

**LOWERING CREATININE LEVELS BY HERBAL TREATMENT AND YOGA: A PILOT
CONTROLLED TRIAL**

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ABSTRACT

Background: Elevated creatinine levels are a well-known measure of kidney dysfunction, and a criterion for dialysis, with its low life expectancy problems. Despite this, dialysis is commonly used to lower creatinine levels as it is the only recognised means of doing so. Here we present results of a pilot controlled trial showing that treating newly diagnosed diabetic patients with herbal juices and/or Yoga can also lower creatinine levels. **Methods:** a three month controlled trial was conducted on 112 incarcerated males aged 40.8 ± 11.1 yrs with newly diagnosed elevated fasting blood sugar levels. Informed Consent was obtained from all participants. Ethical Clearance: was obtained from S-VYASA's IEC. Interventions comprised fresh herbal juices and yoga; yoga; and no intervention controls. Assessments of creatinine levels were made on days zero and 90, pre/post the intervention. Those performing the assessments were blind to the reason for, and nature of, the study. Statistical analysis used SPSS-20. **Findings:** Significant reductions (all $p < 0.001$) of creatinine levels were observed in the herbal juices and yoga group (0.15 ± 0.06), and yoga alone group (0.09 ± 0.06) Control group levels increased by 0.12 ± 0.07 . Between group differences were also significant. **Interpretation:** Results suggest that a combination of daily intake of herbal juices and regular Yoga practice improves kidney function more than regular Yoga practice alone. **Trial Registration:** Clinical Trial Registration of India, Ref/2015/03/008680. **Funding:** The study was privately funded by Bhopal Central Jail and the first author. **Conflict of Interest:** P. Datey is founder-owner of Bhopal's five *Rasahara Kendra* clinics.

KEY WORDS: Interventions comprised fresh herbal juices and yoga; yoga; and no intervention controls.

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) has been described as a disease that presents the 21st century with grave challenges,^[1] particularly because of epidemiological predictions of unsustainable increases in global health expenditure. High priority needs to be given to its prevention, particularly use of integrated approaches to encompass its heterogeneity,^[1] and must necessarily include the wide range of its associated pathologies. Despite new approaches to treatment, further clinical trials are necessary to identify means to treat and prevent the disease, including prevention of degradation of β -cell function, and removal of present side-effects.^[2] Obesity greatly increases risk of diabetes, and may explain much of Asia's T2DM epidemic and the increasing numbers of young contracting it;^[3] treatment methods that also reduce BMI should be identified.

In India, a high proportion of newly diagnosed T2DM patients show chronic complications as well. A cross-sectional survey of 4,600 such new T2DM cases observed the following percentages: neuropathy 13.1%, retinopathy 6.1%, and nephropathy 1.06%; macro vascular complication risk factors stood at hypertension

23.3%, obesity 26%, and dyslipidemia 27%; 6% already had ischemic heart disease.^[4] Correspondingly many patients reported multiple symptoms. A consequence of the early appearance of such complications is that routine screening for them may be advisable,^[4] and that the increasing costs of diabetes^[1] have probably been underestimated. These factors mean that alternative strategies of treatment should be urgently considered. South Asia possesses a range of systems of traditional complementary and alternative medicine (TCAM) such as Ayurveda and Yoga, each with well-defined and increasingly well understood concepts of health, and means to restore it.^[5-7]

Ayurveda has a growing evidence base that is increasing in quality,^[8-11] but research on Yoga is far more extensive and Yoga medicine presents an increasingly accepted method of treating most kinds of chronic disorder. A medically-oriented system of modern Yoga, developed by a team of conventionally trained biomedical doctors and scientists is the Integrated Approach to Yoga Therapy (IAYT), which, since its first applications to asthma,^[12,13] has been widely applied to chronic disorders.^[14] Other examples of its applications

include both physical, to back pain,^[15] and mental including depression.^[16, 17] Improving patient quality of life in potentially terminal diseases like cancer is a well established application in both India^[18] and the US.^[19-22]

For type 2 Diabetes (T2DM),^[23] twenty randomized and a similar number of non-randomized controlled trials have been conducted, and special modules have been formulated.^[24, 25] Yoga for T2DM RCTs have documented the extent to which regular yoga practice over time periods from several months to a year can improve diabetes parameters such as blood sugar levels, HbA1C, and various blood lipid levels. In the present context a small pilot study of twelve T2DM patients combining methods of both Yoga and Ayurveda is relevant.^[26] A combined Ayurveda *panchakarma* therapy and Yoga intervention over 6 weeks in residence with 12 weeks home follow up found good reduction in FBS (-19.9%), PPBS (-20.2%), HbA1C (-13.6%) and key blood lipids.^[26] Here we report another Ayurveda-Yoga intervention, using a three arm controlled trial of Ayurveda and Yoga methods for newly diagnosed cases of T2DM over a period of three months focusing on possible kidney dysfunction and chronic kidney disease (CKD).

Treatment of CKD by Yoga has been the subject of two recent reviews,^[27,28] both of which emphasize the need for technical expertise in selection of Yoga practices appropriate for the condition. One study requiring further follow-up has reported improvements.^[29]

Kidneys work 24/7 purifying the blood. Though progress can be slowed, kidney dysfunction almost inevitably ends in fatality due to failure to remove potentially problematic materials from the blood. One such is creatinine, a final product of impaired muscle metabolism, which as a result is used as the standard marker for renal failure, and for decisions to prescribe dialysis. In this study, choice of interventions was based on experience at five natural health clinics in the central Indian city of Bhopal where treatments combine freshly prepared herbal juices, Yoga practices and strictly regulated diet and life-style prescriptions. Good improvements have been observed in metabolic syndrome related conditions, including diabetes, and particularly associated kidney disorders. Recent patient records include two groups of patients with elevated levels of creatinine who showed good improvements in creatinine levels. Ten who had approached the clinics specifically for improvement in kidney condition, and received individualized herbal juice combinations specifically aiming to improve kidney function, achieved an average decrease in creatinine level of 0.84 mg/dl per month over time periods ranging from 1 to 7 months. Nine patients who approached the clinics for other reasons, usually metabolic syndrome related, and who also happened to be undergoing regular creatinine assessment tests at the insistence of their G.P., also showed improvements in creatinine levels, but far lower,

about 0.1 mg/dl per month. This group was used for G*Power analysis. A pertinent observation in this regard is that all clients attending the clinics who were compliant with herbal juice, yoga practice, and daily routine prescription, and whose creatinine levels were being regularly assessed, showed improvements in them. None failed to do so. Treatments seem 100% reliable for compliant clients. In the cases of two kidney related clients who alternated between compliance and non-compliance, their creatinine levels see-sawed correspondingly.

As a result of all experiences at the clinics including the observations of creatinine level changes, an overall study was proposed: a pilot controlled trial (CT) of herbal juice treatments and Yoga for early detected T2DM in males not yet on medication, but with elevated levels of fasting and post-prandial blood sugar and/or Hb1Ac i.e. probably in early stages of T2DM. However, the research hypotheses were also influenced by the above observations of improvements observed in clients reporting with renal problems since 2013. Of the ten greatly improved elevated creatinine clients the condition of two of the three on dialysis improved enough following treatment for one to four months for them to be able to come off dialysis.

As a result of these observations, one of the trial research hypotheses was that participant's kidney function would improve creatinine levels, which were included among some 16 measured variables. Here we present the study's results for that specific variable.

METHODS

Study Design: a three arm controlled trial of three months duration conducted in the Central Jail, City of Bhopal, Madhya Pradesh, India, at the invitation of the prison authorities.

Participants: After a wide screening of inmates conducted by the prison, 567 were found to have elevated fasting blood sugar levels and were informed of the possibility of participating in the trial. 417 declined for various reasons: 264 said they had insufficient time, 109 were 'not interested', and 44 point blank refused. 150 male prison inmates aged 40.8±11.1 yrs incarcerated in the jail. As no previous studies of effects of yoga practice on elevated creatinine levels are in the literature, G*Power analysis was performed using data from the group of nine clinic patients mentioned above for whom creatinine data were available. Requiring both α and β to be 0.05 yielded N = 20.

Inclusion Criteria: age \leq 70.9, elevated FBS level; not previously diagnosed as at risk of diabetes; jail sentence duration extending over at least the duration period of the RCT; willing and able to practice Yoga.

Exclusion Criteria: age $>$ 71.0. BMI $<$ 20, unable/unwilling to practice yoga, mental disorder,

already having diabetes complications: kidney damage, retinopathy, stroke, heart attack.

Assignment to groups was carried out by assigning each participant to groups 1, 2 and 3 successively according to position in sequence of initial FBS levels, to assure comparable means and standard deviations in that variable.

Interventions: Group 1: herbal juices and yoga; Group 2: yoga; Group 3: no intervention.

The herbal juice preparation, uniform for the whole of Group 1 was freshly prepared from

Wheatgrass juice: 50ml from 25 gms of wheatgrass blended in filtered water;

Tinospora Cardifolia (local name Giloe) 50 ml from 15 gms stem blended in filtered water; *Adhatodavasica Nees* (local name Adusa) 50 ml from 4gms green leaves blended in filtered water;

Embilica Officianalis (local name Amla) 50 ml solution prepared from 8 gm dried powder, soaked for 12 hours.

The Yoga Intervention consisted of: Sukshma Vyayama flexion exercises of head and neck, limbs and torso to warm muscles and stimulate lymph flow (about 10 mins); 10 rounds of standard 12 posture Sun Salutation (Suryanamaskara) (about 15 mins); IAYT SMET program (35 mins) consisting of three different relaxation sequences, ending with 7 mins supine posture, 10 rounds of alternating single nostril (anuloma-viloma) pranayama breathing exercise, 10 rounds of Bhrmhari pranayama breathing exercise, and two rounds of Nadanusandhana (separate vocalization of 'A', 'U' and 'Mmm...').

Assessments: creatinine levels were measured pre and post the intervention.

Statistical Analysis: Was performed using SPSS-20, and Graphpad for certain 't' tests.

RESULTS

Tables 1: Group Mean Creatinine Levels Pre and Post Intervention

Group	1. Herbal Juices and Yoga		2. Yoga Only		3. Control	
	Pre	Post	Pre	Post	Pre	Post
Mean	.80	.65	.83	.74	.82	.94
SD	±.12	±.10	±.17	±.16	±.14	±.27
Decrease	0.15		0.09		0.12 (increase)	
Signif: t / p	9.4 / 0.0001		5.09 / 0.0001		2.55 / 0.0013	

Table 2: Between Group Differences Significances of Group-Time Interactions

Group	't'-value	p-value
1 and 2	2.55	0.0128
1 and 3	7.20	0.0001
2 and 3	5.48	0.0001

567 inmates of Bhopal central jail were screened. Of the 150 who agreed to participate, 38 immediately withdrew on learning trial requirements, leaving 112 who agreed to complete the trial, giving 38, 37 and 37 in each group. After this initial problem, there was no attrition.

Pre and Post Creatinine levels and their differences are presented in Table 1. It is noteworthy that creatinine levels decreased in both Groups 1 and 2 (Herbal Juices and Yoga, and Yoga only), by 0.15 ± 0.06 and 0.09 ± 0.06 respectively (significance excellent for both), while they increased in Group 3 by 0.12 ± 0.07 (all units mg/dl, giving Mean ± 2 SE's), also with good significance (all t tests one sample t tests). Results of t tests for group-time interaction differences are given in Table 2. The three groups are all significantly different from each other with good statistical significance.

DISCUSSION AND CONCLUSIONS

In India, TCAM systems are administered by the recently formed Ministry for AYUSH, permitting such systems to be taken into the equation and included in medical

policy. An alternative strategy to treating each identified pathology as a chronic disease, and therefore as essentially incurable and a long-term health cost burden, would be to institute TCAM treatments known to improve overall health including all such parameters, rather than focusing on individual symptoms and attempting to treat each individually. The advantage of such an approach is that complementary systems of medicine assess levels of imbalance of underlying metabolic and regulatory conditions, and by restoring them to normality can prevent further pathologies arising from the same imbalances. Merely palliating symptoms of one disease leaves a patient with metabolic or regulatory imbalances open to further pathologies developing.

Current methods of treating T2DM and its complications remain inadequate, so their prevention is preferable. Both observational studies and clinical trials of dietary modification support the hypothesis that T2DM is preventable, so further studies of means to prevent T2DM and its complications like kidney failure are of

high importance to public health. The decrease in Group 1 creatinine values was consistent with the research hypothesis, based on previous results obtained from patients attending the Rasahara (Herbal Juice) Clinics in the city of Bhopal: of ten recent kidney patients who attended the clinics and were on dialysis at the start of treatment, two have been able to return to normal kidney function, while clinically significant improvements have been seen in most of the others (about 40). The decrease in Group 2 patients, though less, was also statistically significant $p < 0.0001$. It is consistent with reports from a private kidney hospital in the city of Thrissur in the state of Kerala in South-West India, which treats kidney patients on a strict Yoga and life-style regime, and has unpublished records¹ of many successful cases of bringing kidney patients off dialysis.

These results require follow-up studies with larger numbers of patients to confirm trends seen in pre-diabetic participants in this study. Since the present Indian government is committed to encouraging practice of integrative medicine at its leading nationally funded AIIMS group of hospitals, further studies should be carried out under leading nephrologists, and, if successful, similar treatments widely implemented.

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REFERENCES

- Zimmet P.Z., Magliano D.J. Hermann W.H. Shaw J.E. Diabetes: a 21st Century Challenge. *The Lancet Diabetes and Endocrinology*, 2014; 2: 56-64.
- Kahn S.E. Cooper M.E. Del Prato S. Pathophysiology and treatment of type 2 diabetes: perspectives on the past, present, and future. *The Lancet*, 2014; 383: 1068-83.
- Tuoni T. Santoro N. Caprio S. Cai M. Weng J. Groop L. The many faces of diabetes: a disease with increasing heterogeneity. *The Lancet*, 2014; 383: 1084-1094.
- Sosale A. Kumar K.M.P. Sadikor S.M. Nigam A. Bajaj S. Zargar A.H. Singh S.K. Chronic complications in newly diagnosed patients with Type 2 diabetes mellitus in India. *Ind J Endocrin Metab*, 2014; 18: 355-360.
- Hankey A. Ayurvedic Physiology and Etiology: Ayurvedo Amritanaam. The Doshas and Their Functioning in Terms of Contemporary Biology and Physical Chemistry. *J Alt Complement Med*. 2001; 7(5): 567-574.
- Hankey A. The Scientific Value of Ayurveda. *J Alt Complement Med*. 2005; 11(2): 221-225.
- Hankey A. J. A new approach to biology and medicine: an expanded role for regulation. *J Science of Healing Outcomes*, 2015; 7(28): 13-18.
- Prasher B. Negi S. Aggarwal S. Mandal AK. Sethi TP. et al. Whole genome expression and biochemical correlates of extreme constitutional types defined in Ayurveda. *J Transl Med*, 2008; 6: 48.
- Aggarwal S. Negi S. Jha P. Singh PK. Stobdan T. Pasha MAQ. et al. EGLN1 involvement in high-altitude adaptation revealed through genetic analysis of extreme constitution types defined in Ayurveda. *PNAS*, 2010; 107(44): 18961-18966, doi: 10.1073/pnas.1006108107.
- Aggarwal S. Gheware A. Agrawal A. Ghosh S. Consortium IGV. Prasher B. Mukerji M. Combined genetic effects of EGLN1 and VWF modulate thrombotic outcome in hypoxia revealed by Ayurgenomics approach. *J Transl Med* 2015; 13: 184 DOI 10.1186/s12967-015-0542-9.
- Govindaraj P. Nizamuddin S. Sharath A. Jyothi V. Rotti H. Raval R. et al Genome-wide analysis correlates Ayurveda Prakriti. *Scientific Reports*, 2015; 5: 15786.
- Nagarathna R. Nagendra H.R. Yoga for bronchial asthma: a controlled study. *BMJ Clinical Research*, 1985; 291: 1077-1079.
- Nagarathna R. Nagendra H.R. An integrated approach of Yoga therapy for bronchial asthma: a 3-54 month prospective study. *J Asthma*, 1986; 23(3): 123-129.
- Monroe R. Nagendra H.R. Yoga for Common Ailments. Swami Vivekananda Yoga Prakashan. Bangalore, 1991.
- Tekur P. Nagarathna R. Chametcha S. Hankey A. Nagendra H.R. A comprehensive yoga program improves pain, anxiety and depression in chronic low back pain patients more than exercise: an RCT. *Complementary therapies in medicine*, 2012; 20(3): 107-118.
- Naveen GH. Rao MG. Vishal V. Thirthalli J. Varambally S. Gangadhar BN. Development and feasibility of yoga therapy module for out-patients with depression in India. *Ind J. Psych*. 2013; 55(7 Supp.): 350-356. DOI:10.4103/0019-5545.116305 PMID: 24049198
- Naveen G.H. Thirtalli J. Rao M.G. Varambally S. Christophe R. Gangadhar B.N. Positive therapeutic and neurotropic effects of yoga in depression: A comparative study. *Ind J Psych*. 2013; 55 (Suppl 3): S400-S404. doi:10.4013/0019-5545.116313
- Vadiraja H.S. Raghavendraro M. Nagarathna R. Nagendra HR. Rekha M. Vanitha N. et al. Effects of yoga program on quality of life and affect in early breast cancer patients undergoing adjuvant radiotherapy: A randomized controlled trial. *Complement Ther Med*. 2009; 18: 274-280. doi.org/10.1016/j.ctim.2009.06.004.
- Chandwani K.D. Thornton B. Perkins GH. Arun B. Raghuram N.V. Nagendra H.R. et al. Yoga improves quality of life and benefit finding in women undergoing radiotherapy for breast cancer. *J Soc Int Onc*. 2010; 8(2): 43-55.
- Chandwani K.D. Perkins G. Nagendra H.R. Raghuram N.V. Nagarathna R. Cohen L. et al.

- Randomized, Controlled Trial of Yoga in Women With Breast Cancer Undergoing Radiotherapy. *JCO*, 2014; 32(10): 1058-65. Online: March 3, 2014; doi:10.1200/JCO.2012.48.2752.
21. Danhauer S.C. Addington E.L. Sohl S.J. Chaoul A. Cohen L. Evidence Supports Incorporating Yoga Alongside Conventional Cancer Treatment for Women with Breast Cancer. *Breast Diseases* 2015; 26(3): 189-193. doi:10.1016/j.breastdis.2015; 07.036.
 22. Milbury K. Mallaiah S. Lopez G. Liao Z. Yanga C. Carmack C. et al. Vivekananda Yoga Program for Patients With Advanced Lung Cancer and Their Family Caregivers. *Integrated Cancer Therapies*, 2015; Online Pub 27.04.2015 doi: 10.1177/1534735415583554
 23. Nagendra HR. Nagarathna R. Yoga for Diabetes. Swami Vivekananda Yoga Prakashan, Bangalore, 2001.
 24. Vaibhavi B. Satyam T. Sanjibkumar P. Nagarathna R. Nagendra H.R. Effect of Holistic Module of Yoga and Ayurvedic Panchakarma in Type 2 Diabetes Mellitus—A Pilot Study. *Open Journal of Endocrine and Metabolic Diseases*, 2013; 3(1): 28059. doi:10.4236/ojemd.2013.31014.
 25. Vinod P. Jagannathan A. Angadi P. Thulasi A. Nagarathna R. Umamaheshwar K. Development validation and feasibility testing of a Yoga for Programme of Patients with Type 2 Diabetes Mellitus. *Int J Yog Ther* 2015; accepted for publication.
 26. Vaibhavi B. Satyam T. Sanjibkumar P. Nagarathna R. Nagendra HR. Effect of Holistic Module of Yoga and Ayurvedic Panchakarma in Type 2 Diabetes Mellitus—A Pilot Study. *Open Journal of Endocrine and Metabolic Diseases*, 2013; 3(1): 28059. Doi:10.4236/ojed.2013.31014.
 27. Mokham M. Yoga as a Therapeutic Intervention in Patients with Chronic Kidney Diseases. *J Ped. Nephrology* 2014; 2(4): 129-131.
 28. Kashinath GM, Hemant B, Praerna C, Nagarathna R, Nagendra HR. Role of Yoga in Chronic Kidney Disease: A Hypothetical Review. *J Nephrol Ther* 2014; 4(3): 1000167.
 29. Yurtkuran M. Dilek K. A modified yoga-based exercise program in hemodialysis patients: A randomized controlled study. *Complementary Therapies in Medicine* 2007; 15(3): 164-171.