

Chapter - 6
APPRAISAL

6.1. Summary and Conclusion

In this study, the short and long-term effects of *Yoga* was assessed in improving glycemic control and homeostasis in T2DM and conducted following 3 different studies;

1. Multi-centric randomized controlled study
2. Two weeks Integrated residential *Yoga*: Retrospective study
3. A cross-sectional study on long term *Yoga* practice on systemic inflammation, genetic expression, systemic homeostasis.

6.1.1. Glycaemic control through *Yoga*

6.1.2. Retrospective study

A short-term study of 15 days' intense *Yoga* based residential program produced a significant decrease in FBS and PPBS levels in patients with T2DM (See table 40 below). This suggests that residential *Yoga* intervention has potential to produce greater reduction in FBS and PPBS despite the intervention is only 2 weeks. Also, we observed significant decrease in anti-diabetic medication score (Table 41 below).

Table 40: Table showing pre-post changes in variables after 15 days of RIYP in T2DM patients

Variables	N	Pre (Mean ± SD)	Post (Mean ± SD)	Mean diff	95% Confidence Interval of the Difference		p - Value
					Lower	Upper	
FBG (mg/dl)	568	156.95±84.82	134.26±51.46	22.69	-47.055	-35.645	<0.001**
PPBS (mg/dl)	568	202.79±77.29	192.24±79.62	10.55	-28.974	-16.394	<0.001**
^a Paired samples t test							

Table 41: Improvement in anti-diabetic medication score following 2-week intense residential *Yoga* intervention.

Variables	Pre (Mean ± SD)	Post (Mean ± SD)	df	95% Confidence Interval of the Difference		P ^a Value
				Lower	Upper	
Medication Score	4.76±3.30	3.88±3.20	597	19.313	23.623	<0.001**
Oral hypoglycemic medication requirement reduced significantly (p<0.001) from an average of 4.76/day to 3.88/day						

6.1.3. Multi-centric RCT

Another multi-centric randomized controlled trial with 3-month *Yoga* intervention produced a significant decrease in FBS and PPBS. These studies suggest that *Yoga* helps in improving glycemic control in T2DM. After 3-month *Yoga* practice in the *Yoga* group

Table 42: Pre-post changes in FBS and PPBS following 3-month *Yoga* intervention.

Variables	<i>Yoga</i> group (n=137)			Control group (n=114)			Between group Comparison
	Baseline	Post	Mean diff	Baseline	Post	Mean diff	
FBG	142.99± 32.20	96.26 ± 11.92** ^a	-32.68	137.62 ± 34.33	133.59 ± 50.86	-2.94%	<0.001 ^b
PPBG	203.65 ± 45.92	132.83 ± 22.24** ^a	-34.77	190.97 ± 53.83	189.29 ± 78.11	-0.88%	<0.001 ^b
FBG-Fasting blood glucose level; PPBG-Post-prandial blood glucose level. ** -Statistical significance at 0.001 levels; ^a - Paired sample t test, ^b - Independent t test							

6.1.4. Restoration of homeostasis

This study is intended to test whether *Yoga* can help in restoring homeostasis in T2DM. In the retrospective study in addition to a reduction in the mean value, there was reduction in standard deviation also for FBS and PPBS in both multi-centric study and retrospective study. This is suggestive of restoration in homeostasis. Further, we observed significant decrease in pulse rate, systolic blood pressure and diastolic blood pressure; this is an indication of restoration of homeostasis (Table 43).

Table 43: Study 2-RIYP-changes after 15 days of residential <i>Yoga</i> in T2DM patients.						
Variables	Pre (Mean ± SD)	Post (Mean ± SD)	Df	95% CI of df		P ^a Value
				Lower	Upper	
Pulse Rate (bpm)	79.63±9.24	60.93±27.79	597	86.12	55.82	<0.001
Systolic BP (mmHg)	126.81±18.08	108.08±24.46	597	-37.37	-30.482	<0.001
Diastolic BP (mmHg)	74.6±10.45	63.13±31.53	597	15.37	20.365	<0.001

In long term *Yoga* practitioner, there was better renal functions and liver function compared to non- *Yoga* practitioners suggestive of better homeostasis status in long term *Yoga* practitioners than non- *Yoga* practitioners.

6.1.5. Comparison of Biochemical variables

In the cross-sectional study biochemical measures showed better renal function, liver function and stress hormone status in long term *Yoga* practitioners compared to non- *Yoga* practitioners. This is also an indication of better homeostasis status in long term *Yoga* practitioners compared to non- *Yoga* practitioners.

Table 44: Study 3 – long term *Yoga*, cross sectional-controlled study- Mean and SD of biochemical variables in *Yoga* and non-*Yoga* groups

Variables		<i>Yoga</i> (n=22)		non- <i>Yoga</i> (n=20)	
		Mean	SD	Mean	SD
Stress hormone	Cortisol µg/dL	12.82	13.14	22.24	24.35
Cytokine	IL-2	36.36	11.29	33.18	8.87
Liver function test	ALT (IU/L)	13.74	5.78	17.75	9.19
	AST (IU/L)	21.22	4.63	27.00	12.30
	ALB g/dL	47.83	2.69	46.75	5.26
	D Bil-V mg/dL	0.00	0.00	0.04	0.20
	ALP IU/L	81.13	27.32	95.29	61.04
	Glum mol/L	187.96	112.64	199.38	83.46
Renal function test	Urea	29.78	9.48	33.58	15.71
	Cre mg/dL	1.01	0.28	1.15	0.76
	UrA mg/dL	5.43	1.53	5.92	1.86
Psychological questionnaires	DSS	20.00	4.81	43.32	14.06
	PSS	14.79	6.03	16.41	6.03

Pancreatic polypeptide is an important biomarker for pancreatic function and insulin activity. In the cross-sectional study, among 20 long term *Yoga* practitioners, 16 had PPT<129pg/ml suggestive of better insulin activity, whereas, in the controls only 13 patients had PPT<129pg.ml. This is suggestive of better systemic homeostasis in long term *Yoga* practitioners compared to non- *Yoga* practitioners.

Table – 45: Study 3 – long term <i>Yoga</i>, cross sectional-controlled study		
PPT	<i>Yoga</i> (n=20)	Control (n=22)
<129pg/ml	16	13
pathologic values (>129pg/ml)	4	9

Table – 46: Proinsulin to insulin ration in the *Yoga* group was less compared to non- *Yoga* group, suggesting better insulin sensitivity in the *Yoga* group compared to non- *Yoga* group.

Variable	<i>Yoga</i> Mean (SD)	Control Mean (SD)	P value
Proinsulin: Insulin	0.007	11	<0.05

Liver enzymes in the *Yoga* practitioners were in the better level compared to non- *Yoga* practitioners suggesting of better live of 22 long term *Yoga* practitioners, 19 had most of the assessed variables within normal range, suggestive of better homeostasis state, whereas, in the non- *Yoga* group, of 20, only 13 practitioners had normal range for most of the variables.

Table 47: Number of participants with systemic metabolic homeostasis in the <i>Yoga</i> and the control group						
Status	Control		<i>Yoga</i>		Total	p chi ²
	n	%	n	%		
Homeostasis	13	59.09	19	95	32	<0.05
Non-homeostasis	09	40.91	1	5	10	<0.05

6.1.6. Strengths of study

- The study looked at the efficacy of *Yoga* in long term practitioners of participants with T2DM (study 3).
- It has demonstrated the unique effect of *Yoga* in improving systemic homeostasis in T2DM after long term practice of *Yoga* -based life style change. This offers a new insight into the concept of homeostasis and its relevance in T2DM.
- First multi-centric RCT study (Study 2)
- The first study to demonstrate the significant difference between *Yoga* and non- *Yoga* groups of T2DM on expression of genes related to platelet aggregation (study 3)

- This study supports earlier evidences on the beneficial effects of *Yoga* on glucose values in both short term and long-term practitioners of *Yoga* in T2DM.
- Similar results in both the prospective controlled multi-centric study and cross section retrospective study.
- Similar results on glyceimic non- *Yoga* after residential and non-residential intervention.
- Various aspects such as homeostasis, glyceimic non- *Yoga*, systemic inflammation, organ functions, and molecular parameters studied.
- Advanced and sophisticated gene assay methods were used.
- No adverse events were observed after *Yoga* intervention.
- A new model combining *Yoga*, Ayurveda and modern medicines been proposed for the etiology and progression of T2DM which seems to give a new insight into the reversibility of the disease process.

6.1.7. Limitations of the study

The limitations of each of the 3 studies are given below:

6.1.7.1. Limitations of Study 1: Multi-centric RCT study

- Small sample size.
- Short term study.
- No information on diet non- *Yoga*.
- Lack of more specific variables such as HbA1C, serum insulin etc.
- Lack of medication information.

6.1.7.2. Limitations of study 2 – Retrospective study

- Lack of control group
- Short term study
- Intervention is difficult to follow with day today activities.

6.1.7.3. Limitations of Study 3 - Long term effects study

- Sample size for long term study was too small
- Baseline data was not available for some variables
- Details about diet control were not recorded.

6.1.8 Recommendations:

1. Lifestyle programs for primary and secondary prevention of T2DM has established the role of add, on high fiber diet, increased physical activity. The role of abstinence from alcohol, smoking, stress management and good sleep, is given lesser importance. The role of prevention of constipation and regular bowel emptying is not at all taken into consideration. Present study recommends integration of detoxification as an important add-on to life style programs. The present study offers evidence to addition of breathing, chanting and mindfulness to physical activity in reversing the disease.
2. Future prospective metacentric long-term studies may be planned in a bigger sample size to validate this concept of homeostasis which seems to be unique to *Yoga*.
3. Studies to compare the drug trials with *Yoga* trials on homeostasis may be planned.
4. Studies on different modules of *Yoga* may be planned
5. Studies in different ethnic groups are recommended
6. It has been projected that India is going to be the global capital for diabetes. India being the home of *Yoga*, acceptability of this culturally rooted technique should be harnessed as a national program to prevent the trends.

6.1.9. Suggestion for Future work

- Future long-term prospective studies will provide confirmatory evidence from the conclusions from this study.
- Future study should consider larger sample size and long-term intervention.
- More specific and robust variables such as HbA1C, insulin and specific genetic changes should be studied.
- Diet and physical activity components should also be monitored.
- Three-armed design to compare treatment as usual, active control intervention with exercise-based life style intervention and the experimental arm with *Yoga* -based life style intervention is recommended.
- Need to look for homeostatic effect in Interventional studies on other life style and metabolic disorders.