Nurse Case Management Fails to Yield Improvements in Blood Pressure and Glycemic Control


Study Overview

Objective. To determine the effectiveness of a nurse-led, telephone-delivered behavioral intervention for diabetes (DM) and hypertension (HTN) versus an attention control within primary care community practices.

Study design. A 9-site, 2-arm randomized controlled trial.

Setting and participants. Study participants were recruited from 9 community practices within the Duke Primary Care Research Consortium. The practices were chosen because they traditionally operate outside of the academic context. Subjects were required to have both type 2 DM and HTN, as indicated by their medications and confirmed by administrative data as well as patient self-reporting. Participants had to have been seen at participating practices for at least 1 year and have poorly controlled DM (indicated by most recent A1c ≥ 7.5%), but they were not required to have poorly controlled HTN. Exclusion criteria included fewer than 1 primary care clinic visit during the previous year, serious comorbid illness, type 1 diabetes, inability to receive a telephone intervention in English, residence in a nursing home, and participation in another hypertension or diabetes study [1]. Participants were randomly assigned using a computer-generated randomization sequence [1] to either the intervention or control groups at a 1:1 ratio, stratified by clinic and baseline blood pressure (BP) control.

Intervention. A single nurse with extensive experience in case management delivered both the behavioral intervention and attention control by telephone. In both arms, calls were conducted once every 2 months over a 24-month period.

The calls in the intervention arm consisted of tailored behavior-modifying techniques according to patient barriers. This content was divided into a series of modules relevant to behaviors associated with improving control of BP or blood sugar, including physical activity, weight reduction, sodium intake, smoking cessation, medication adherence, and others. These modules were scheduled according to patient needs (based on certain parameters such as high body mass index or use of insulin) and preferences [1].

The calls in the attention control were not tailored but rather consisted of didactic health-related information unrelated to HTN or DM (eg, flu shots, skin cancer prevention). This content was also highly scripted and designed to limit the potential for interaction between the nurse and patient.
Main outcome measures. A1c and systolic blood pressure (SBP) were primary outcomes. Key secondary outcomes were diastolic blood pressure (DBP), overall BP control, weight, physical activity, self-efficacy, and medication adherence. Study staff obtained measurements at baseline and 6, 12, and 24 months [1].

Results. The researchers assessed 2601 patients for eligibility and excluded 2224. Most patients were excluded for not meeting inclusion criteria (n = 1156), in particular because of improved HbA1c control (n = 983), and 1064 declined to participate. They randomized 377 patients—193 to the intervention arm and 184 to the attention control arm. Participants had an average age of 58.7, 49.1% had an education level of high school or less, 50.1% were non-white, and 54.9% were unemployed/retired. Patient characteristics in the intervention and control arms were similar at baseline. Seventy-eight percent of patients completed the 12-month follow-up and 70% (263) reached the 24-month endpoint. Patients in the intervention arm completed 78% of scheduled calls while patients in the control group completed 81%.

After adjusting for stratification variables, the estimated mean A1c and SBP were similar between arms at 24 months (intervention 0.1% higher than control, 95% CI −0.3% to 0.5%, P = 0.50 for A1c; intervention 0.9 mm Hg lower than control, 95% CI −5.4 to 3.5, P = 0.69 for SBP). There were also no significant differences between arms in mean A1c or SBP at 6 or 12 months. However, A1c levels did improve within each arm at the end of the study, with the intervention group improving by approximately 0.5% and the control group improving by approximately 0.6%. In terms of secondary outcomes, there were no significant differences between arms in DBP, weight, physical activity, or BP control rates throughout the 2-year study period.

Conclusion. Overall, the intervention and control groups did not differ significantly in terms of A1c, SBP, or any of the secondary outcomes at any point during the 2-year study.

Commentary
The prevalence of type 2 diabetes and its comorbidities (such as hypertension and obesity) have increased due to a variety of factors including an aging population and an increasingly sedentary lifestyle. Several nurse management programs for DM and HTN have been shown to be efficacious in reducing blood sugar levels [2–4] and promoting BP control [5,6]. However, these interventions were conducted in tightly controlled academic settings, and it is unclear how well these programs may translate into community settings. The aim of this study was to test the effectiveness of a nurse-led behavioral telephone intervention for the comanagement of DM and HTN within non–academically affiliated community practices. Results indicated no significant differences between the intervention and control groups for A1c levels or SBP at any point during the 2-year study, but A1c levels did improve for both arms.

Despite this being a negative study, it is a unique and important contribution to the literature. It is the only trial as of yet that has tested the effectiveness of a nurse management intervention targeting both DM and HTN in a real-world, community setting. This novel approach is supported by data that suggests BP control is actually more cost-effective than intensive glycemic control in treating patients with type 2 diabetes [7]. There were several strengths to the study design, including the use of intention-to-treat analysis, stratified randomization, a diverse patient population, and blinding of the study staff who took BP and A1c measurements. Furthermore, a single nurse conducted all telephone calls, ensuring that differences in counseling skill levels would not affect the results of the study. The few weaknesses of the study included the fact that the nurse who delivered the intervention (as well as the patients) could not be blinded to treatment allocation, and the income of study participants was not reported.

The reasons for the negative outcomes of this study are unclear. The authors claim that similar interventions within academic settings have been shown to be effective and speculate that time and financial pressures of community practices may be reasons that the intervention was not successful. However, the “successful” interventions that they cite were quite different from and more intensive than this intervention. For instance, many of these studies used at least 1 call per month [3,4,8], and one even conducted several calls each week [3]. Furthermore, a DM study conducted by Blackberry et al in a community setting with less than 1 call per month (8 calls over 18 months) similarly failed to produce significant results [9], and therefore more frequent calls may be necessary in DM and HTN interventions. In a systematic review, Eakin et al demonstrated that 12 or more calls in a 6- to 12-month period were associated with better outcomes in physical activity...
and diet interventions [10], and this may also translate to closely related DM and HTN interventions.

In addition to the infrequent calls, this intervention also lacked communication and integration with patients’ primary care teams. Several studies have demonstrated that integration with primary care teams can improve outcomes in DM and HTN interventions [11,12], and nearly all of the successful studies cited by the authors also included at least some form of communication with patients’ primary care providers (PCPs) [2–4,5,8]. In many of these studies the nurse also had prescribing rights to alter medications [2,3,5]. The nurse in this study met monthly with an expert team of clinicians to discuss patient issues but did not communicate directly with any of the patients’ PCPs [1]. The authors acknowledge that this lack of integration may have contributed to their negative results and point to the fact that it is harder to integrate interventions within community practices that often lack internal integration. However, Walsh, Harris, and Roberts demonstrated that integration between primary and secondary care teams was both feasible and effective for a diabetes initiative within community practices [13].

An additional important feature not present in this intervention was self-monitoring of BP levels. Home self-monitoring of BP has been demonstrated to significantly improve BP levels [14], and 2 of the successful studies in academic settings cited by the authors also included a BP self-monitoring component [5,6]. In one of these studies [6], Bosworth et al conducted a 2 × 2 randomized trial to improve HTN control in which the arms consisted of (a) usual care, (b) bimonthly nurse administered telephone intervention only (this arm was highly similar to the intervention arm in this study), (c) BP monitoring 3 times a week only, and (d) a combination of the telephone intervention with the BP monitoring. Interestingly, the only arm that was successful relative to usual care was the combination of the telephone intervention and BP self-monitoring; the arm consisting only of bi-monthly telephone calls (very similar to this intervention) failed despite the study taking place in an academic setting (it was also less effective than BP monitoring only). Thus, the addition of self-monitoring to a nurse case management telephone intervention can achieve better results.

Applications for Clinical Practice

A telephone-based intervention delivered by a trained nurse for co-management of DM and HTN was not more effective than an attention control delivered by the same nurse in a community setting. This may have been due to several factors, including low intensity marked by less than 1 call per month, a lack of integration with other members of the primary care team, and lack of a BP self-monitoring component. Future studies are needed to determine the optimal type and duration of nurse care management interventions targeting glucose and BP control for diabetic patients in community settings.

—Sandeep Sikerwar, BA, and Melanie Jay, MD, MS

References

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Which Revascularization Strategy for Multivessel Coronary Disease?


Study Overview

Objective. To compare percutaneous coronary intervention (PCI) using second-generation drug-eluting stents (everolimus-eluting stents) with coronary artery bypass grafting (CABG) among patients with multivessel coronary disease.

Main results. Among 116,915 patients assessed for eligibility, 82,096 were excluded. Among 34,819 who met inclusion criteria, 18,446 were included in the propensity score–matched analysis. With a 1:1 matching algorithm, 9223 were in the PCI with everolimus-eluting stent group and 9223 were in the CABG group. Short-term outcomes (in hospital or ≤ 30 days after the index procedure) favored PCI with everolimus-eluting stents over CABG, with a significantly lower risk of death (0.6% vs. 1.1%; hazard ratio [HR], 0.49; 95% confidence interval [CI], 0.35 to 0.69; P < 0.002) as well as stroke (0.2% vs 1.2%; HR, 0.18; 95% CI, 0.11 to 0.29; P < 0.001). The 2 groups had similar rates of myocardial infarction in the short-term (0.5% and 0.4%; HR, 1.37; 95% CI, 0.89 to 2.12; P = 0.16). After a mean follow-up of 2.9 years, there was a similar annual death rate between groups: 3.1% for PCI and 2.9% for CABG (HR, 1.04; 95% CI, 0.93 to 1.17; P = 0.50). PCI with everolimus-eluting stents was associated with a higher risk of a first myocardial infarction than was CABG (1.9% vs 1.1% per year; HR, 1.51; 95% CI, 1.29 to 1.77; P < 0.001). PCI with everolimus-eluting stents was associated with a lower risk of a first stroke than CABG (0.7% vs. 1.0% per year; HR, 0.62; 95% CI, 0.50 to 0.76; P < 0.001). Finally, PCI with everolimus-eluting stents was associated with a higher risk of a first repeat-revascularization procedure than CABG (7.2% vs. 3.1% per year; HR, 2.35; 95% CI, 2.14 to 2.58; P < 0.001).

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Conclusion. In the setting of newer stent technology with second-generation everolimus-eluting stents, the risk of death associated with PCI was similar to that associated with CABG for multivessel coronary artery disease. In the long-term, PCI was associated with a higher risk of myocardial infarction and repeat revascularization, whereas CABG was associated with an increased risk of stroke. In the short-term, PCI had lower risks of both death and stroke.

Commentary
Coronary artery disease is a major public health problem. For patients for whom revascularization is deemed to be appropriate, a choice must be made between PCI and CABG. In previous studies that compared PCI and CABG, CABG was shown to have less need for repeat revascularizations as well as mortality benefits [1–3]. However, these prior studies compared CABG with older generations of stents. In the past decade, stent technologies have improved, as the bare-metal stent era gave way to the first generation of drug-eluting stents (with sirolimus or paclitaxel), to be followed by second-generation drug-eluting stents (with everolimus or zotarolimus) [4].

In this article, Bangalore and colleagues addressed the issue of whether the use of second-generation drug-eluting stents close the outcome gap that favors CABG over PCI in patients with multivessel coronary artery disease. In patients who were considered to have had complete revascularization performed during PCI (ie, revascularization of all major vessels with clinically significant stenosis), they noted mitigation of the outcome differences between the PCI group and the CABG group. They conclude that the decision-making process by patients and their providers regarding revascularization be placed in the context of individual values and preferences.

One major limitation is that the study is an observational study from registry data. Despite the use of sophisticated statistical techniques including propensity score matching to adjust for confounders that are implicit in any nonrandomized comparison of treatment strategies, observational studies suffer from the definitely proof of causality. These limitations are especially important when the two groups being compared have modest differences in outcome.

Applications for Clinical Practice
This observational study, together with a recent randomized clinical trial in which CABG was compared with PCI with the use of everolimus-eluting stents from the BEST trial [5], provided new insights of the two revascularization strategies. Clinicians should engage and empower patients with a shared decision-making approach. The early hazard of CABG in stroke and death may be unacceptable to some patients, whereas others might want to avoid the later hazards of PCI in repeat procedure or having a myocardial infarction. Until a definitive study is available, patients should be informed of the best current knowledge of the pros and cons of the two revascularization strategies.

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References