A Randomized Controlled Trial Evaluating a Community-Based Diabetes Optimization Program for Patients Awaiting Elective Cardiac Surgery

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Abstract

Background: The diabetes prevalence varies from 7%-20% among Cardiovascular Surgery (CS) patients. The patients with suboptimal glycaemic control are at a higher risk of postoperative morbidity and mortality.

Objective: To explore feasibility and effectiveness of preoperative Diabetes Optimization Program (DOP).

Design: Unblinded parallel group randomized controlled trial.

Methods: Between 2013 to 2015, consecutive, consenting elective CS patients with HbA_{1c}>7% were randomized to Standard of Care (SOC) group or to the DOP group. The DOP is a community-based diabetes education and optimization program. The SOC includes diabetes care from their Primary Care Physician (PCP).

Outcome: The primary outcome was DOP feasibility. Secondarily, rate of change in HbA_{1c} between the groups over the study period was evaluated. The DOP feasibility was assessed through the participants' consent and adherence rate and generalized estimating equation was used for secondary outcomes analyses.

Results: Thirty three out of 57 patients consented to participate in the study (consent rate 58%); 19 randomized to SOC group and 14 to the DOP group. The DOP group protocol adherence rate was 71%. There was no difference in the rate of HbA_{1c} change between the groups over time (p=0.994).

Conclusion: Providing preoperative diabetes optimization, through intervention such as DOP, for elective CS patients is feasible. Even so, its effectiveness reducing HbA_{1c} appears comparable to the SOC in this feasibility trial. Perhaps, a shared diabetes care including the primary care provider and an integrated diabetes education and management program would resonate with the identified patients' preference, with higher diabetes optimization efficacy.

Keywords: Diabetes; Cardiac surgery; Preoperative; Specialized care; Diabetes education; Diabetes dependent quality of life; Perioperative care

Abbreviations: ADDQoL: Audit of Diabetes Dependent Quality of Life; DTSQ: Diabetes Treatment Satisfaction Questioner; DOP: Diabetes Optimization Program; FP: Family Physician; HbA_{1c}: Glycated Haemoglobin; HRQoL: Health-Related Quality of Life; ICU: Intensive Care Unit; LOS: Length of Stay; PHQ-9: Patient Health Questioner; SF-12: Short Form Health Status; SOC: Standard of Care

Introduction

Diabetes affects more than 3 million Canadians, making it one of the most common chronic conditions [1]. The prevalence of diabetes among cardiac surgery patients varies from 7% to 20% [2]. Thus,

diabetes screening is recommended for all patients undergoing cardiac surgery [3]. Glycated hemoglobin (HbA_{1c}) is a useful clinical measure to quantify long-term glucometabolic state. Diabetes Canada clinical practice guidelines recommend a target of HbA_{1c} <7% for long-term glycemic control in patients with diabetes [4]. However, approximately 25% of cardiac surgery patients have sub-optimal HbA_{1c} levels (i.e. HbA_{1c} >7%) and 10 % of these patients have undiagnosed diabetes [5]. Higher HbA_{1c} is a strong predictor of mortality and morbidity, length of hospital stay and decreased long-term survival irrespective of previous diabetic status in patients undergoing Coronary Artery Bypass Grafting (CABG) procedure [5-10]. Furthermore, the higher preoperative HbA_{1c} level is associated with increased risk of post-operative complications including acute renal failure, cerebrovascular accident, postoperative myocardial infarction as well as an increase in sternal wound infection in patients undergoing CABG [5-8].

In a previous quality improvement initiative at our institution, it was identified that of all the patients undergoing elective cardiac surgery, 35% patients had a history of diabetes. The average preoperative HbA_{1c} was 8.5% among the diabetic CS patients. These findings identified a need for improved diabetes optimization in elective cardiac surgery patients at our center. Leveraging diet, exercise and diabetic medications to optimize glycemic levels play a critical role in achieving efficient glycemic and therefore an optimal diabetes control [11-15]. The elective cardiac surgery patients are placed on a waiting-list for ~4 weeks. We hypothesized that during the waiting period (prior to a patient's surgical procedure) the diabetic patients could be engaged to optimize their glycemic levels. The objective of this study was to evaluate the feasibility of preoperative diabetes optimization program to improve HbA_{1c} levels in elective cardiac surgery patients. Secondly, we sought to determine whether an intervention during the waiting period could effectively optimize HbA_{1c} levels and improve the postoperative outcomes in these patients. The optimization would include an intervention that focused on assessing patients' current diabetes management practices and to provide diabetes self-management education at a dedicated community-based diabetes clinic (Figure 1).

Method

Study design

This study was carried out in collaboration between the Cardiac Science Program, Saint Boniface Hospital and Youville Diabetes Center (Winnipeg, Manitoba, CA). We sequentially randomized patients undergoing elective cardiac surgery in a prospective, parallel group design with 1:1 randomization (Figure 1). The study focuses primarily

on determining the feasibility of preoperative diabetes optimization program and its effectiveness in improving HbA_{1c} levels in patients awaiting cardiac surgery. Cardiac surgery patients were screened from October 2013 up until December 2015. The study was approved by Research ethics board, Bannatyne Campus, University of Manitoba (Research Ethics Board: HS21553 (B2018:015); Clinical trial registration NCT01824277).

Study population

Participants were identified at the time of the cardiac surgeon's consultation at an outpatient clinic. The research coordinator approached patients who were placed on the waiting list for elective cardiac surgery and had a recent (<2 months) HbA_{1c} levels >7%. For patients without a recent HbA_{1c} measurement, screening consent was obtained by the cardiac catheterization clinic nurse and HbA_{1c} levels were measured during the cardiac catheterization procedure. All screened patients were informed about the study (risk/benefits, participation, procedures and implications). Patients were given enough time to reflect on the information and had any questions answered prior to consent. Participants were informed that not participating in the study would not affect their standard perioperative care. They were also assured that if they consented to participate they were free to withdraw from the study at any time without prejudice to future medical treatment.

Adult patients (age ≥ 18 years) with suboptimal diabetes control i.e. HbA_{1c} >7%, who were on the waiting list for elective cardiac surgery, able to speak and understand the English language, and able to provide informed consent met the inclusion criteria for this study. Patients who were either aged <18 years, unable to provide informed consent, had a cognitive disorder limiting ability to participate in the diabetes optimization program or to provide informed consent, undergoing emergent or urgent cardiac surgery or had recent <7% were excluded from the study.

Study intervention

Participants undergoing elective cardiac surgery were sequentially randomized in a prospective, parallel group design with 1:1 randomization (Figure) and were assigned to one of the two groups: 1) Standard of Care (SOC) (control) group and 2) Diabetes Optimization Program (DOP) (intervention) group at a dedicated community-based diabetes program (Youville Diabetes Clinic). The current standard care for patients undergoing elective cardiac surgery includes pre-operative health assessment, cardiac surgical care, and three-month postoperative cardiac surgeon's consultation. All diabetes cardiac surgery patients are managed by their Primary Care Provider (PCP) (current standard practice) for medication, maximum glycemic control, and other associated diabetes care during the waiting period.

Participants randomized to Standard of Care (SOC) group continued receiving standard diabetes care from their community PCP while waiting for surgery. Participants randomized to Diabetes Optimization Program (DOP) group were referred to a community-based diabetes education and care program (at Youville Diabetes Center, Winnipeg, Manitoba). The DOP team consists of a Certified Diabetes Educator (CDEs), nurse and dietitian with backup contact with an endocrinologist. The team assessed patients' current diabetes self-management, glycemic status, nutrition status, physical activity level, other co-morbidities and barriers to healthy behaviors. The team then provided self-management education to improve diabetes control.

In addition, the team worked with each patient's PCP and made recommendations for changes in diabetes medications and followed the participants until surgery and afterwards.

Outcome measurement

The primary outcome was the feasibility of providing diabetes optimization intervention during the preoperative period as assessed by the rate of consent and adherence to protocol. The consent rate was calculated based on the proportion of participants agreeing to participate in the study. The adherence rate was calculated based on the proportion of participants' completing the study protocol. In addition, validated questionnaires evaluating diabetes treatment satisfaction, diabetes self-management engagement, quality of life, and perceived depression were administered at the baseline, preoperatively and postoperatively at 3-month time points. The questionnaires included Audit of Diabetes Quality of Life Measure (ADDQoL), Diabetes Treatment Satisfaction Questionnaire (DTSQs and DTSQc), the Patient Health Questionnaire-9 (PHQ-9), and the 12-item short form survey version 2 (SF-12) Health-Related Quality of Life (HRQoL) Questionnaire [16-20].

Data collection and management

Study sample: The annual estimated total provincial cardiac surgery volume was ~1000-1100 patients. A total of 360 patients are expected to meet the age and elective surgical status (inclusion criteria). For this feasibility randomized controlled trial, a total recruitment of 80 patients (40 per group) was targeted to allow for an overall dropout rate of 10%.

Statistical methods

Perioperative characteristics were collected for all individuals recruited into the clinical trial. Continuous variables were expressed as median (interquartile range) and categorical variables were expressed as N (%) for the SOC and DOP study groups. For available

characteristics, these summary statistics were also obtained for all elective cardiac surgery patients with a clinical diagnosis of diabetes according to the Manitoba Cardiac Surgical Database (MaCS). These summary statistics were obtained to provide a comparison to the study eligible patient population during the recruitment period. The consent and adherence rate were calculated to evaluate the DOP feasibility. Generalized Estimating Equations (GEE) were used to analyze all secondary outcomes over the study period [21]. All data analyses were conducted based on the principle of intention to treat. All statistical analysis was performed using SAS version 9.3.

Results

Out of 334 patients assessed for eligibility, a total of 57 patients met the study eligibility criteria and were approached for study enrollment. However, 24 patients declined participation (consent rate of 57%). The remaining 33 participants (baseline HbA_{1C} Mean: 8.3%) were randomized, 14 patients to the DOP group (intervention) and 19 patients to the SOC group (control) (Figure 1). A total of 10 participants randomized to the DOP group attended the Youville clinic (protocol completion rate of 71%), while the remaining four did not attend. Furthermore, after group allocation, four patients dropped out in the postoperative period (one from the SOC group and three from the DOP group).

The baseline patients' characteristics (Table 1) did not differ between the groups. The median age was 67 years for the control group and was 69 years for the intervention group. Thirty percent of participants were females; 26% in the control group and 36% in the intervention group. The patients in the control group had a higher median baseline HbA_{1C} of 8.8% (7.6-10.4) compared to the intervention group of 7.9% (7.4-8.5). The participants were generally at low-risk for early postoperative mortality; median Euro SCORE II of 2.48 (1.75-4.07). A total of 18 (55%) study participants underwent a CABG procedure, 5 (15%) an isolated valve only procedure, 5 (15%) underwent CABG and valve combined procedure and 5 (15%) underwent other procedures.

Characteristic	Elective Diabetics in Study Period (N=334)	All Patients Randomized (N=33)	SOC (N=19)	DOP (N=14)
Preoperative				
Demographics				
Age	68 (61-74)	67 (61-72)	66 (60-74)	69 (61-72)
Gender (Female)	76 (23%)	10 (30%)	5 (26%)	5 (36%)
Body Mass Index (kg/m ²)	30.5 (27.0-34.2)	32.9 (31.2-38.0)	32.3 (29.7-34.9)	35.4 (32.7-40.9)
Body Surface Area (m ²)	2.07 (1.89-2.24)	2.07 (2.01-2.30)	2.08 (2.01-2.19)	2.06 (1.99-2.42)
Diabetes characteristics				
Baseline HbA _{1c} (%)	-	8.3 (7.5-10.0)	8.8 (7.6-10.4)	7.9 (7.4-8.5)
Diabetes Duration (Years)	-	15 (5-20)	15 (6-20)	17 (5-20)
Oral Hypoglycemic Use	221 (66%)	29 (88%)	16 (84%)	13 (93%)
Insulin	85 (25%)	11 (33%)	7 (37%)	4 (29%)
Comorbidities				

Hypertension	288 (86%)	21 (64%)	12 (63%)	9 (64%)
Hyperlipidemia	256 (77%)	23 (70%)	13 (68%)	10 (71%)
Myocardial Infarction	92 (28%)	6 (18%)	3 (16%)	3 (21%)
Atrial Fibrillation	41 (12%)	4 (12%)	3 (16%)	1 (7%)
Transient Ischemic Accident	23 (7%)	1 (3%)	0 (0%)	1 (7%)
Cerebrovascular Accident	20 (6%)	2 (6%)	0 (0%)	2 (14%)
Chronic Obstructive Pulmonary Disease	25 (7%)	1 (3%)	1 (5%)	0 (0%)
Peripheral Vascular Disease	41 (12%)	1 (3%)	0 (0%)	1 (7%)
Chronic Kidney Disease	29 (9%)	3 (9%)	2 (11%)	1 (7%)
Creatinine (u/mmol)	81 (70-109)	81 (69-92)	79 (69-92)	82 (68-92)
Cardiac status				
Cardiac Surgery Wait Time (Days)	34 (15-73)	74 (34-107)	76 (20-128)	58 (34-87)
EuroSCORE II (%)	1.85 (1.16-3.22)	2.48 (1.75-4.07)	2.58 (1.92-4.72)	2.07 (1.46-3.88)
Ejection Fraction				
<30	15 (5%)	2 (7%)	2 (11%)	0 (0%)
30-50	89 (32%)	6 (20%)	4 (22%)	2 (17%)
>50	173 (62%)	22 (73%)	12 (67%)	10 (83%)
*Based on Non-Missing Data; Continuous variables expressed as Median (Quartile 1-Quartile 3); Categorical variables expressed as N (%)				

Table 1: Patients characteristic comparison between the randomized cohorts.

Table 2 describes the secondary outcome measure (operative and postoperative) between the randomized cohorts. Postoperatively, the control group patients had a longer duration of Intensive Care Unit (ICU) stay (median stay: 48 hrs.) versus the intervention group (median stay: 29 hrs). Hospital length of stay demonstrated no difference between the intervention and control group. The control group, pre-operative HbA_{1C} decreased by an average of 0.8% and the 3 month follow-up HbA_{1C} decreased by 1.1% compared to baseline (Figure 2). For the intervention group, preoperative HbA_{1C} level

decreased by an average of 0.2% and the 3 month follow-up HbA_{1C} postoperatively decreased by 1.3% compared to baseline. The SOC group appeared to have consistently higher levels of HbA_{1C} over the study period (Group Effect coefficient 0.720; p-value=0.085). Both groups have a decline in HbA_{1C} over the course of the study (Time Effect coefficient -0.006; p-value<0.01), however there was no difference in the rate of change (i.e. decline) in HbA_{1C} level between groups (model coefficient 0.00; p-value=0.994).

Survey	Baseline		Operative		3 Month Follow-Up	
	SOC (N=19)	DOP (N=14)	SOC (N=19)	DOP (N=14)	SOC (N=19)	DOP (N=14)
HbA _{1C} (%)	8.8 (7.5-10.4)	7.9 (7.4-8.5)	8.1 (6.8-9.3)	7.4 (7.2-7.8)	7.4 (7.0-8.5)	7.0 (6.4-7.3)
SF-12v2						
No. of Completed Surveys ^a	17	11	10	7	13	7
Physical Component Score (0-100)	52.6 (47.5-55.6)	52.6 (46.0-56.0)	52.3(48.8-57.0)	55 (49.6-58.4)	50.1 (43.1-56.3)	50.4 (44.9-52.9)
Mental Component Score (0-100)	27.1 (16.8-32.1)	26.8 (21.0-30.1)	23.4 (15.8-28.7)	20.2 (17.3-36.0)	20.4 (17.7-25.1)	22.5 (19.6-31.9)
ADDQoL						
No. of Completed Surveys ^b	17	11	10	7	14	8

Total Mean Weighted Impact Score (-9 to 3)	-1.2(-2.3 to -0.5)	-1.9(-3.5 to -0.4)	-1.1(-1.8 to -0.4)	-1.2(-1.9 to -0.4)	-1.1(-2.1 to -0.3)	-1.8(-2.8 to -0.1)
General Quality of Life (-3 to 3)	1 (1 to 1)	1 (-1 to 2)	1 (1 to 1)	1 (0 to 1)	2 (1 to 2)	2 (1 to 2)
Quality of Life Without Diabetes (-3 to 1)	-1 (-2 to -1)	-1 (-3 to 0)	-2 (-2 to -1)	-1 (-1 to 0)	-1 (-2 to 0)	-1 (-2 to 0)
DTSQ						
No. of Completed Surveys ^{a,c}	16	11	9	7	14	8
Total Satisfaction Score (0 to 36)	24(21-30)	26(21-33)	25(22-32)	24(21-29)	28 (24-35)	25(23-30)
Perceived Glucose Control Score (0 to 12)	6 (5-7)	4 (2-6)	6 (5-7)	5 (4-5)	3 (2-5)	4 (2-5)
PHQ-9						
No. of Completed Surveys ^d	17	11	10	7	14	8
Total Score (0-27)	5 (2-9)	6 (3-8)	4 (3-5)	3 (2-6)	3 (1-4)	3 (1-8)
Mild Depression (5 or Higher)	9 (53%)	6 (55%)	4 (40%)	2 (29%)	3 (21%)	2 (25%)
Moderate Depression(10 or Higher)	3 (18%)	2 (18%)	1 (10%)	1 (14%)	0 (0%)	2 (25%)

^aResults based on surveys with complete information; PHQ-9=Patient Health Questionnaire Version 9; ADDQoL=Audit of Diabetes-Dependent Quality of Life Survey; DTSQ=Diabetes Treatment Score Questionnaire; SF-12v2=Short Form 12 Questionnaire Version 2. Summary represented as median (Quartile 1-Quartile 3) and N(%) where appropriate. ^bDTSQs was administered at baseline, DTSQc was administered at operative and 3-month follow-up, a higher Score corresponds to better functioning, b higher score corresponds to the greater quality of life, c higher score corresponds to higher satisfaction, d higher score corresponds to a higher risk of depression

Table 2: HbA_{1C} and survey results in comparison between randomized cohorts.

Figure 2: Change in average HbA_{1C} (%) over study period.

The participants in the SOC group has a slightly higher decline in the SF-12 v2 MC score (Group/Time Effect p-value=0.052) and experienced a greater decline in the PHQ-9 score (Group/Time Effect p-value=0.088) as compared to the DOP group. The participants in the control group perceived higher glucose control compared to the DOP group (Group Effect p-value=0.064). No statistically significant difference was observed in the Physical component score (SF12 V 2), ADDQoL, and total satisfaction score -DTSQ between the groups and over the study period.

Discussion

Through implementing a preoperative diabetes optimization program *via* a specialized outpatient clinic, we aimed to evaluate the feasibility of such a program. In addition, we measured the program's effectiveness in optimizing HbA_{1C}. We experienced a low recruitment (consent rate) and a low adherence (protocol completion) rate. Furthermore, the study results demonstrate that patients randomized to DOP achieved a mean reduction in HbA_{1C} that is comparable to patients randomized to SOP. Similarly, the changes in ADDQoL and DTSQ scores are comparable between the groups. The efficacy of DOP through the specialized clinic in optimizing HbA_{1C} was equivalent to the efficacy of SOC.

A key challenge to recruitment was patients' refusal. In total, 42% (24 patients) of the patients refused to participate in the study with the following reasons: patients overwhelmed by their health status (44%), preferred family physician to receive diabetes-related preoperative care (31%), travel barrier (19%), no interest in participation (13%) and language barrier (6%). In addition, of the 33 patients randomized, nearly 25% either did not attend the program or dropped out of the trial. In addition, the preference for PCP (considering 31% of patients refused to participate because they preferred family physicians for diabetes care) and the higher baseline DTSQ score (Total satisfaction score: control group=24 and intervention group=26) altogether signifies higher treatment satisfaction among patients for diabetes-related care received from a primary care physician. A study by Sahani et. al demonstrated similar finding of patients being more satisfied with their primary care physician compared to the specialized care [22].

Numerous studies have demonstrated that a multiple session diabetes education and problem-solving intervention is more effective in improving behavioral and physiological aspects; ensuring a

significant improvement in the HbA_{1C} [23-25]. Interestingly, both SOC and DOP groups experienced a reduction in HbA_{1C} level at 3-month postoperatively compared to baseline. However, there was no difference in the rate of mean HbA_{1C} reduction between the patients' receiving preoperative diabetes care at a specialized clinical (i.e. DOP group) compared to those receiving diabetes care at family physician (i.e. SOC group) (p-value=0.994). This finding is contradictory to the result from a study by Lee et al where the decline in postoperative HbA_{1C} was significantly greater in the preoperative diabetes optimization group than that observed in the usual care group [26]. In this study, cardiac surgery patients received multiple session interventions, a key difference from our study where 42% of patients randomized to DOP group attended a single or less session.

A limitation of this study was the low sample size. In addition to patients' refusal to participate, only 17% (57 participants) could be approached to participate at the first place because of screening difficulties (such as unavailability of patients' HbA_{1C} for review at the time of cardiac surgeon's consultation). Thus the study is a small cohort demonstrating feasibility. However, a larger study will be necessary to validate feasibility as well as effectiveness of the DOP program. Furthermore, implementing such intervention in a jurisdiction, where wait times are shorter and would intentionally delaying surgery in patients having suboptimal HbA_{1C} be appropriate, remains to be investigated.

Conclusion

There is a high prevalence of diabetes among patients presenting for cardiac surgery. It has been demonstrated that preoperative, suboptimal glycemic control is associated with poor postoperative clinical as well as patient-related outcomes. An optimal, evidence-based, coordinated preoperative diabetes optimization intervention can lead to improved postoperative outcomes. However, there are limited studies evaluating the feasibility as well as effectiveness of such intervention among patient presenting for cardiac surgery.

In this study, we administered a diabetes optimization intervention during the preoperative waiting period for patients undergoing elective cardiac surgery. The study demonstrates feasibility of providing diabetes optimization intervention through a specialized clinic. However, we identified implementation barriers including patients' preference for family physician for receiving diabetes care. Furthermore, its effectiveness of optimizing diabetes is comparable to a family physician driven diabetes care. The efficacy of such intervention in reducing HbA_{1C} requires further investigation to establish an ideal implementation approach that defines the best practice of care. Based on the findings from this study, a shared care model, between the PCP and a specialized diabetes education and management program, may be more successful. A qualitative study evaluating patients' and PCPs' perspective of the current standard of diabetes care could guide future initiatives that will improve patients' "buy in" of such care, in turn may augment diabetes care.

Key Messages

The suboptimal glycemic control is commonly found among cardiac surgery patient. A specialized diabetes care during waiting period may optimize perioperative glycemic level (i.e. HbA_{1C}) and improve postoperative health related quality of life.

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Authors' Disclosures

The authors declare no conflict of interest. All authors equally contributed towards study development (designing, planning and implementation). All authors provided critical feedback and helped shaped the research, analysis and manuscript.

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