SCNS after discharge. The successful delivery of the intervention demonstrates the acceptability of the intervention type to all participants, with most of the interventions focusing on the action stage of change, and conviction and confidence levels. This is consistent with the fact that patients who stopped smoking were actually in the action stage. This favourable result helps to establish solid ground for future studies.

Contrary to expectations, this pilot study found no clinically or statistically significant effect of a post-discharge program for smoking cessation that was extended from an in-hospital smoking intervention. There were similar smoking cessation rates in both groups at six months. Although the restricted number of patients in our sample limits the interpretation, there are several possible explanations for the lack of efficacy of the intervention.

First and foremost, this pilot study was designed to evaluate the change in smoking status associated with the intervention and was not powered to detect a significant difference between groups. Although a larger sample size would have been able to detect such a difference, if it existed, these preliminary efficacy results are not encouraging, and show no advantages of the post-discharge smoking cessation intervention. Second, these results may be conservative because a large number of participants were lost to follow-up and, therefore, were automatically classified as smokers consistent with ITT analysis even though some of them may have quit. Third, it is possible that the biggest influence on smoking cessation occurred before the intervention, during hospitalization, when patients from both groups received usual care smoking cessation counselling from the SCNS. Among patients classified as non-smokers at the end of the study, all but one patient reported having

quit smoking during hospitalization. It is also possible that the realization of the severity of their condition was motivation enough for many patients to stop smoking—thus enhancing receptivity to the smoking cessation intervention (Rigotti et al., 2008). Last, the lack of statistical power (type II error) in all pilot studies may have accounted for the observed results.

There were imbalances between groups in this pilot study, despite randomization procedures. Compared to the CG, the EG included more patients with characteristics that are considered unfavourable to smoking cessation (such as being older, or unemployed). The EG also had double the prevalence of diabetes, hypertension, dyslipidemia and obesity. The SCNS reported anecdotally that patients with longstanding and more advanced illnesses combined with other risk factors reported social isolation and having “nothing else” but smoking. This suggests that compared to the CG, the EG included more smokers who could be considered “hard-core” (Costa et al., 2010), who perhaps needed more intensive intervention. On the other hand, compared to the EG, more patients in the CG lived with a smoking partner and reported smoking more than one package of cigarettes per day—both obstacles to smoking cessation and contributors to smoking relapse (U.S. Department of Health and Human Services, 2008). Although we applied statistical control for these imbalances, the insufficient statistical power may have contributed to the results.

Regardless of these baseline imbalances, is also possible that the dose of the intervention (duration, frequency) was not intensive enough—given that both groups included smokers with approximately 40 years of daily smoking and significant nicotine dependence. To improve smoking cessation rates among these individuals, more intensive, comprehensive, and multidisciplinary interventions that are sustained over time may be required (Rigotti et al., 2008), and interventions aimed at increasing social support for smoking cessation may also be warranted among some sub-categories of smokers (Browning, Baker, McNally, & Wewers, 2009).

In the present sample, controlling for the type of cardiac illness (ACS, previous MI versus other cardiac illness) did not modify the differences between the groups in smoking cessation. However, a study using a larger sample size might allow identification of the particular cardiac diagnoses and treatments that predict the greatest risk of smoking relapse after hospitalization. Hajek, Taylor, and Mills (2002) suggested that type of cardiac illness might impact smoking cessation—specifically that smokers with ACS would be more likely to stop smoking than those undergoing bypass surgery. In addition, Peterson et al. (2010) found that compared to patients with other illnesses, patients who had undergone angioplasty surgery expressed less need to modify their cardiovascular risk factors because they believed they were cured (i.e., their problem had been solved).

Conclusion

This pilot study explored the feasibility and acceptability of extending an in-hospital smoking cessation intervention to cardiac patients for an additional three months after discharge. It revealed the potential for certain problems with recruitment, follow-up and validation of smoking status that may offer important guidance to researchers in the design of future studies. It demonstrated the acceptability to patients of regular nurse-led telephone interventions over three months. The preliminary results did not show any efficacy advantage of the post-discharge intervention compared to referral to community smoking cessation services in this sample of long-time smokers with cardiac illness and significant nicotine dependence. We suggest that more intense and multifaceted interventions should be tested in future studies to achieve desired outcomes among the current smoking population. ♥

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RESEARCH COLUMN

Situating Methodology within Qualitative Research

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Abstract

Qualitative nurse researchers are required to make deliberate and sometimes complex methodological decisions about their work. Methodology in qualitative research is a comprehensive approach in which theory (ideas) and method (doing) are brought into close alignment. It can be difficult, at times, to understand the concept of methodology. The purpose of this research column is to: 1) define qualitative methodology; 2) illuminate the relationship between epistemology, ontology and methodology; 3) explicate the connection between theory and method in qualita-

tive research design; and 4) highlight relevant examples of methodological decisions made within cardiovascular nursing research. Although there is no "one set way" to do qualitative research, all qualitative researchers should account for the choices they make throughout the research process and articulate their methodological decision-making along the way.

Key words: methodology, qualitative research, epistemology, ontology, theory, method, cardiovascular, nursing

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Abregé

Les infirmières chercheuses en méthodologie qualitative doivent expliciter les choix méthodologiques complexes effectués au cours de leur travail. La méthodologie de la recherche qualitative est une approche globale dans laquelle la théorie (les idées) et la méthode (faire) doivent être parfaitement cohérents. Il peut parfois être difficile de comprendre ce concept méthodologique. Le but de cet article sur la recherche est de : 1) définir la méthodologie qualitative; 2) éclairer la relation

entre l'épistémologie, l'ontologie et la méthodologie; 3) expliciter le lien entre la théorie et la méthode de recherche qualitative choisie; et 4) démontrer, à l'aide d'exemples provenant de la recherche en soins infirmiers cardiovasculaires, des choix méthodologiques pertinents aux recherches illustrées. Bien qu'il n'y ait pas une manière unique de faire de la recherche qualitative, tous les chercheurs qui utilisent ce type de méthodologie doivent rendre compte de leurs choix tout au long du processus de recherche et argumenter leurs décisions méthodologiques.

Qualitative nurse researchers locate themselves within the social world: studying things in their natural settings, making sense of and interpreting phenomena (Denzin & Lincoln, 2011). Qualitative approaches are valuable for the advancement of cardiovascular nursing practice because they make visible the interpretive and material practices of people living with cardiovascular disease (Denzin & Lincoln, 2011). However, qualitative research can be complex in its design. Qualitative nurse researchers are required to make deliberate and sometimes complex methodological decisions regarding their work. Often, this complexity is due to iterative approaches common within qualitative research and the intricacies of working with theory. Methodological considerations involve the qualitative researcher fusing theory and method to ensure that a comprehensive approach is taken to the research design. The purpose of this research column is to define *methodology* within the context of qualitative research and to discuss the role of methodology in both study design and implementation. To do so, I will: 1) define qualitative methodology; 2) illuminate the relationship between epistemology, ontology and methodology; 3) explicate the connection between theory and method in qualitative research design; and 4) highlight examples of some of the methodological decisions made

within current cardiovascular nursing research. These methodological decisions can be nuanced at times. Therefore, in this column, I attempt to address basic concepts that help to situate qualitative researchers' methodological choices. It should be noted that some qualitative researchers might be resistant to "over-structuring" their methodology. However, they still carry, as do all qualitative researchers, the responsibility of being able to articulate and account for their methodological choices within their study design and analysis.

Background

Methodology within qualitative research is a comprehensive approach in which the research design, questions and analysis align closely with foundational theoretical and philosophical assumptions of the study (Hesse-Biber & Leavy, 2006). Often, methodology is described as a bridge between theory (ideas) and method (doing), offering consistency and coherence throughout the entire research process and "serving as a strategic, but malleable guide throughout the research experience" (Hesse-Biber & Leavy, 2006, p. 36). However, it can be difficult, at times, to understand how methodology unfolds. More specifically, the term methodology often has several connotations, from wider descriptions of a type of research

approach (i.e., qualitative versus quantitative) to the reasons guiding the steps taken throughout the research process. To further clarify the role of methodology in the context of qualitative research, it is important to speak directly to the related concepts of epistemology, ontology, theory and method, as well as the role of methodology within study design and implementation. I will address each of these points in turn, beginning with the discussion of how epistemology (theory of knowledge) and ontology (nature of reality) influence the methodological choices of the qualitative researcher.

Epistemology, Ontology and Paradigms

A relevant starting point for understanding the role of methodology within qualitative research design is the discussion of *epistemology*. Epistemology is often described as the “theory of knowledge” embedded within a theoretical perspective that informs all aspects of the research process (Hesse-Biber & Leavy, 2006). Within a qualitative research perspective, it refers to the question of how reality can come to be known, the relationship between the knower and known, as well as the characteristics, principles and assumptions that guide the process of knowing and the achievement of research findings (Vasilachis de Gialdino, 2009). The question of who can be a knower and what can be known is posed, laying a foundation for the knowledge-building process (Denzin & Lincoln, 2011; Hesse-Biber & Leavy, 2006). The epistemological position a researcher takes influences every aspect of the research process, from the topic selected to the creation of research questions, selection of theoretical lens, method, and overall methodology (Hesse-Biber & Leavy, 2006). Furthermore, Hesse-Biber and Leavy (2006) remind us that all qualitative researchers bring their own conscious and unconscious questions, assumptions and beliefs to their work. This influences the truths we seek through our research and what we believe, as researchers (Lincoln, Lynham, & Guba, 2011). Helpful questions to uncover a researcher’s initial epistemological stance are: *What is the relationship between the researcher and that being researched?* (Creswell, 2007). *What are the foundations between truth and knowledge within the research design? How do we come to know the world?* (Denzin & Lincoln, 2005).

Qualitative researchers often operate within particular worldviews or assumptions in their search for new knowledge (Schwartz, 2007). The term *ontology*, borrowed from metaphysics, is used to describe this. Ontology is concerned with what exists (what is), with being and reality, and how entities are organized (Adams St. Pierre, 2011). The most common ontological question posed within qualitative study design is: *What is the nature of reality?* (Creswell, 2007). This question may appear difficult to answer. However, qualitative researchers reflect on the nature of reality within their work to determine their research approach and to account for the philosophical foundations of their study. The qualitative research process can be described as being “ontologically complex” because “all observers view an object of inquiry from their own vantage points in the web of reality, no portrait of a social phenomenon is ever exactly the

same as another” (Kincheloe & McLaren, 2005, p. 319). Qualitative researchers Kincheloe & McLaren (2005) provide a relevant analogy to the ontologically complex nature of qualitative work by describing the world as a flowing river in which the exact contents of the water are never the same; qualitative researchers watch this river and produce descriptions of an event based on which part of the river they have seen.

Methodology, then, at the first level and in its broadest terms links both the ontological and epistemological tenets of the study and focuses on the best means for acquiring knowledge about the world (Denzin & Lincoln, 2005). Key methodological questions to ask during qualitative study design are: *How do we know the world and gain knowledge of it?* (Denzin & Lincoln, 2005). *What is the process of research that best enables us to acquire that knowledge?* (Creswell, 2007).

One approach to organizing the complexity of the epistemological and ontological decisions a qualitative researcher makes is to position the study within a research paradigm. Paradigms are defined by Denzin and Lincoln (2011) as “the net that contains the researcher’s epistemological, ontological and methodological premises” (p. 13). Paradigmatic forms of inquiry may include (but are not restricted to): *positivism*, *postpositivism*, *critical theory*, *constructivism* and *participatory* (Lincoln et al., 2011). It is beyond the scope of this column to outline these paradigms in detail, but they are worth mentioning because they are useful for helping qualitative researchers to “approach the world with a framework (theory, ontology) that specifies a set of questions (epistemology), which are then examined (methodology, analysis) in specific ways” (Denzin & Lincoln, 2011, p. 11). Not every qualitative researcher will seek to place their research within a paradigmatic position, and some will even cross between and combine differing paradigms, while others may argue against or be resistant to the notion of paradigms themselves. Lincoln et al. (2011) recognize that there are controversies, contradictions and confluences within the research paradigms themselves. However, despite the difference in these positions, research paradigms remain a useful tool for novice researchers who are learning how to think about their methodology. In summary, all qualitative researchers, regardless of their level of experience, should be able to dialogue the coherence between the epistemological and ontological foundations of their study design.

Beginning reflections on qualitative methodology are grounded within the epistemological and ontological assumptions related to the researcher’s study. A continuance of the qualitative research process involves the selection of a theoretical position that adequately represents and guides these central tenets.

Theory

Silverman (2010) states that decisions about methodology are always theoretically loaded. Hamera (2011) expands this point by explaining that “methodology is infused with theoretical commitments and theory is incarnated through

methodology” (p. 319). The theoretical perspective that the qualitative researcher takes influences the overall research design and approach to the area of study. As Garner (2010) notes, “theories are claims that there are patterns in the empirical world; theorists invent concepts that help us to see these patterns” (p. ix). Theories are created by assumptions that are made about the nature of reality and these same assumptions generate theoretical concepts, which are collected into more comprehensive theories (Willis et al., 2007). The role of theory, then, is to chart and, at times, provide explanations of social reality (Garner, 2010). Theories are interpretations of reality; they should not be conceptualized as research hypothesis because they are not meant to be “tested” with the data. Rather, they provide a lens by which the researcher can extract meaning, understand processes and, in turn, generate theory itself.

Theory has a central and significant role within qualitative research design. Silverman (2010) describes the role of theory within qualitative research:

**Box 1: An Example of the Use of Social Theory/
Philosophy in Cardiovascular Nursing Research**

Cardiovascular nurse researcher Heather Russell (2012) explored the ER encounters between women with symptoms of heart disease and health care professionals in her doctoral study entitled “An Uneasy Subjection: The Emergency Room Encounters of Health Professionals and Women with Cardiac Symptoms.” Her study was framed by Holstein & Gubrium’s (2005) *Analytics of Interpretive Practice*, a theoretical analytic approach informed, in part, by the work of social philosopher Michel Foucault and a form of social inquiry known as ethnomethodology (ten Have, 2004, p. 14). Russell sought to address the following research questions within her study:

1. How does the ER encounter serve to construct the identity, understandings and practices for women with symptoms of heart disease, as well as health professionals?
2. In what ways are the articulated understandings and practices of women with symptoms of heart disease divergent from those of health professionals?

Data collection for the study included field observations and interviews with both the women and health care professionals. Russell found that the HCP orientation towards efficiency, flow and scientific rationality during the ER encounter limited the possibilities for understanding the complexity of the health issues of those women seeking care for cardiac concerns in the ER. The ER encounter also limited the HCP’s desire to make a profound difference in the lives of those who sought care. The structure of the ER encounter itself eclipsed the acknowledgement of the experiential wisdom of the women with cardiac symptoms and the anxiety-ridden complexity of their daily lives (p. 9). Source: Russell, H.E. (2012).

Theory, then, should be neither a status symbol nor an optional extra in a research study. Without theory, research is impossibly narrow. Without research, theory is mere arm-chair contemplation (p. 141).

Therefore, qualitative nurse researchers should be familiar with theoretical perspectives both inside and outside of the discipline of nursing. This may include (but is not limited to) philosophy, the social sciences or the humanities. Other disciplinary perspectives may offer a richer theoretical history and serve as a way to further extend and generate nursing knowledge. Although disciplines may exchange and, at times, use theory in differing ways, it is helpful to think of theory as a “flowing, changing river [which we all draw from in the search for knowledge], with mainstream and controversial countercurrents” (Garner, 2010, p. xi). Theories are continually revisited, rethought and produced through disagreement among theorists. Research helps to generate further theoretical insights, approaches and knowledge. Nursing research, in particular, is positioned to bridge the theory/practice divide and offer new insights into theory development.

It is important to remember that theories are observations of reality, not set rules or truths. Most importantly, theory is used as a guide to approach complex phenomena rather than as prescriptive approach to organizing the research process. An example of this in nursing research is the common use of phenomenology as method without highlighting the theoretical/philosophical tenets informing the approach taken. Qualitative researchers need to make the theoretical considerations within their work explicit. The specific relationship between theory and method will be addressed later in this column.

A growing number of cardiovascular researchers, as well as medical sociologists, are using interdisciplinary theories and philosophies to explore cardiac health issues (Angus et al., 2007; Clark, MacIntyre, & Cruickshank, 2007; Clark, Whelan, Barbour, & MacIntyre, 2005; Russell, 2012; Wheatley, 2005). For example, cardiovascular nurse scientist Heather Russell (2012) explored through her doctoral study how the emergency room (ER) encounter between women with heart disease and health care professionals served to construct the identities, understandings and practices among both of these groups. Her theoretical stance within the study was complex, serving as an overarching philosophy (using the work of social philosopher Michel Foucault) and as a theoretical analytic framed by Holstein & Gubrium’s (2005) *Analytics of Interpretive Practice*. In this case, the theoretical stance allowed the researcher to take a common interaction within the cardiovascular nursing world, the exchange of information at a triage desk, and uncover the complexity of the interaction itself by examining discourses emerging within it (see Box 1).

Qualitative researchers should have the skills to recognize theoretical concepts, as they arise in the data (Willis et al., 2007). Sometimes, the initial theory no longer fits or does not serve to articulate the emerging findings within the data. Therefore, qualitative researchers must also know when

to move forward to find another frame of reference for their ongoing research. Most importantly, nurse researchers should learn to *think theoretically*, but not seek to interpret the data purely from pre-chosen theoretical perspective (Hammersley & Atkinson, 2007). Theoretical reflection involves researchers coming back to the theoretical or philosophical assumptions of their work on a regular basis and continually determining the theoretical fit, as the analysis unfolds. A significant influence on researchers' ability to continually reflect on the methodological implications for their study is to choose a method that complements, as well as advances their search for knowledge. Once qualitative researchers have reached a certain level of theoretical and methodological comfort, they can draw on those elements of tradition or methods that work for them and are suitable to the study at hand (Prasad, 2005).

Method

It is common for qualitative researchers to be asked in what "type" of qualitative research they engage. The use of the term *method* has varying connotations, from a reference to the various "traditions" qualitative researchers use (i.e., action research, ethnography, phenomenology, grounded-theory, narrative, etc.) to the formulation of research questions, modes of data collection (i.e., interviewing, participant observation) and analytic approaches to the data (i.e., visual methodologies, textual analysis). Denzin and Lincoln (2011) point out that qualitative research "does not have a distinct set of methods or practices that are entirely its own, and no specific method or practice is privileged over another" (p.6); there is not one legitimate way to "do" qualitative research (Vasilachis de Gialdino, 2009). Sometimes the use of the term *methodology* is readily (and mistakenly) interchanged with *method*. This does not mean that these terms are not related but, rather, that method describes the specifics of "doing" qualitative research, while methodology outlines the reasons why a researcher makes specific choices in the design itself. Methodology is a bridge between theory and method, with the central focus on

articulating why certain methods are appropriate given one's theoretical stance. It is important to note that working within a particular qualitative tradition is not a prescriptive process nor, at the other extreme, a loose appropriation of central ideas and terminology, but rather a guide to study design. The merging of epistemological and ontological foundations, theory, and method is a complex task, as demonstrated in the previous sections. To further articulate the continuing role of methodology through the analytic process, I turn to the concept of methodological coherence in the final section.

Methodological Coherence

The majority of the conversation within this column has focused on study design and the initial methodological choices qualitative researchers often make. As alluded to earlier, analysis of the data collected can sometimes stimulate researchers to rethink their methodological approach. The term *methodological coherence* is used within the context of qualitative rigour to describe the ways qualitative researchers remain sensitive to the relationship between their emerging data, initial research questions and theoretical framework (Morse, Barrett, Maya, Olson, & Spiers, 2002). For example, if the emerging data do not speak to the initial research questions, or if significant sub-themes/typologies within the data arise, researchers may need to refine their research questions in order to more rigorously explore the data. Likewise, researchers may also be required to use a different theoretical concept in order to come to understand a particular phenomenon emerging within the data. To explain this further I draw on the work of Nielsen et al. (2012), a group of cardiovascular researchers who explored how and under what circumstances immigrants to Canada combined diabetes self-care with cardiac rehabilitation (CR) program recommendations. These specific findings were noted during the analysis of a larger qualitative study of 32 CR participants focusing on a gender comparison of strategies used to incorporate recommended health practices. During the study analysis, it was noted by the researchers that more than 50%

Table 1: Highlighting Methodological Coherence Using the Study by Nielsen et al. (2012)

Research Questions	Theoretical Focus	Theoretical Rationale	Tradition	Methods
1) What are the everyday circumstances of immigrant participants in CR? 2) How did the participants combine activities of diabetic self-care and CR education?	Post-Colonial Theory focused on the concepts of transnationalism and hybridity	Transnationalism provides a framework from which to examine the layered and complex nature of immigrant health practices and access to resources	Critical Ethnography: A tradition recognizing a critical theory-based approach to ethnography; merging theory and method (Soyini Madison, 2012).	<i>Data Collection:</i> Two qualitative in-depth interviews Collection of demographic data (age, family income, years in Canada, countries of origin) <i>Purposeful sampling</i> of 18 immigrant participants (8 men and 10 women) from a larger study of 36 participants based on an emerging typology with the larger study data. <i>Analysis</i> revealed a developing immigrant typology, which rested in the blending of knowledges (as well as practices) and into recurrent references to "home"

Source: Nielsen, L.S., Angus, J.E., Lapum, J., Dale, C., Kramer-Kile, M., Abramson, B., ... Clark, A.M. (2012).

of the participants within the study identified themselves as immigrants and that there were major inconsistencies between immigrant and non-immigrant participants that warranted additional exploration. To explore this phenomenon further, two of the researchers formed a sub-team to analyze the transcripts of the immigrant study population using a different theoretical lens (post-colonial theory), set of research questions, and method (critical ethnography). In Table 1 the methodological decisions made within this study are highlighted to show that re-aligning methodology to further explore an emerging typology requires the same methodological consideration and reflection as the initial study design. Methodological coherence, then, is reflected on within a variety of instances within the qualitative research process.

Conclusion

In this research column, I have highlighted the place of methodology within qualitative research design and analysis. Methodology is a comprehensive approach to the overall research design aligning theory (ideas) and methods (doing).

Qualitative researchers strive throughout the research process to ensure methodological alignment by thinking about the relationship between their theoretical position, selected methods and emerging analysis of the data. Therefore, qualitative nurse researchers engaged in the study of cardiovascular health should also demonstrate an understanding of the application of theory from both inside and outside of nursing as a discipline. Most importantly, I also recognize that qualitative research continues to be complex in its design and implementation. Although there is no “one set way” to engage within a qualitative approach, all qualitative researchers should account for the choices they make throughout the research process and articulate their methodological decision-making along the way. ♥

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