Brief Communication

# Completion report: Effect of Comprehensive Yogic Breathing program on type 2 diabetes: A randomized control trial

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## ABSTRACT

**Background:** Yoga has been shown to be benefi cial in diabetes in many studies, though randomized control trials are few. The aim of this randomized control trial was to see the effect of Sudarshan Kriya and related practices (comprehensive yogic breathing program) on quality of life, glycemic control, and cardiac autonomic functions in diabetes. Diabetes mellitus is a risk factor for sudden cardiac death. Cardiac autonomic neuropathy has been implicated in the causation of sudden cardiac death. Therefore, a maneuver to prevent progression of cardiac autonomic neuropathy holds signifi cance. **Materials and Methods:** A total of 120 patients of diabetes on oral medication and diet and exercise advice were randomized into two groups: (1) Continued to receive standard treatment for diabetes. (2) Patients administered comprehensive yogic breathing program and monitored to regularly practice yoga in addition to standard treatment of diabetes. At 6 months, quality of life and postprandial plasma glucose signifi cantly improved in the group practicing yoga compared to baseline, but there was no significant improvement in the fasting plasma glucose and glycated hemoglobin. **Results:** On per protocol analysis, sympathetic cardiac autonomic functions signifi cantly improved from baseline in the group practicing comprehensive yogic breathing. **Conclusion:** This randomized control trial points towards the beneficial effect of yogic breathing program in preventing progression of cardiac neuropathy. This has important implications as cardiac autonomic neuropathy has been considered as one of the factors for sudden cardiac deaths.Keywords: comprehensive yogic breathing program, diabetes mellitus, cardiac autonomic function

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## Background

Diabetes mellitus is a risk factor for sudden cardiac death. Cardiac autonomic neuropathy has been implicated in the causation of sudden cardiac death. Therefore a maneuver to prevent progression of cardiac autonomic neuropathy holds significance.

## Introduction

We earlier published interim analysis[1,2] of a randomized control trial in diabetes showing improvement in quality of life,[1] post prandial plasma glucose and cardiac autonomic functions[2] with practice of comprehensive yogic breathing program. Here we describe the final findings on completion of the study.

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## Materials and Methods

In this randomized controlled trial,120 patients of type 2 diabetes, controlled on stable dose of medication, glycemic control, quality of life and cardiac autonomic functions

**Table 1: Change in parameters of glycemic control at 12 months as compared to at six months**

| Parameters | SKY group | | Standard group | | |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | *P* |
| FBS | 5.85 | 29.35 | 4.05 | 27.85 | 0.73 |
| PP | −4.67 | 45.04 | 14.10 | 47.78 | 0.02 |
| HbA1c | −0.02 | 01.23 | −0.36 | 01.34 | 0.14 |

FBS: Fasting blood sugar, PP: Postprandial, SD: Standard deviation

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were assessed. Patients were then randomized into two: (1) receiving standard therapy (2) receiving comprehensive yogic breathing program with Sudarshan Kriya yoga plus standard therapy for diabetes.

Glycemic control, quality of life and cardiac autonomic function tests (CAFT) were repeated after 6 months of intervention and compared with those before randomisation.

## Materials and Methods

Analysis by Student's *t*-test, Wilcoxon-Mann-Whitney test, and exact test for two-way symmetry. Stata/IC 11.1 software was employed.

## Results

There was significant lowering of the postprandial but not the fasting plasma glucose and glycated hemoglobin in the SKY group compared to standard group [Table 1].

Psychological (domain 1), environmental (domain 4), and total quality of life (WHO BREF QOL) improved significantly in the SKY compared to standard group [Table 2].

Total and parasympathetic cardiac autonomic functions did not show any significant difference in both groups.

On per protocol analysis, the sympathetic cardiac autonomic functions showed significant difference in the SKY to the standard group [Table 3].

This change in sympathetic CAFT is not seen in the standard group [Table 4]. Neither of the groups showed any significant change in intention to treat analysis.

## Discussion

This study shows that practice of Comprehensive Yogic breathing program improves quality of life. In a chronic diseases like diabetes, quality of life is important as it effects the compliance.

**Table 2: WHO BREF QOL mean scores at baseline and 3 and 6 months post randomisation**

| | Domain 1 | | | Domain 2 | | | Domain 3 | | | Domain 4 | | | Total mean score | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | M SKY | SD Non SKY | *P* | M SKY | SD Non SKY | *P* | M SKY | SD Non SKY | *P* | M SKY | SD Non SKY | *P* | M SKY | SD Non SKY | *P* |
| Pre rand | 68.54±10.85 | 68.10±11.61 | 0.83 | 62.93±9.59 | 59.75±10.75 | 0.09 | 70.12±9.20 | 70.06±9.47 | 0.97 | 65.98±9.00 | 67.32±8.64 | 0.41 | 268.89±28.37 | 264.77±33.48 | 0.49 |
| 3 month post rand | 67.43±7.41 | 62.80±8.18 | 0.001 | 61.73±6.25 | 57.75±7.04 | 0.001 | 71.22±10.94 | 68.00±9.88 | 0.11 | 68.79±9.24 | 67.89±7.91 | 0.56 | 269.25±27.02 | 257.02±25.24 | 0.01 |
| 6 month poat rand | 68.90±9.76 | 66.17±11.76 | 0. 16 | 63.21±9.51 | 57.78±12.08 | 0.006 | 69.08±10.63 | 65.90±11.10 | 0.13 | 68.53±9.67 | 65.25±7.89 | 0.04 | 269.87±31.48 | 254.90±37.83 | 0.02 |

SD: Standard deviation, WHO: World Health Organisation, QOL: Quality of life

**Table 3: Change in sympathetic functions in SKY Group at 6 months as compared to at randomization (per protocol analysis)**

| Sympathetic functions at randomisation | Sympathetic functions after 6 months | | | |
|---|---|---|---|---|
| | Normal | Borderline | Abnormal | Total |
| Normal | 1 | 5 | 0 | 6 |
| Borderline | 6 | 0 | 0 | 6 |
| Abnormal | 2 | 8 | 20 | 30 |
| Total | 9 | 13 | 20 | 42 |

*P*=0.0093

**Table 4: Change in sympathetic functions in standard Group at 6 months as compared to at randomisation**

| Sympathetic functions at randomisation | Sympathetic functions at 6 months after randomisation | | | |
|---|---|---|---|---|
| | Normal | Borderline | Abnormal | Total |
| Normal | 1 | 3 | 0 | 4 |
| Borderline | 3 | 2 | 0 | 5 |
| Abnormal | 1 | 6 | 17 | 24 |
| Total | 5 | 11 | 17 | 33 |

*P*=0.061

It shows significant decrease in the post prandial plasma glucose and the decrease in progression of sympathetic CAFT in per protocol analysis. This means that if practiced regularly, comprehensive yogic positively effects CAFT.

Both derangement of post prandial plasma glucose[3] and cardiac autonomic neuropathy[4] have been implicated in sudden cardiac death in diabetes.

This study has follow up only for 6 months and shows significant effect on CAFT. Since the $HbA_1c$ did not change, this effect on CAFT is independent of the effect on glycemic control. It indicates that, if added to lifestyle, comprehensive yogic breathing program has potential of preventing sudden cardiac death.

Longer period follow up in larger number of patients is needed to assess effect on progress of CAFT and glycemic control. That such studies are feasible, has been shown earlier[5] and this area of research needs to be explored.

## Conclusions

There is significant improvement in QOL, post prandial plasma glucose and sympathetic CAFT in patients practicing SKY.

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