Research Article

Using a register-recall system in primary care for patients with poorly controlled diabetes; a cluster-randomized trial

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ABSTRACT

Background: Structured and regular review of patients with diabetes has shown to be effective in improving the process of their care. However, a register-recall system that periodically identifies patients not meeting their treatment targets and actively recalls them for review is not widely implemented in Saudi primary care clinics. **Objectives:** To examine whether using a register-recall system in a primary care setting will result in improvement in glycemic control among patients with poorly controlled diabetes. **Materials and Methods:** In this open-labeled prospective trial, two out of eleven primary care clinics at King Abdul-Aziz housing city, with closely matched demographics, were identified and cluster-randomized to receive intervention (register-recall) versus control (routine care) during the month of August 2015. One hundred and twenty eight patients with uncontrolled diabetes (glycated hemoglobin [A1c] ≥ 7.5%) were identified in both clinics and patients were then followed up for 6 months. A1c, blood pressure (BP), and low-density lipoprotein (LDL) were noted at baseline, 3 months and the end of the trial. **Results:** Modest improvements in glycemic control were achieved among the intervention group at 6 months (mean difference [MD] = −0.44, 95% confidence interval [CI] = −1.06-0.18, $P = 0.16$). The odds of having uncontrolled diabetes (A1c ≥ 7.5%) among the intervention group was less than the control group (odds ratio [OR] = 0.24, 95% CI = 0.03-2.19, $P = 0.37$). Significant improvement in systolic blood pressure (SBP) (MD = −7, 95% CI= −12.7 to −1.3, $P = 0.015$) was noted at 6 months, while changes in LDL levels were marginal (MD = 0.1, 95% CI = −0.23-0.43, $P = 0.55$). Except for SBP, none of the observed results quite reached statistical significance. **Conclusion:** Modest, statistically insignificant, glycemic improvements were observed in this trial, while significant SBP improvement was achieved. The role of register-recall is unclear when dealing with very poorly controlled disease (A1c ≥ 10.5%).

KEY WORDS: Register-recall; Diabetes; Primary Care; Saudi Arabia

INTRODUCTION

Diabetes mellitus is a challenging chronic condition and health burden.[1] Previous studies in Saudi Arabia have estimated the prevalence of diabetes among adults to be around 23%.[2] Primary care clinics have an essential role in the prevention, diagnosis and management of diabetes. Strategies to improve diabetes control include interventions that facilitate structured review of patients, patient education, and enhancement of nurses' role in patients care.[3] Register-recall systems have been one method used in guiding physicians to annually review patients with chronic conditions.[4,5] Structured and regular review of diabetics have shown to be effective in improving the process of their care.[6,7] Reports have shown positive outcomes from utilizing register-recall systems such as improvement in glycemic control, quality of life, as well as in the number of recommended laboratory screening.[3,6-10]

The majority of primary care clinics in Saudi Arabia are walk-in clinics that are supported by secondary or tertiary care

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hospitals. Although computerized systems are widely utilized in sending reminders to patients for scheduled appointments, a register-recall system that periodically identifies patients not meeting their treatment targets (e.g., uncontrolled diabetes) and actively recalls them for review is lacking. At King Abdul-Aziz housing city, eleven primary care clinics serve a catchment area of about 53,000 registered patients with over 2000 patients having type 2 diabetes. The clinics are walk-in clinics with no register-recall system in place. A large number of patients with uncontrolled diabetes attend those clinics.[11-13]

The objective of this study was to examine whether implementing a register-recall system in a primary care setting, to identify patients with uncontrolled diabetes annually and actively recall them for review, is superior in improving glycemic control as compared to routine care.

MATERIALS AND METHODS

Subjects and Setting

In this open-labeled trial, two out of elevan primary care clinics at King Abdul-Aziz housing city with closely matched demographics were selected. The two clinics were then cluster-randomized to receive intervention (register-recall) versus routine care (no recall). Uncontrolled diabetes was defined as having A1c level of 7.5% or above, and patients were identified in both clinics using a computerized database for diabetics at King Abdul-Aziz housing city, Riyadh. Register-recall intervention was done through a clinic coordinator via phone calling, and patients were offered a twenty-minute appointment with their primary care physician within one week of the phone call. During the recall session, patients' medications and compliance were reviewed and then managed accordingly. No new medical intervention was utilized among the two groups (i.e., both groups received routine medical treatment as available at King Abdul-Aziz housing city and as guided by American Diabetes Association guidelines.[14] Patients from both clinics were then followed up for 6 months (August 2015-January 2016). Baseline characteristics of the two groups were noted from computerized records and included: Age, gender, type and duration of diabetes, body mass index, glycated hemoglobin, blood pressure, and low-density lipoprotein levels. Outcome measures (A1c as well as BP and LDL) were compared at 3 months and the end of the trial.

Sample Size and Data Analysis

A total of 128 patients were studied. Power was set at 80%, Type I error set at 5%, and standardized effect size of 0.5 yielding an estimated sample size of 64 patients per group.[8,15] Data collection was performed independently, an intention to treat analysis was applied, and SPSS was used for data analysis. Mean A1c values and categorical A1c were used in comparing the two groups. *T*-test and Chi-square were used to compare mean A1c values and categories, respectively. A P-value < 0.05 was considered to be significant in this study.

Exclusion Criteria

Active patients with an A1c level of 7.5% or above were included in our study, while inactive patients (not seen within the past 2 years) and patients with A1c < 7.5% were excluded.

Ethical Considerations

Patients were treated equally in both groups. No new medications were specifically trialed. The only intervention was "register-recall" of patients with uncontrolled diabetes to attend the clinic for review. Patients' autonomy was respected should they declined attending for review (verbal consent over the phone). Data were collected in a confidential manner and approval was granted by King Abdullah International Medical Research Center (KAIMRC).

RESULTS

Glycemic Control

At 3 months, the mean difference (MD) of A1c between the two groups was −0.39 (95% CI = −1.01-0.23, P = 0.22). While at 6 months, the MD of A1c between the two groups was −0.44 (95% CI = −1.06-0.18, P =0.16) (Tables 1 and 2). Different A1c thresholds for uncontrolled diabetes were used in comparing the two groups. At 6 months, the odds ratio (OR) of having uncontrolled diabetes (A1c ≥ 7.5%) in the intervention group was less than the control group (OR = 0.24, 95% CI = 0.03-2.19, P =0.37). The odds of having uncontrolled diabetes in the intervention group continues to be less than that in the control group when increasing the defining A1c threshold of uncontrolled diabetes. However, the odds increase with increasing A1c threshold: (OR = 0.4, 95% CI = 0.16-0.99, P = 0.07) when defining uncontrolled diabetes as A1c ≥ 8.5%, and (OR = 0.59, 95% CI = 0.2-1.2, P = 0.2)

Table 1: Outcome measures at 3 months (n=128)

Outcome variable	Intervention (n=64)	Control (n=64)	MD*	95% CI
Mean A1c (%)	9.88 (1.75)	10.27 (1.82)	−0.39	−1.01-0.23
Mean SBP (mmhg)	124 (15)	133.9 (19.9)	−9.9	−16.1-−3.74
Mean DBP (mmhg)	72.5 (8.9)	70.6 (10.8)	1.9	−1.56-5.36
Mean LDL (mmol/l)	2.74 (1)	2.69 (0.95)	0.05	−0.29-0.39

*MD: Means difference, CI: Confidence interval, A1c: Glycated hemoglobin, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, LDL: Low-density lipoprotein

at A1c ≥ 9.5%. At a presumptive threshold of A1c ≥ 10.5% for uncontrolled diabetes, the odds of having uncontrolled diabetes become equal between the two groups (OR = 1, 95% CI= 0.49-2.02, *P* = 1). However, none of the above results reaches statistical significance (Table 3).

Systolic BP (SBP)

At 3 and 6 months, the MD of SBP between the two groups was statistically significant (MD = –9.9, 95% CI = –16.6-–3.74, *P* = 0.002) and (MD = −7, 95% CI = –12.7-1.3, *P* = 0.015), respectively (Tables 1 and 2).

Diastolic BP (DBP)

At 3 months, the MD of DBP between the two groups was 1.9 (95% CI = –1.56-5.36, *P* = 0.28), while increasing to 3.1 (95% CI = 0.02-6.18, *P* =0.048) at 6 months.

LDL

No statistically significant difference was observed in Low density liporotein (LDL) levels between the two groups at 3 and 6 months (MD = 0.05, 95% CI = –0.29-0.39, *P* = 0.77) and (MD = 0.1, 95% CI = –0.23-0.43, *P* = 0.55), respectively (Tables 1 and 2).

Table 2: Outcome measures at 6 months (*n*=128)

Outcome variable	Intervention (*n*=64)	Control (*n*=64)	MD*	95% CI
Mean A1c (%)	9.86 (1.83)	10.30 (1.76)	−0.44	−1.06-0.18
Mean SBP (mmHg)	124.4 (13.5)	131.4 (18.5)	−7	−12.7-−1.3
Mean DBP (mmhg)	71.8 (9.1)	68.7 (8.5)	3.1	0.02-6.18
Mean LDL (mmol/l)	2.75 (0.98)	2.65 (0.92)	0.1	−0.23-0.43

*MD: Means difference, A1c: Glycated hemoglobin, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, LDL: Low-density lipoprotein

DISCUSSION

Patients included in both arms of this study had a relatively advanced disease. Mean A1c and duration of diabetes in the intervention and control groups at baseline were 10.14% and 7.6 years versus 10.4% and 7.9 years, respectively. While mean body mass index was 32.4 for the intervention group and 32.6 for the control group. The two groups had close demographics and characteristics at baseline (mean age, gender, type of diabetes, treatment modality, BP, and lipid control) (Table 4). The response rate in the intervention group was 64.1%, and patients were analyzed in their respective group in an intention to treat analysis to account for "no show." Modest glycemic improvements were observed at 3 and 6 months (MD −0.39 and −0.44, respectively) in the intervention group. The results although encouraging did not reach statistical significance (Tables 1 and 2). Categorical A1c groups were also compared between the two groups, and different thresholds for defining uncontrolled disease were used to detect potential differences between the two groups. When setting "acceptable control" of diabetes to a level up to 7.5%, the odds of having uncontrolled disease (≥7.5%) in the intervention group was lowest (OR = 0.24, 95% CI = 0.03-2.19, *P* = 0.37). The odds of having uncontrolled disease increase with increasing A1c threshold, despite continuing to be less in the intervention group, until a threshold of 10.5% where the two groups start to have the same odds of having an uncontrolled disease (OR = 1, 95% CI = 0.49-2.02, *P* = 1) (Table 3). Although the results are of no statistical significance, the trend is interesting and can perhaps be explained by the challenge faced in managing uncontrolled diabetes at an A1c level ≥ 10.5%, at which level re-calling patients, *per se*, may not have a direct effect on glycemic improvements. Among those interviewed (*n* = 41) in the intervention arm, reasons contributing to uncontrolled diabetes state included: Non-compliance to treatment (24.4%), suboptimal treatment (65.9%), and non-compliance to lifestyle advice (82.9%). Non-compliance to treatment involved: Not taking the medications at all, not taking the medications as prescribed, or not taking the medications regularly. While suboptimal treatment involved:

Table 3: Odds ratio of having uncontrolled diabetes for different glycemic control thresholds at 6 months (*n*=128)

A1c threshold (%)	Intervention (*n*=64) (%)	Control (*n*=64) (%)	OR	95% CI
A1c <7.5	4 (6.3)	1 (1.6)	0.24	0.03-2.19
A1c ≥7.5	60 (93.7)	63 (98.4)		
A1c <8.5	17 (26.6)	8 (12.5)	0.4	0.16-0.99
A1c ≥8.5	47 (73.4)	56 (87.5)		
A1c <9.5	29 (45.3)	21 (32.8)	0.59	0.29-1.2
A1c ≥9.5	35 (54.7)	43 (67.2)		
A1c <10.5	38 (59.4)	38 (59.4)	1	0.49-2.02
A1c ≥10.5	26 (40.6)	26 (40.6)		

OR: Odds ratio, A1c: Glycated hemoglobin, CI: Confidence interval

Table 4: Baseline characteristics of the intervention and control groups

Variable	Intervention (*n*=64)	Control (*n*=64)
Age in years (mean+SD)*	52 (12.7)	51.6 (9.6)
Gender		
Male	30 (47%)	32 (50%)
Female	34 (53%)	32 (50%)
Type of diabetes		
Type II	64 (100%)	64 (100%)
Treatment type		
Oral (metformin, gliclazide, sitagliptin)	30 (46.9%)	26 (40.6%)
Oral (metformin, gliclazide, sitagliptin)+Insulin (glargine, lispro, pre-mixed)	34 (53.1%)	38 (59.4%)
Duration of diabetes in years	7.6 (2.6)	7.9 (2.5)
Mean A1c (%)	10.14 (1.6)	10.4 (1.6)
Mean SBP (mmhg)	125.5 (13.8)	128.7 (15.9)
Mean DBP (mmhg)	72.2 (9.3)	69.4 (8.6)
Mean LDL (mmol/l)	2.7 (1)	2.75 (1.3)
Mean BMI	32.4 (5.6)	32.6 (8)

*Mean+SD used for age, duration of diabetes, A1c, SBP, DBP, LDL, and BMI. *SD: Standard deviation, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, LDL: Low-density lipoprotein, BMI: Body mass index. Percentages used for: Gender, type of diabetes, and treatment type

Oral treatment needing escalation, insulin needing to be started, and insulin dose needing escalation.

In a Canadian study by Lin et al., where they followed 68 diabetics for 3 years, improvements in A1c were observed in the intervention group who received reminder phone calling and thirty-minute appointments as well as using structured flow sheets. A1c reduction of 0.6% was statistically significant (95% CI = −0.086 to −1.1, P <0.05) in the intervention group.[9] There results, despite encouraging, did not quite reach their set guideline targets of A1c < 7%. Moreover, Lin et al. did not mention the baseline glycemic control for their patients in their report.[9] A larger study by Eccles et al. (dream trial), where 3608 patients in 58 practices randomized to receive register-recall versus control were followed up for 15 months, found almost no difference in glycemic control between the two compared groups at the end of their trial (MD = −0.04, 95% CI = −0.18-0.10).[6] Importantly, diabetic patients in the dream trial had a significantly better control of diabetes compared to our group of patients at baseline (A1c: 7.5% vs. 10.14%). Changes in BP reading between the two groups in our study were a secondary outcome. Interestingly, statistically significant improvements in SBP in the intervention group were observed at 3 and 6 months (MD = −9.9, P = 0.002) and (MD = −7, P = 0.015), respectively. Despite being a positive outcome that supports a regular review of patients to achieve better BP control, it is important to mention that both groups had a relatively controlled BP at the beginning of the trial (Table 4). Other studies have reported improvement in SBP (4.7 mmHg) among patients with diabetes after a comparable intervention.[9] However, their results were not of statistical significance (95% CI = 2.7-–12, P = 0.21). Non-significant SBP observation was also reported in the dream trial (MD = −1.56, 95% CI = −4.54-1.42).[6] Changes in DBP, barely reaching statistical significance, were noted in the intervention group at 6 months (MD = 3.1, P = 0.048). However, the small change is unlikely to be of clinical significance. Marginal and non-statistically significant changes were observed at 3 and 6 months for LDL between the two groups in our study (MD = 0.05 and 0.1, respectively). Our results vary from Lin et al. study where a statistically and clinically relevant improvement in LDL was observed (−0.59 mmol/l, 95% CI = −0.2-0.97, P < 0.01). Their follow-up was longer than ours, and perhaps this could explain the above difference in results.[9] Eccles et al., have also demonstrated a significant reduction in cholesterol levels among patients with diabetes receiving register-recall intervention (MD = 0.15, 95% CI = –0.25-–0.06).[6]

Limitations of our study include being of a relatively small sample size and short duration of follow-up. On the other hand, strengths of our current study include being prospective and randomized; thus reducing the risk of bias.

CONCLUSION

Modest, statistically insignificant, glycemic improvements were observed in this trial of patients with poorly controlled diabetes, while significant SBP improvement was achieved. The role of register-recall is unclear when dealing with very poorly controlled disease (A1c ≥ 10.5%).

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REFERENCES

1. International Diabetes Federation. IDF Diabetes Atlas. 6th ed. Available from: http://www.idf.org/diabetesatlas. [Last accessed on 2015 Oct 12].
2. Al-Nozha MM, Al-Maatouq MA, Al-Mazrou YY, Al-Harthi SS, Arafah MR, Khalil MZ, et al. Diabetes mellitus in Saudi Arabia. Saudi Med J. 2004;25(11):1603-10.
3. Renders CM, Valk GD, Griffin SJ, Wagner EH, Eijk Van JT, Assendelft WJ. Interventions to improve the management of diabetes in primary care, outpatient, and community settings: A systematic review. Diabetes Care. 2001;24(10):1821-33.
4. Georgiou A, Burns J, Penn D, Infante F, Harris M. Register-recall systems: Tools for chronic disease management in general practice. Health Inf Manage. 2004;33:31-5.
5. Penn D, Burns J, Georgiou A, Davies P, Harris M. Evolution of a register recall system to enable the delivery of better quality of care in general practice. Health Inf J. 2004;10:165-76.
6. Eccles MP, Whitty PM, Speed C, Steen IN, Vanoli A, Hawthorne GC, et al. A pragmatic cluster randomised controlled trial of a diabetes recall and management system: The DREAM trial. Implement Sci. 2007;2:6.
7. Del Prato S, Felton A, Munro N, Nesto R, Zimmet P, Zinman B. Improving glucose management: Ten steps to get more patients with Type 2 diabetes to glycemic goal. Recommendations from the global partnership for effective diabetes management. Int J Clin Pract. 2005;59:47-57.
8. Glasgow RE, Nutting PA, King DK, Nelson CC, Cutter G, Gaglio B, et al. Randomized effectiveness trial of a computer-assisted intervention to improve diabetes care. Diabetes Care. 2005;28(1):33-9.
9. Lin D, Hale S, Kirby E. Improving diabetes management: Structured clinic program for Canadian primary care. Can Fam Physician. 2007;53(1):73-7.
10. McDermott RA, Schmidt BA, Sinha A, Mills P. Improving diabetes care in the primary healthcare setting: A randomised cluster trial in remote Indigenous communities. Med J Aust. 2001;174:497-502.
11. Alsulaiman TA, Al-Ajmi HA, Al-Qahtani SM, Fadlallah IM, Nawar NE, Shukerallah RE, et al. Control of Type 2 diabetes in King Abdulaziz Housing city (Iskan) population, Saudi Arabia. J Fam Community Med. 2016;23:1-5.
12. Alsulaiman TA, Mahmoud AM, Fadlallah IM. Assessment of diabetics' follow-up in a primary care setting, Riyadh, Saudi Arabia. J Health Spec. 2015;3:224-7.
13. Alsulaiman T. Assessment of diabetes control in a primary care setting, Riyadh. Fam Pract Rep. 2015;2:1-3.
14. American Diabetes Association. Standards of medical care in diabetes-2014. Diabetes Care. 2014;37:14-62.
15. Chan YH. Randomised controlled trials (RCTs) - Sample size: The magic number? Singapore Med J. 2003;44(4):172-4.

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