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ORIGINAL ARTICLE

# Structured diabetes care (Freedom 365*) provides better glycemic control than routine medical care in type 2 diabetes: proof of concept observational study

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**Abstract**
*Objective* To evaluate the efficacy of a structured diabetes care program (Freedom 365*) as compared to routine medical care (RMC), for management of type 2 diabetes.
*Method* A retrospective study of Freedom 365* program versus RMC for diabetes management was carried out. 388 participants (247 men, 141 women; mean age 57 years), who completed 1 year since first contact were analysed. All the participants received a detailed diabetes patient education program, at first contact with the centre and had the choice of opting for either Freedom 365* or RMC.
*Results* Out of 388 participants at baseline, 244 (154 men, 90 women) patients opted for Freedom 365* and 144 (93 men, 51 women) opted for RMC. The Freedom 365* group showed 90 % improvement, 2 % had no change and 8 % had deterioration in HbA1c levels. In the RMC group 82 % had improvement, 3 % had no change and 15 % showed deterioration in HbA1c levels. The Freedom 365* group had significantly greater drop in HbA1c [median 1.4 (−2.5, 7.7) vs.0.9 (−2.1, 8.9): $p<0.004$], from baseline to follow up. The Freedom group had significantly better compliance in terms of frequency of screening/monitoring per annum for glycemic control [HbA1c –median 3(2, 4) vs. 2(0, 2): $p<0.001$], lipid profile (100 vs. 95 %: $p<0.001$), microalbuminuria (100 vs. 38 %: $p<0.0001$), anaemia screening (100 vs. 29 %: $p<0.0001$) and liver function test (100 vs. 29 %: $p<0.0001$).
*Conclusion* Freedom 365*, a structured diabetes care program of on-going diabetes education, diet and lifestyle correction, biochemical investigations, clinical monitoring and treatment at regular intervals, results in better clinical outcomes and adherence to therapy in management of type 2 diabetes as compared to RMC.

**Keywords** Type 2 diabetes · Structured diabetes care · Routine medical care · Compliance · Clinical outcomes

## Introduction

India is in a grip of dual epidemics of obesity and diabetes with unprecedented rise in the number of people with these two conditions in the last few decades. A recent epidemiological study [1], in India has reported that the approximate number of people with diabetes mellitus (DM) has risen above 62 million along with 77 million people with pre-diabetes. According to the International Diabetes Federation [2], as the numbers grow and India continues to be the diabetes capital of the world, there are serious concerns about meeting the healthcare cost of management of diabetes and its complications.

In absence of state health care support and limited resources, the economic cost of diabetes treatment is bound to be out of reach for millions of un-affording people who are forming the bulk of new cases of diabetes in India. According to a recently published Indian study [3] on health care costs of diabetes care, people with diabetic foot and any other associated complication spent about four times more as compared to other patients as in-patient cost and those with other complications such as diabetic nephropathy and/or retinopathy, and cardiovascular disease spent about three times more for hospital admission due to their prolonged stay. The cost of in-patient care tends to go up with the number of associated complications.

Landmark studies such as the DCCT (Diabetes Control and Complications Trial) [4] in type 1 diabetes subjects and UKPDS (United Kingdom Prospective Diabetes Study [5] in type 2 diabetes subjects have emphasized the importance of good glycemic control in reducing the risk of development

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and progression of diabetic microvascular complications. In addition to reducing the occurrence of microvascular complications, the DCCT established that the benefits of good glycemic control were not restricted to short term benefits and these subjects demonstrated sustained reduced risk of developing microalbuminuria and hypertension of up to 40 %, even after 7–8 years of the cessation of the trial, confirming the benefits of good glycemic control and leading to coining of the term 'good glycemic memory effect'.

A similar effect was seen in the UKPDS, which demonstrated a continuum of overall risk reduction of about 25 % for development of all microvascular complications (retinopathy, nephropathy and neuropathy), in general with intensive glycemic control. The UKPDS data also demonstrated a continuous relationship between the risks of microvascular complications and glycemic control, in a way that for every percentage point decrease in HbA1c (e.g., from 9 to 8 %), there was a 35 % reduction in the risk of development of microvascular complications. However, these studies did not demonstrate any beneficial effects on macrovascular complications.

Recently, the ADVANCE [6] study reported a significant relative risk reduction of 10 % in the combined outcome of major macrovascular and microvascular events in type 2 diabetes subjects. In addition, there was a relative risk reduction of 21 % for development of new or worsening nephropathy by intensive control (HbA1c≤6.5 %) as compared to the standard control (HbA1c≤7.3 %). The findings from the above studies [4–6] establish the importance of intensive glycemic control with a target HbA1c of≤7 in reducing the risk for development and progression of micro and macrovascular complications.

In spite of widely agreed importance of glycemic control in the prevention of diabetic complications, observational studies assessing the status of glycemic control worldwide, have reported presence of a significantly high proportion of people with uncontrolled diabetes [7], suggesting that diabetes management is far from optimal. In a recent Indian study, more than two third of people with diabetes were found to have uncontrolled diabetes with HbA1c of >7 % [8].

There are many barriers for optimal diabetes care, with poor adherence to recommended diet, lifestyle modification and medication being the foremost causes [9]. In addition, poor motivation amongst patients due to lack of sustained diabetes related education is another important factor for irregular therapy [10]. As a result, managing diabetes becomes an uphill task for most of the patients and a majority continue to be at risk of progression of their disease and developing irreversible diabetic complications.

In order to bridge the gap between patient behaviour and clinical outcomes, and recommended glycemic and other clinical parameters, several practice based studies [9–13] have been carried out examining the effect of combining structured diabetes education with standard care as compared to standard care alone. Although these studies demonstrated a general increase in the awareness about diabetes and its complications, the clinical outcomes have been variable with some studies showing no clinical benefit [10] to some reporting modest drop in HbA1c [9] and some demonstrating long-term good clinical benefits [11, 13].

However, these studies [9–11, 13] were based largely on imparting diabetes education over and above standard care. Notwithstanding the absence of randomised controlled trial evidence, the idea of offering Freedom 365* to diabetes patients was to combine patient education and individualised lifestyle advice with biochemical and clinical investigation and treatment at fixed regular intervals and compare its efficacy as compared to standard care, in achieving best clinical outcomes and compliance to therapy.

## Material and methods

### Participants

A retrospective cohort analysis was performed in patients who availed medical services at 'JUST Diabetes' (JD) medical centre in Mumbai. These patients were divided into two cohorts depending on their choice of diabetes care pathway such as routine medical care (RMC) or a structured diabetes care program (Freedom 365*). All diabetes patients referred for clinical services at JD, were educated about diabetes, which consisted of providing information on signs and symptoms, diagnosis, disease progression, clinical monitoring, essential investigations, modes of medical treatment, and prevention of diabetic complications.

These subjects were also given information on the importance of lifestyle modification (quitting smoking, reducing stress), customised diet, daily exercise, disease monitoring through biochemical tests and clinical assessments (weight, blood pressure, foot assessment, peripheral neuropathy, retinopathy and systemic examination), at regular intervals and adherence to prescribed diabetes treatment, to achieve best clinical outcomes and prevent/delay diabetic complications. On completion of the session, the patients were briefed about Freedom 365* program and RMC and were given an option to choose either of the two, for their diabetes care. All the participants were given a booklet on diabetes for further reading to enhance their understanding about diabetes.

Freedom 365* (Fig. 1) is an annual structured diabetes care program based on the clinical practice recommendations of American diabetes association (ADA) and national institute of clinical excellence (NICE),UK and adapted to patient suitability in India. RMC was chosen by patients, who did not sign up for Freedom 365 for various reasons such as economic constraints, did not feel the need for such a program, inability to travel frequently and lack of motivation. RMC patients were

**Fig. 1** The freedom 365* program

| **Visit 1** | **Visit 2** | **Visit 3** | **Visit 4** | **Visit 5** |
|---|---|---|---|---|
| **Day 1** | **After 3 weeks** | **After 4 months** | **After 8 months** | **After 11 months** |
| FBG,PPBG,HbA1c | SMBG Review | FBG,PPBG,HbA1c | FBG,PPBG,HbA1c | FBG,PPBG,HbA1c |
| Urea | | | Urea | |
| Serum Creatinine EGFR | | Dental screening & Cleaning | Serum Creatinine EGFR | |
| Uric Acid | | | Uric Acid | |
| Lipid Profile | | | Lipid Profile | |
| Liver Function Test | | | Liver Function Test | |
| Thyroid Function Test | | | CBC + ESR | |
| CBC + ESR | | | Urine ACR | |
| Urine ACR | | | Urine Routine | |
| Urine Routine | | | | |
| ECG | | | | |
| Sonography (Abdomen and Pelvis) | | | | |
| Chest X ray | | | | |
| Retinal Screening | | | Retinal Screening | |
| Comprehensive foot assessment | | | Comprehensive foot assessment | |
| Consultations : | | | | |
| Diabetologist | Diabetologist | Diabetologist | Diabetologist | Diabetologist |
| Ophthalmologist | Psychiatrist | Physiotherapist | Ophthalmologist | Diabetic Educator |
| Dietician | Diabetic Educator | Dentist | Dietician | |
| Physiotherapist | Dietician | | | |

also advised to do the same biochemical tests and clinical consultations at intervals recommended in Freedom 365* program, however, the choice to do the tests and consultations, and its frequency rested with the patients.

All the study subjects had type 2 DM and were more than 18 years of age at time of diagnosis. Since the RMC group had irregular follow-up, the inclusion criteria included having at least two readings of HbA1c, one at baseline and others within a year of first contact with the centre. The exclusion criteria were, age less than eighteen, pregnant women, congestive cardiac failure, subjects on dialysis, severe hepatic disease and malignancy. All these patients were identified from the JD patient database.

Freedom 365* patients had their follow up visits as per the program schedule, whereas RMC patients attended the clinic at their discretion. The clinical progress of both the patient groups was monitored by a specialist nurse by telephone or in person during their visit to the centre. The patients were advised on lifestyle modification and titration of diabetes medication according to self-monitoring of blood glucose (SMBG) levels. In addition, patients were advised on the treatment of any other clinical issues and/or abnormal biochemical parameter, as and when they presented to the centre. The frequency of clinical appointments and repeat blood tests was determined by individual needs and advised accordingly to both groups. HbA1c was measured every 3–4 months.

## Data collection

In each cohort, data was collected using standardized clinical proforma and entered into the research database. The following variables were included – family history of diabetes, duration of diabetes, history and duration of hypertension, smoking, presence/absence of erectile dysfunction in men and duration of sleep. Clinical measurements such as weight, blood pressure, foot health measures (ankle brachial index, vibration perception threshold), and presence/absence of retinopathy and all the concomitant medications were recorded.

Data was collected on the biochemical profile such as fasting blood glucose (FBG), post prandial blood glucose (PPBG), haemoglobinA1c (HbA1c), serum creatinine, estimated modification of diet in renal disease (MDRD) glomerular filtration rate (GFR), serum bilirubin, serum glutamic oxaloacetic transaminase (SGOT), Serum glutamic pyruvic transaminase (SGPT), gamma-glutamyl transferase (GGT), serum Alkaline phosphatase, serum total protein, serum albumin, serum globulin, serum albumin: globulin ratio, serum total cholesterol, serum triglyceride, low density lipoprotein (LDL) cholesterol, high density lipoprotein (HDL) cholesterol, total cholesterol: HDL cholesterol ratio, total cholesterol: LDL cholesterol ratio, haemoglobin, urine microalbumin, urine albumin: creatinine ratio, at baseline and follow-up.

## Statistical analysis

The primary outcome in the study was to examine the difference in the proportion of reduction of HbA1c in both the groups at follow up as compared to baseline. The secondary outcome was to examine the difference in proportion of people who achieved good glycemic control target (HbA1c $\leq$7 %). The statistical analysis was performed by SPSS (Statistical Package for Social Sciences) Version 17. The results of the analysis have been presented as mean (95 % CI) for

parametric data, and as median values, for non-parametric data.

Paired *t* test was employed for comparison of parametric data and Wilcoxon rank sum two related sample test for non-parametric data at baseline and follow-up, in the same subject. Comparisons between groups were carried out using the student's *t* test for parametric data and Kruskal-Wallis and Mann–Whitney U-tests for non-parametric data. Differences between the groups with respect to the distribution of categorical variables were examined using the Chi-square and Fisher's exact tests. A $p$-value$\leq$0.05 was considered to be statistically significant. Univariate analysis was done to examine correlations amongst various variables and linear regression models were undertaken to establish predictors for an outcome.

## Results

### Baseline patient characteristics (Table 1)

There were no differences in the age (57±10 vs.58± 12 years: $p$= =NS), weight (74±14 vs.75 kg±15: $p$=NS) and body mass index (28.3±5.4 vs. 27.6±5.3: $p$=NS) of Freedom 365* and RMC subjects. Both the groups did not differ in the gender ratio (154 M: 90 F vs. 93 M: 51 F; $p$=NS) and the proportion of smokers (16 vs. 9 %; p=NS). Freedom 365* group had higher (115 vs. 92: $p$<0.0001) proportion of people with family history of DM, and duration of diabetes [9 (1, 40) vs. 6 (1, 38) years: $p$<0.003] as compared to RMC group.

**Table 1** Patient characteristic and demographics at baseline

| Variables | Groups | | $p$ value |
|---|---|---|---|
| | Freedom 365* | RMC | |
| Number | 244 | 144 | NS |
| Age (years) | 57±10 | 58±12 | NS |
| Gender (M: F) | 154:90 | 93:51 | NS |
| Smokers (%) | 16 | 9 | NS |
| DM duration (yrs) | 9 (1, 40) | 6 (1, 38) | <0.003 |
| SBP (mmHg) | 136±18 | 142±17 | <0.004 |
| DBP (mmHg) | 84±8 | 82±8 | 0.030 |
| Weight (Kg) | 74±14 | 75 kg±15 | NS |
| BMI | 28.3±5.4 | 27.6±5.3 | NS |

Demographic, clinical characteristics and biochemical parameters in Freedom 365 and RMC (routine medical care) subjects. Normally distributed parameters represented as mean±standard deviation. Non-normally distributed parameters represented as median (range), *NS* non-significant. *M: F* Male: Female, *DM* Diabetes mellitus, *SBP* Systolic blood pressure, *DBP* Diastolic blood pressure, *BMI* Body Mass Index

At baseline, the RMC group had significantly higher systolic (142±17 vs.136±18 mm of Hg: $p$=0.004) and diastolic (84±8 vs. 82±8 mm of Hg: $p$=0.030) blood pressure as compared to Freedom 365* group. Post treatment, there was overall significant reduction in systolic (139±18 vs.135± 16 mm of Hg: $p$<0.0001) and diastolic (83±8 vs. 82±9 mm of Hg: $p$=0.013) pressure. However, in individual analysis, only the RMC group showed reduction in systolic (142±17 vs.137±18 mm of Hg: $p$<0.004) and diastolic (84±8 vs. 82± 8 mm of Hg: $p$=0.032) pressure, as compared to the Freedom group, which showed significant fall only in the systolic (136±18 vs.134±15 mm of Hg: $p$=0.017) blood pressure. A greater proportion of people achieved target blood pressure (≤140/80 mm of Hg) in the freedom 365 group (64 vs. 55 %: $p$=NS (0.06), as compared to RMC group. Table 1 summarizes the demographic details at baseline in both the groups.

### Biochemical parameters (Table 2)

#### *Glycemic control*

The Freedom 365* group had significantly poor glycemic control [FBG (178±61 vs. 160±52 mg/dl: $p$<0.002), PPBG (261±83 vs. 227±92 mg/dl: $p$<0.0001), HbA1c (9.2±1.8 vs. 8.5±1.7 %: $p$<0.001)] at baseline as compared to RMC group. At follow-up, 88 % of the total subjects showed improvement in glycemic control with lowering of FBG (171± 59 vs. 139±50 mg/dl: $p$<0.0001), PPBG (250±88 vs. 200± 76 mg/dl: $p$<0.0001) and HbA1c (9.0±1.8 vs. 7.4±1.3 %: $p$<0.0001). Two per cent subjects had no change and 10 % of subjects had deterioration in follow up HbA1c, as compared to baseline.

In individual group analysis, the Freedom 365* group showed 90 % improvement in glycemic control with lowering of FBG (178±62 vs. 144±51 mg/dl: $p$<0.0001), PPBG (262 ±83 vs. 208±77 mg/dl: $p$<0.0001) and HbA1c (9.2±1.8 vs. 7.4±1.2 %: $p$<0.0001). Two per cent subjects had no change and 8 % had deterioration in HbA1c levels. In the RMC group 82 % had improvement in glycemic control with lowering of FBG (158±53 vs. 131±46 mg/dl: $p$<0.0001), PPBG (227±94 vs. 185±70 mg/dl: $p$<0.0001) and HbA1c (8.6±1.7 vs. 7.4± 1.4 %: $p$<0.0001). Three per cent subjects had no change and 15 % showed deterioration in HbA1c levels.

In terms of relative glycemic improvement, the Freedom 365* group had significantly greater drop in HbA1c [median 1.4 (−2.5, 7.7) vs.0.9 (−2.1, 8.9) %: $p$<0.004], from baseline to follow up, as compared to RMC group. In Univariate analyses, the difference in HbA1c drop at follow up, had a positive correlation with Freedom 365* group ($r$=0.158: $p$= 0.004), baseline glycemic status {(FBG ($r$=0.534: $p$<0.001), PPBG ($r$=0.489: $p$<0.001), HbA1c ($r$=0.716: $p$<0.001)},

**Table 2** Comparison of biochemical values at baseline and follow up

| Variables | Freedom* | | *p* value | RMC | | *p* value |
|---|---|---|---|---|---|---|
| | Baseline | Follow-up | | Baseline | Follow-up | |
| Glycemic control | | | | | | |
| FBG (mg/dl) | 178±61 | 144±51 | <0.0001 | 160±52 | 131±46 | <0.0001 |
| PPBG (mg/dl) | 261±83 | 210±77 | <0.0001 | 227±92 | 187±71 | <0.0001 |
| HbA1c (%) | 9.2±1.8 | 7.4±1.2 | <0.0001 | 8.5±1.7 | 7.4±1.2 | <0.0001 |
| Renal profile | | | | | | |
| Creatinine (mg/dl) | 1.0±0.3 | 1.0±0.5 | NS | 0.9±0.4 | 1.0±0.3 | NS |
| MDRD eGFR (ml/min) | 76±20 | 76±19 | NS | 80±20 | 76±22 | NS |
| Microalbuminuria(mg/L) | 36 (0,400) | 22(1, 400) | 0.015 | 29 (0,1229) | 22(0, 83) | 0.065 |
| Lipid profile (mg/dl) | | | | | | |
| Total cholesterol | 175±46 | 162±36 | <0.0001 | 173±42 | 169±40 | NS |
| Serum triglyceride | 158 (48,729) | 130(27, 471) | <0.0001 | 138 (30,968) | 135(53, 347) | NS |
| LDL cholesterol | 100±40 | 90±31 | <0.001 | 97±38 | 95±34 | NS |
| HDL cholesterol | 46±11 | 46±11 | <0.001 | 49±15 | 46±13 | 0.055 |
| T_ Chol: HDL ratio | 3.9±1 | 3.6±0.8 | <0.0001 | 3.8±1.1 | 3.9±2 | NS |
| LDL Chol: HDL ratio | 2.2±0.9 | 2±0.7 | 0.001 | 2.2±0.9 | 2.2±0.8 | NS |
| Anaemia | | | | | | |
| Haemoglobin (g/dl) | 12.4±1.5 | 12.3±1.4 | NS | 12.2±2.2 | 11.6±1.8 | NS |

Biochemical parameters in Freedom 365 and RMC (routine medical care) subjects at baseline and follow-up. Normally distributed parameters represented as mean ± standard deviation. Non-normally distributed parameters represented as median (range), *NS* non-significant. *FBG* Fasting Blood Glucose, *PPBG* Post prandial Blood Glucose, *HbA1c* Glycosylated A1c, *MDRD eGFR* Modification of diet in renal disease estimated glomerular filtration rate, *LDL Cholesterol* Low density lipoprotein cholesterol, *HDL Cholesterol* High density lipoprotein cholesterol

baseline triglyceride levels ($r$=0.164: $p$=0.003) and negative correlation with age ($r$=−0.123: $p$<0.025).

To determine the predictors of difference in HbA1c levels at follow up, those variables (mentioned above) which correlated with the difference in HbA1c levels in univariate analyses, were included in a logistic regression model, which explained over 58 % of the variance in HbA1c levels (Nagelkerke $R^2$=0.584), demonstrated baseline glycemic parameters {post meal blood glucose ($p$<0.045) and HbA1c ($p$<0.0001)} as independent predictors for drop in HbA1c levels at follow up (Table. 3).

On presentation at baseline, there were 9 % (23 patients) with good glycemic control (HbA1c≤7 %), 23 % (56 patients) with fair control (HbA1c between 7.1 and 8 %) and 68 % (166 patients) with poor control (HbA1c>8 %). At follow-up there

**Table. 3** Logistic regression model for predictors of differential change in HbA1c at follow up

Dependent variable: difference in HbA1c at follow up from baseline (Nagelkerke $R^2$=0.584)

| Model independent variables at baseline | Unstandardized coefficients | | Standardized coefficients | *t* | Sig. *p* value | 95.0 % confidence interval for B | |
|---|---|---|---|---|---|---|---|
| | B | Std. error | Beta | | | Lower bound | Upper bound |
| (Constant) | −4.933 | 0.765 | | −6.448 | 0.000 | −6.440 | −3.426 |
| Group (Freedom/RMC) | 0.211 | 0.347 | 0.026 | 0.609 | 0.543 | −0.472 | 0.894 |
| Age | 0.004 | 0.007 | 0.023 | 0.538 | 0.591 | −0.010 | 0.018 |
| FBG | −0.002 | 0.002 | −0.086 | −1.121 | 0.263 | −0.006 | 0.002 |
| PPBG | 0.003 | 0.001 | 0.139 | 2.019 | 0.045 | 0.000 | 0.005 |
| HBA1c | 0.653 | 0.057 | 0.739 | 11.493 | 0.000 | 0.541 | 0.765 |
| Uric Acid | −0.002 | 0.044 | −0.002 | −0.040 | 0.968 | −0.088 | 0.085 |
| Serum Triglyceride | 0.000 | 0.001 | 0.008 | 0.191 | 0.848 | −0.001 | 0.002 |

Independent variables in the logistic regression model. *FBG* Fasting Blood Glucose, *PPBG* Post prandial Blood Glucose, *HbA1c* Glycosylated A1c

was significant improvement in the glycemic control with 43 % (104 patients) with good glycemic control, 37 % (91patients) with fair control and lowering in the proportion of poor control subjects at 20 % (49 patients), in the Freedom 365* group.

In the RMC group at baseline, there were 20 % (18 patients) with good glycemic control, 17 % (16 patients) with fair control and 63 % (58 patients) with poor control. At follow-up, the RMC group also showed overall improvement in glycemic control with 47 % (43 patients) in good control, 33 % (30 patients) in fair control and 20 % (19 patients) in the poor control group. There was a trend for greater improvement in the proportion of people with good glycemic control (9 to 43 % versus 20 to 47 %), from baseline to follow-up, in the Freedom 365* group as compared to RMC.

*Renal profile*

Overall, there was no significant change in serum creatinine at follow-up from baseline. The Freedom 365* group showed a significant drop in urine microalbumin [37 (0, 400) vs. 22 (1, 400) mg/L: $p<0.0001$] and urine albumin: creatinine ratio [71 (0, 824) vs. 40 (0, 694) mg/gm: $p<0.0001$] as well at follow-up, as compared to baseline. Although, the RMC group demonstrated a drop in urine microalbumin [29 (0, 1229) vs. 22 (0, 83) mg/L: $p$=NS] and urine albumin: creatinine ratio [56 (1.2, 775) vs. 35 (3.9, 598) mg/gm: $p$=NS], it was not statistically significant.

*Lipid profile*

The Freedom 365* group demonstrated significant reduction in total cholesterol (175±46 vs. 161±36 mg/dl: $p<0.0001$), serum triglyceride [158 (48, 729) vs. 130 (27, 471) mg/dl: $p<0.0001$), serum LDL cholesterol (100±40 vs. 90±31 mg/dl: $p<0.001$), total cholesterol: HDL cholesterol ratio (3.9±1 vs. 3.6±0.8 mg/dl: $p<0.0001$), LDL cholesterol: HDL cholesterol ratio (2.2±0.9 vs. 2.0±0.7 mg/dl: $p<0.001$), with no significant change in HDL cholesterol levels (46±11 vs. 46±11 mg/dl: $p$=NS). A significantly greater proportion of people achieved target lipid levels in the freedom 365 group (72 vs. 61 %: $p=0.032$), as compared to RMC.

*Compliance*

A greater compliance with prescribed treatment was seen in the Freedom 365* group. The number of HbA1c [median 3 (2, 4) vs. 2 (0, 2): $p<0.001$] measurements in a year, in the freedom group was significantly higher in the Freedom 365* group. In addition, the proportion of patients who did at least one measurement of lipid profile (100 vs. 95 %: $p<0.001$), urine microalbumin (100 vs. 38 %: $p<0.0001$), liver function test (100 vs. 29 %: $p<0.0001$) and complete blood count (100 vs. 29 %: $p<0.0001$) was significantly higher in the Freedom 365* group as compared to patients in the RMC group.

## Discussion

The major findings in the study were i) structured diabetes care resulted in significantly better glycemic control in people with diabetes ii) a greater number of people achieved optimal blood pressure and target lipid profile in the Freedom 365* group as compared to RMC and iii) there was better patient compliance to adherence to frequency of clinical visits, recommended clinical tests and biochemical estimations, and treatment in the Freedom 365* group.

There are very few studies [9–11, 13] looking at effectiveness of structured diabetes care for management of diabetes. To our knowledge, this is the first Indian study reporting the effectiveness of a structured diabetes care program as compared to RMC. A recent study [14] has reported that the main barriers to treatment were a lack of understanding of both the aetiology and management of diabetes in subjects with diabetes, and also presence of clinical inertia in health professionals. Thus suggesting that to implement best clinical practice recommendations and to achieve maximum adherence to prescribed therapy, educating both - patients with diabetes and diabetes health care professionals is equally important.

In the current study, as compared to RMC, patients in Freedom 365* group had significantly poor glycemic control at baseline. Over a period of time, there was improvement in the glycemic control in both the groups, however, Freedom 365* group had a greater fall in HbA1c as compared to RMC. In univariate analyses, the improvement in HbA1c levels were positively associated with being in the Freedom 365* group.

Overall, baseline glycemic parameters such as post meal blood glucose and HbA1c, were significant predictors for drop in HbA1c levels at follow up. In addition, there were higher proportion of people with good glycemic control, lipid profile and optimal blood pressure, at follow up in the Freedom 365* group. The relatively better adherence to prescribed clinical and biochemical follow up with appropriate treatment may have led to better clinical outcomes in the structured diabetes care group, suggesting that structured diabetes care is more effective than RMC for better management of people with diabetes.

The economic cost of treatment of diabetes and its complications is prohibitive to most Indians with diabetes [3], especially if they undergo hospitalisation. Clinical inertia may prove to be disastrous for diabetes management in India with a burgeoning population of people with diabetes, limited resources, and sub-optimal state health care support. Several studies such as the DCCT [4], UKPDS [5], ADVANCE [6] have demonstrated the benefits of good glycemic control in

short term and in prevention and progression of diabetic complications. Even a modest drop of a percentage decrease in HbA1c has been shown to significantly reduce the risk of development of microvascular complications by almost 35 %.

In spite of generally understood importance of good glycemic control in the prevention of diabetic complications, due to various reasons, the proportion of people with uncontrolled diabetes remains high in India [8] and worldwide [7], suggesting that diabetes management is far from optimal. To overcome the barriers for optimal diabetes care, such as poor adherence to therapy (diet, lifestyle modification and medication) [9], poor motivation [10], irregular follow-ups and clinical inertia, 'structured diabetes care' has been recommended by various studies in this area [9–11, 13].

The significantly greater improvement in the clinical triad of glycemic status, lipid profile and blood pressure, in the Freedom 365* group as compared to RMC, suggests that structured diabetes care is the way forward for diabetes management in India to reduce the risk of developing diabetic complications and hospitalisation; which in turn may help to contain the burden of health care costs, in these people.

The 'proactive care approach' of Freedom 365 program with on-going diabetes education, customised diet and exercise therapy, regular clinical and biochemical estimations, and adjustment to therapy, may have led to a greater improvement in the glycemic control, and optimal blood pressure and biochemical parameters (lipid profile, haemoglobin and microalbuminuria). The current study establishes that as compared to standard care, structured diabetes care results in better clinical outcomes, as reported before [9–11, 13].

There are several limitations of this study. First and foremost, this is a cross-sectional and retrospective study, so the findings need to be interpreted with care. Secondly, the study duration was only 12 months, which is a short period to examine the clinical outcomes of good glycemic control in the long run. However, we believe that these drawbacks do not undermine our major findings, which emphasizes the overriding importance of structured diabetes care in achieving good adherence to therapy and better clinical outcomes as compared to routine medical care. Further studies with larger patient groups are required to confirm and extend our findings.

According to ADA [15], approximately 33.4 to 48.7 % of people with diabetes in US do not meet the optimum targets for either good glycemic control, lipid profile and blood pressure. In view of this, ADA observes that optimal diabetes management requires an organized, systematic approach by a coordinated team of dedicated health care professionals working in a patient-centred clinical care environment, as seen in Freedom 365*. In conclusion, Freedom 365* program can play a pivotal role in improving the quality of care of people with diabetes by overcoming clinical inertia, improving adherence to therapy, providing on-going diabetes education and proactive clinical care at regular intervals in a structured and organised way as suggested by ADA and help prevent the occurrence/progression of diabetic complications.

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