Sustainable blood pressure after an intervention

ORIGINAL ARTICLE

BLOOD PRESSURE 2 YEARS AFTER A CHRONIC DISEASE MANAGEMENT INTERVENTION STUDY

Sheldon Tobe 1, Lloyd Vincent 1, Joan Wentworth 3, Denise Hildebrandt 1, Alexander Kiss 1, Nancy Perkins1, Susan Hartman 3, Laurie Ironstand 3, Jacquie Hoppe 3, Katie Hunter1, George Pylypchuk 2

1 Sunnybrook Health Sciences Centre, Toronto, Canada
2 St. Paul’s Hospital, University of Saskatchewan, Saskatoon, Canada
3 Battleford’s Tribal Council Indian Health Services, North Battleford, Canada

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ABSTRACT

Objectives. To follow blood pressure change over time in participants who had participated in a 1-year chronic disease management program focused on blood pressure reduction. The expectation was that blood pressure would return back to the baseline once the study was completed.

Study design. Prospective, single-arm observational study.

Methods. Study participants were Status Indians living on-reserve with type 2 diabetes and persistent hypertension who had participated in the DREAM3 study. Blood pressure was measured with the BpTRU automated device every 6 months for 2 years. The primary endpoint was the change in systolic blood pressure over the follow-up period.

Results. Sixty of the original 96 participants agreed to participate in the follow-up. Mean blood pressure at the beginning of the follow-up was 130/76 (SD 18/12) mmHg. Mean blood pressure at the end of the follow-up period was 132/76 (17/9 SD) mmHg. Target blood pressure (<130/80 mmHg) was present in 53%. The 99% confidence limit around change of blood pressure over the 24 months of follow-up was ±4.7mmHg.

Conclusions. Contrary to expectations, the participants maintained their blood pressure control and did not revert to baseline levels. Community awareness and engagement resulting from the chronic disease management program led to a sustainable improvement in the health parameters of the participants and the community that lasted beyond the duration of the 1-year DREAM3 project. (Int J Circumpolar Health 2010; 69(1):50-60)

Keywords: hypertension, diabetes mellitus, home care nurse, Aboriginal health, chronic disease management
INTRODUCTION

Type 2 diabetes mellitus has reached epidemic proportions among the Canadian population and in particular among the Aboriginal population, with prevalence ranging between 20% and 30% for diabetes and even higher for metabolic syndrome (1). Lowering blood pressure prevents cardiovascular and renal complications of diabetes (2), and it reduces the microvascular and macrovascular complications of diabetes reducing both cardiovascular and renal sequelae (3). Achieving blood pressure targets has been shown to be cost-saving in the United Kingdom Prospective Diabetes Study (4) and in an Australian study of blood pressure control in an Aboriginal population, largely driven by the avoidance of dialysis (5). Given the proven efficacy of blood pressure control in people with diabetes and evidence-based clinical practice guidelines for blood pressure control (6), the challenge is to achieve a sustainable implementation of blood pressure targets, particularly among those at high risk.

Clinical practice guidelines call for blood pressure treatment targets of less than 130/80 mmHg for people with diabetes (7–9), but these targets are achieved in less than 10% of the diabetic population (10). The prevalence rate of type 2 diabetes had been predicted to rise rapidly in the general population (11–12). Despite efforts at primary prevention, rates have risen as predicted, with adjusted prevalence rates rising to 8.8% in the general population in the province of Ontario, a 69% jump over the decade ending 2005 (13). While primary prevention programs remain important, secondary prevention strategies are urgently needed for the growing numbers of people worldwide who are at risk of developing target organ damage from type 2 diabetes (14).

To achieve target blood pressure in people around the world with diabetes would lead to dramatic reductions in cardiovascular and renal events. However, when blood pressure is followed after an intervention study and participants have returned to usual care, their blood pressure returns to prestudy levels (15). In the long-term follow-up of the United Kingdom Prospective Diabetes Study, loss of blood pressure control occurred within 2 years after termination of the study and was associated with a loss of sustainability of the benefits previously found for lower blood pressure (16). Implementing a systems change approach that uses a chronic disease management model involving physicians and health care organizations can result in greater rates of blood pressure control (17).

The DREAM3 study, a randomized controlled study of blood pressure control in First Nations people with diabetes, was recently completed in collaboration with the Battleford’s Tribal Council Indian Health Services (18). This study was the third step in the community’s goal of reducing rates of end-stage renal disease by adopting clinical practice guidelines for chronic disease management. Using the principles of chronic disease management as outlined by Wagner (18), the DREAM3 study compared 2 levels of an antihypertensive management strategy. Both levels were implemented by a multidisciplinary home care team, following the Canadian Diabetes Association Clinical Practice Guidelines (19). Based in North Battleford, this team is part of the Battleford’s Tribal Council Indian Health Services and provides
Sustainable blood pressure after an intervention
care for the 7 First Nations communities in the region. Following the DREAM3 study, the Home and Community Care Team of the Battleford’s Tribal Council Indian Health Services continued a community-wide chronic disease management model for healthy lifestyles developed during the DREAM3 study. The program included guideline-based client education on lifestyle changes, measurement of achieved goals, systems design, decision and self-management support and also supported ongoing guideline-based continuing education for the primary care physicians in the community. Management of glycemic control was in accordance with clinical practice guidelines (20). The primary care physicians of this community were invited to hear the results of the DREAM3 study and to learn about the DREAM3 follow-up program in a series of continuing education events conducted by the authors. In this article, we report on blood pressure levels in study participants 2 years after completion of the DREAM3 study. Additionally, broader community data are presented on the number of people requiring dialysis over the same time period.

MATERIAL AND METHODS

Study participants were those who completed the DREAM3 study. They were Status Indians living on-reserve and were served by the Battleford’s Tribal Council Indian Health Services of the North Battleford area in west-central Saskatchewan. All patients were aged 18 or over and were diagnosed with type 2 diabetes and persistent hypertension ($\geq 130$ mmHg systolic and/or $\geq 80$ mmHg diastolic) at the time of the DREAM3 study (18). Participants were enrolled in the DREAM3 study from September 2001 to March 2003 and followed for a 1-year period. They were randomly separated into 2 groups: a treatment group where hypertension was managed by a home and community care nurse, according to a guideline-based treatment algorithm of pharmacologic antihypertensive therapy, and a control group where treatment decisions were made by the participants’ primary care physicians. Both groups received identical lifestyle management counselling. The inclusion and exclusion criteria have been reported (18).

At the end of their participation in the study, all participants of the DREAM3 cohort were invited to participate in a longitudinal follow-up study to have their blood pressure measured every 6 months for at least 2 years following the study. The final participant completing the DREAM3 study in 2004 finished 2 years of follow-up in March 2006. Participants were included in the analysis if they had at least 1 blood pressure reading, obtained by the Home and Community Care Team, at least 6 months following the participant’s completion of the DREAM3 study.

Approval for the DREAM3 follow-up study was obtained from Battleford’s Tribal Council Indian Health Services. The protocol was in accordance with the Declaration of Helsinki and was approved by the ethics committees of the Sunnybrook Health Sciences Centre, the University of Toronto and the University of Saskatchewan.

One of the home care nurses saw participants in the clinics on their reserve every 6 months after enrollment to the end of March 2006. Home health aides from the participants’ own reserve accompanied participants if requested, to help with language and cultural
issues. Participants were instructed to take their morning medications before each visit. Blood pressure was measured at each visit by the home and community care nurse using the BpTRU automated oscillometric BP cuff (VSM Medtech, Vancouver, Canada) (21). BP measurements were obtained non-fasting and were conducted at least half an hour after drinking coffee or smoking cigarettes with the patient seated for a minimum of 30 minutes. The BpTRU takes 6 readings, each 2 minutes apart and averages the final 5 after discarding the first reading. Blood pressure readings were sent to the patient’s primary physician in a letter after each study visit; the letter outlined the results and included the blood pressure guidelines for people with diabetes. Medication adjustments were at the discretion of the primary physician and part of usual care.

The primary endpoint was the change in systolic blood pressure at the end of the follow-up period. To determine if the systolic blood pressure at the end of the study had returned to the level it was at the beginning of the DREAM3 study, the 99th percentile range for the systolic blood pressure at the end of 24 months was calculated from the change that occurred over the follow-up period.

To address both the primary issue of change in hypertension after the 1-year DREAM3 study and the issue of variable follow-up visits, we extracted from each participant 2 blood pressure slope estimates (in mmHg/month units). The first was derived from the initial DREAM3 baseline measurement to the last proper visit of that study. The second, the follow-up slope, was derived from this same last visit of the DREAM3 study to the last visit in the follow-up study. Descriptive statistics were calculated for both slopes and their respective components (i.e., change in systolic blood pressure and the duration over which this change occurred) overall and by treatment groups. In addition, analysis of variance of the group factor and the slope factor (trial vs. follow-up) on blood pressure slopes directly tests whether the change in slopes is different for the 2 groups (i.e., the interaction of group by slope). All analyses were carried out using SAS Version 9.1 (SAS Institute, Cary, NC, USA). The systolic blood pressure was used because diastolic blood pressure tends to level off and fall over time in men and women over age 50 (22).

RESULTS

Of the original 99 participants in the DREAM3 study, 60 participants had blood pressure measurements taken during the follow-up period at least 6 months following the completion of the DREAM3 study. Figure 1 describes the attrition characteristics of those who could not be followed up on. Not all of the 60 participants in the follow-up period completed all scheduled 6-monthly blood pressure measurements because clients were not available or were unwilling to come to the particular study visit. Demographics and initial values from the beginning of the DREAM3 study on the 60 participants and those lost to follow-up are compared in Table I.

The mean number of 6-monthly follow-up blood pressure measurements over the 2-year follow-up period was 2.4 (1.08, SD). For the 60 participants in the follow-up study, blood pressure at the beginning of the follow-up study was 130/76 (18/12 SD) mmHg. Blood pressure at the last follow-up visit was 132/76 (17/9 SD) mmHg and 53% had achieved the target blood
Sustainable blood pressure after an intervention

pressure of <130/80 mmHg. Consistency of blood pressure control is demonstrated in Table II where those who achieved the target blood pressure at the beginning of the follow-up period are compared to those who did not have control at the beginning of the DREAM3 study and at the beginning and end of the follow-up study. It is interesting to note that participants who had not achieved control of blood pressure by the end of the DREAM3 study did show improvement in their blood pressure over the follow-up period. Blood pressure control by allocation to treatment or control arm in the DREAM3 study is found in Table III and demonstrates that those using the treatment arm had better blood pressure control at the beginning of the follow-up period. However, during the follow-up period, blood pressure control continued to improve in those originally allocated to use the control arm.

Figure 1. Attrition characteristics of participants from the DREAM3 study participating in the follow-up study.
Table I. Demographic and physiologic data at beginning of intervention study for all participants.

| Variable                  | Follow-up participants (n=60) | Participants lost to follow-up (n=36) |
|---------------------------|-------------------------------|--------------------------------------|
| Age (years)               | 56.1 (10.4)                  | 54.8 (14.5)                          |
| Gender (% male)           | 35                            | 36                                   |
| BMI (kg/m²)               | 34.1 (2.4)                   | 33.6 (2.7)                           |
| Hip circumference (cm)    | 111.8 (12.5)                 | 112.9 (14.3)                         |
| Waist circumference (cm)  | 110.4 (13.4)                 | 112.5 (14.6)                         |
| Creatinine (umol/L)       | 69.1 (16.4)                  | 74.4 (16.5)                          |
| Potassium (mEq/L)         | 4.1 (0.4)                    | 4.2 (0.4)                            |
| Total cholesterol (mmol/L)| 5.0 (1.0)                    | 5.3 (0.8)                            |
| HDL (mmol/L)              | 1.17 (0.40)                  | 1.12 (0.23)                          |
| A1c (%)                   | 7.74 (1.9)                   | 7.93 (1.8)                           |
| Glucose (mmol/L)          | 10.0 (5.3)                   | 9.7 (4.6)                            |
| ACR (mg/mmol)             | 12.7 (42)                    | 54.7 (130)                           |
| ACR (geometric mean)      | 1.4                          | 5.4                                  |
| Microalbuminuria (%)      | 28                            | 22                                   |
| Overt nephropathy (%)     | 8                             | 25                                   |
| Systolic BP (mmHg)        | 148.3 (17.7)                 | 151.2 (21.3)                         |
| Diastolic BP (mmHg)       | 84.5 (9.6)                   | 86.7 (10.3)                          |

Comparison of variables at baseline of DREAM3 study in participants who had follow-up blood pressure measures and in those that were lost to follow-up. All data presented as mean ±(SD). ACR=albumin:creatinine ratio. Microalbuminuria (ACR 2.8-28 for women and 2.0-20 for men). Overt nephropathy (ACR >2.8 for women and >20 for men).

Table II. Blood pressure at different study points by control of blood pressure (<130/80 mmHg) at the beginning of the follow-up period.

| Time period                      | BP controlled (n=32) | BP not controlled (n=28) |
|----------------------------------|----------------------|--------------------------|
| Beginning of study               | 145/85 (19/17)       | 152/83 (19/11)           |
| Beginning of follow-up period    | 117/71 (11/10)       | 145/82 (12/10)           |
| Last reading from follow-up period | 126/74 (12/9)   | 141/79 (20/9)            |

Table III. Blood pressure at different study points by allocation to treatment or control arm of DREAM3 study.

| Time period                      | Treatment arm (n=30) | Control arm (n=30) |
|----------------------------------|----------------------|--------------------|
| Beginning of study               | 148/86 (19/9)        | 148/83 (16/10)     |
| Beginning of follow-up period    | 124/73 (18/13)       | 136/79 (16/9)      |
| Last reading from follow-up period | 131/75 (21/11)   | 134/78 (14/8)      |
To demonstrate that the mean blood pressure over the follow-up period remained significantly lower, the change of blood pressure over the follow-up period was assessed to see if the upper confidence limit overlapped with the level at the start of the DREAM3 study. The mean change per month for systolic blood pressure in the follow-up period was 0.03 mmHg/month. The upper 99% confidence limit around this mean was 4.7 mmHg at 24 months of follow-up, which did not overlap at all with the systolic blood pressure at the start of the DREAM3 study. The systolic blood pressure over 24 months of follow-up, therefore, remained below baseline levels. These results are displayed graphically in Figure 2. A significant difference was found between the change of systolic blood pressure over the 12-month DREAM3 study and the 24-month follow-up period (p<0.001).

The chronic disease registry maintained by the Battleford’s Tribal Council Indian Health Service’s Home and Community Care Team shows a significant increase in diabetes and hypertension within the community. From 2001 to 2007, the number of people with diabetes rose from 74 to 353, and those with hypertension rose from 65 to 280. During this time, the population recorded for the 8 reserves of the community grew from 4,560 to 5,130. Figure 3 illustrates the number of people living on-reserve with known chronic kidney disease and those requiring dialysis during that time period. The prevalence of people on dialysis fell and remained stable while the number with known chronic kidney disease rose.

![Figure 2. Systolic blood pressure and rate of change of systolic pressure during the DREAM3 study and the follow-up period. Error bar shows 95% confidence intervals.](image_url)
DISCUSSION

The high levels of blood pressure control obtained in the 1-year, community-based DREAM3 study were found to persist on follow-up almost 24 months later. These results are in contrast to those of Menard et al., where participants receiving blood pressure intensification over 1 year were brought to an academic health sciences centre (5). Following cessation of the DREAM3 study, the onus of providing treatment for hypertension shifted solely to the patients’ primary care physicians. We postulate that the DREAM3 study, which was a participatory research project, led to systemic changes in health care delivery which, in part, led to the persistence of better blood pressures. An educated community, along with community leadership, that encourages lifestyle changes may also be why other studies have found improvements through risk-reduction strategies (23).

Many members of the Home and Community Care Team in the DREAM3 study and the follow-up study came from within the local Aboriginal community and were a trusted voice for change. Other factors associated with this participatory community research project may have contributed to persistently lower blood pressure during the follow-up period, including continued programs of community awareness and capacity building, client education on diet, lifestyle modifications, self-care, and disease management counselling (24). These community factors may have contributed to the community being more receptive.

Figure 3. Number of people in the Battleford’s Tribal Council Indian Health Services known to have chronic kidney disease or to be on dialysis from 2000 to 2007.
to the change process and to accepting the organizational changes in the study. Community-based research is needed to identify gaps in care that are relevant to Aboriginal communities (25). The incorporation of the principles of the chronic disease care model as described by Wagner, to implement clinical practice guidelines for blood pressure control, was likely, in large part, responsible for the persistent improvement in the blood pressure outcome in the follow-up period (26). The potential for community changes in practice highlights the need for clustering when designing future studies that use multiple communities (27).

The observation that the number of people from the Battleford Tribal Council Health Services on dialysis was lower following completion of the DREAM3 study and remained low during the follow-up period is possibly a play of chance. However, before a similar observation was made by Hoy et al. after a similar program was initiated for the Tiwi in Australia (28). In most communities the prevalence of people requiring dialysis is still rising (29). The fall in dialysis numbers mirrored by a rise in people with chronic kidney disease suggests that progression to dialysis was delayed. The reduction of dialysis from blood pressure control has been shown to be cost-saving and associated with an improvement in the quality of life as well (5).

Limitations of this study include follow-up visits in just two-thirds of patients from the DREAM3 study. At the baseline of this study, however, participants who eventually were in the follow-up were not distinguishable from the rest (Table I). The results of the follow-up study cannot immediately be generalized to the general population. Only prevalence data for patients on dialysis and with chronic kidney disease were available and not incidence data, making it possible that a sudden increase in exits from dialysis could influence the results. However, the prevalence of patients on dialysis remained lower over 5 years.

The 60 participants included in the follow-up program make up approximately 20% of the known people with diabetes in the community at that time. If the DREAM3 study was, in part, associated with a reduction of target organ damage leading to fewer dialysis starts during this time, then it is suggestive of a broader community change in practice. The persistence of blood pressure control in these participants, including a continued fall in blood pressure in those who had not reached their targets, also suggests that a change in practice had occurred in the community. This association can only generate a hypothesis and should be proven in a future study. The effectiveness of the Home and Community Care Team in implementing other clinical practice guidelines as part of chronic disease management models should be further explored.

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Sustainable blood pressure after an intervention

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Contributors: Sheldon Tobe has had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. All of the authors were responsible for the collection, management and analysis and interpretation of the data and for the review and preparation of the manuscript.

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Sustainable blood pressure after an intervention

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Dr. Sheldon Tobe
Sunnybrook Health Sciences Centre
Toronto, ON, M4N 3M5
CANADA
Email: sheldon.tobe@sunnybrook.ca