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4.0 SCIENTIFIC STUDY

4.1 DIABETES

4.1.1 EPIDEMIOLOGY OF DIABETES

Diabetes is a major health issue across continents and social spectrum. This disease is characterized by insufficient production of insulin by the body or inability of the body cells to use insulin properly, even if produced sufficiently. The medical term for this condition is hyperglycemia. It has two types. Type 1 IDDM (insulin dependent diabetes mellitus) and Type 2 NIDDM (non insulin dependent diabetes mellitus). Type 2 diabetes is more common (Rother K.L, 2007). Though this disease is part of human civilization for long time and mentioned in ancient scriptures under different names, the scenario is worsening in recent years. Because of demographic changes there is increase in the number of people above 65 years of age and this group is more susceptible to diabetes. According to International Diabetes Federation the most vulnerable age group is 45-65 yrs in developing countries and above 64 yrs in developed countries. It is necessary to quantify the prevalence of diabetes for planning and allocation of resources. Earlier the diabetic population of the world was estimated to be 2.8% (177 million) in 2000 and 4.4% (366 million) in 2030 (Shaw E.E, 2004). Revised estimates suggest 7.7% (439 million) in 2030 (Wild S, 2004). Diabetes is far overshooting the estimates made on trends in 2000. As the disease is spreading to younger generation, susceptible age bracket now is 20-79 yrs.

4.1.2 ECONOMIC BURDEN OF DIABETES

The global expenditure on diabetes is expected to be US \$ 490 billion in 2030. Twelve percent of health expenditure would be spent on diabetes related diagnosis and management. It was estimated to be US \$ 1330 per person for year 2010. The expenditure would vary as per region, age group, gender and the income level of

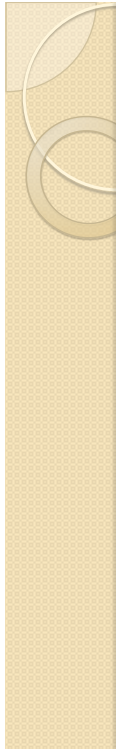
country. Diabetes is a serious problem on the financial health of the country. Expenditure on diabetes varies from 2 - 41% of a country's total health expenditure (Boeffetta P, 2011). Nations have to spend more on health care system which otherwise could be spent on economic and social development. In US, people with diabetes spend 2.5 times more on medication than those without diabetes and that is scenario in India as well. Poor countries need to allot more resources to provide basic diabetes care. Urban poor spend 34% and rural poor 27% of their income on diabetes care in India. The average expenditure per patient per year would be a minimum of Rupees 4,500. Therefore, the estimated annual cost of diabetes care would be approximately Rupees 180,000 million. Of all health care costs, 85 to 95% are borne by individuals and their families from their personal income. The poor are greatly affected as large amounts of their income go into this disease. Not only that, they are more prone to the co-morbid risks. The cost on diabetes is due to ambulatory care (65%) and hospitalization (35%). Ambulatory care comprises of doctor visit (12%), laboratory (22%), drugs (17%), disposables (3%) and other drugs (11%). As per estimates of Indian Diabetes Prevention Program the cost effectiveness to prevent one case of diabetes is a) Rs 47,341 with life style modification b) Rs 49,280 with medicine c) Rs 61,133 with lifestyle modification and medicine. Besides there are indirect cost which comprises of man days lost and loss of personnel and family income. This has been worked out to be Rs 12,756. Hospital costs are worked out by number of hospitalizations multiplied by the average cost per event divided by the duration of each event. Higher cost of treatment is a great burden on the state resources as well the patients among all socio economic groups. The financial strain is alarming among the poor for treating diabetes and they must be provided with the insurance cover (Misra P, 2011).

4.1.3 DIABETES IN INDIA

WHO estimates suggest that mortality rate from diabetes, stroke and heart disease cost India \$210 billion in 2005 which will go up to \$ 333.6 billion in 2015. Indians develop diabetes at a very young age which is earlier by at least 10-15 years in comparison to western population. Earlier occurrence gives ample time for chronic complications of diabetes. The factors responsible are familial history, abdominal obesity, sedentary lifestyle, insulin resistance, urbanization stress (Mohan V, 2007).

4.1.4 CONVENTIONAL DIAGNOSIS AND MEDICAL TREATMENT OF DIABETES

Conventional medicine to treat diabetes comprises of lifestyle modification and medication, the first stage of treatment is meal planning, weight loss and exercising. Drugs used are Sulfonylureas, Meglilnides, Biguanides, Thiazolidinediones, Alpha-glucosidase inhibitors. Pills work only in those patients whose pancreas still makes some insulin. The diagnostic tests are IGT (impaired glucose tolerance), IFT (impaired fasting glucose), HbA1c (glycated haemoglobin), H-FABP (Heart type-fatty acid binding protein), BMI (Body mass index), Lipid profile and new type of tests are under scientific development and validation. Complications that arise due to diabetes are related to heart, kidneys, liver and eyes. As the disease progresses, almost all the systems and organs are affected directly or indirectly. Some of the preliminary tests for diagnosis of complications are Serum Creatinine and Urea (renal problems), Total Cholesterol and Triglycerides (cardiac problems), Alkaline Phosphate, ALT(alanine aminotransferase) and AST(aspartate aminotransferase) for liver disorders; among host of other tests.



Review of Scientific Search

Diabetes Type 2

Prevalence

Diagnosis

Risk Factors and
Complications

Wild S, et.al 2004

Diabetes Care, 2011

Singh, et al 1998

Lacroix, et.al 2006

Esposito, et.al 2010

V Mohan, et.al 2000

4.1.5 CAM AND DIABETES

There are complementary and alternative therapies being practiced mostly to supplement the conventional medicine and rarely as standalone treatment. Most common are biologically based practices and Mind Body medicine. Biologically based practices consist of herbs, minerals and food supplements (Wild S, 2004). Indian system of medicine Ayurveda and Unani are based on herbs, plants and minerals. Ayurveda is an ancient system of medicine practiced for thousands of years. Diabetes is mentioned in the texts of Ayurveda and there are certain preparations (herbs and plants) used for the control and management of diabetes. Sources of study in Ayurveda are 1. Caraka Samhita 2. Susruta Samhita 3. Astanga Sangraha 4. Astanga Hridaya. Food supplements based on natural resources referred to as nutraceuticals, are commonly used especially by the upper economic status society. These are generally called as life style supplements which are validated through science but not classified as drug by FDA. There are lot of herbs and plants which have proven anti diabetic activity viz., garlic,

aloe vera, ivy gourd, gymnema, momordica charantia and fenugreek. Mind body medicine works on the concept that physical body and mind influence each other. Mind body techniques have arisen in various cultures and contexts from time to time. Most of these therapies are derived from eastern traditions such as yoga, tai chi and meditation. Yoga has become very popular in western countries and lot of research has been done there in this field. Yoga includes physical techniques of movements, breathing, meditation, chanting and life style changes. Tai chi is a mind body practice from China with roots in martial arts and ancient healing tradition. It includes coordinates gentle movements with mental focus, breathing and relaxation. Yoga and tai chi come under the category of low to moderate aerobic activity as per the classification of ADA (American Diabetes Association). According to their guidelines patients with diabetes should perform at least 150 min/week of moderate to intense physical activity/aerobics (Rubin R.J, 1994).

4.1.6 YOGA AND DIABETES

Yoga is a mental, physical and spiritual activity originated in ancient India 5000 years ago. The benefits of yoga are many and proved through research. To mention some of the benefits viz., sense of inner peace through breath awareness, better sleep, reduced anxiety and depression, feeling of well being, flexibility and physical strength (National Centre publication). Diabetes occurs because of non functioning of pancreas. β - cells become deactivated and when 80% of the cells are dead, the disease surfaces. Yoga can effectively support by messaging internal organs like liver/ pancreas and activating glandular system responsible for diabetes (Centre for disease control publication). Yoga is a scientific system given to us by ancient sages. Originally a spiritual practice its benefits extend to achieve health and happiness (Gresham GE). Yoga is a technique for balancing the mind. Stress is generated in mind and gets reflected in the body (physical

and mental) in the form of diseases. In diabetes, mastery of mind contributes to stability of blood glucose level around normal values (*Rockville M.D, 1995*). 'Patanjali Yoga Sutra' is the main text of yoga, it has eight main components. These eight components are yama, niyama, asana, pranayama, pratyahara, dharana, dhyana and samadhi. The application of yoga for specific disorders is recent. The medical benefits can be viewed as positive side effects of the primary goal of yoga viz. control over the mind and spiritual development. Practitioners and therapists of yoga view it as a holistic intervention. Modern medicine has shown acceptance for yoga as a supplementary therapy. Well designed short term and long term studies have shown the effect of yoga in Diabetes mellitus type 2 with good glycaemic status for long periods of time with lesser requirement of oral hypoglycemic drugs. Yoga asana and pranayama result in stable autonomic functions in Type 2 DM (diabetes mellitus) cases. Slow pace pranayama activates the parasympathetic system resulting in better glycaemic control (Matcher D.B, 1994). There are studies where yoga practice for 40 days has shown reduced BMI, improved well-being, and reduced anxiety in T2DM (type2 diabetes mellitus) subjects. The program resulted in improvement of the subjective well being scores of the subjects. Therefore yoga can help in primary prevention as well as management of T2DM (Schoenberg BS). Yoga reduces risk factors for T2DM by promoting weight loss, improving glucose levels and reducing blood pressure and lipid levels (Davis PH et.al.,). Yoga is helpful in controlling both symptoms as well as complications associated with type 2 diabetes mellitus. Another benefit associated with yoga is improvement in quality of life. The sources of study in Yoga are 1.Patanjali Yoga Sutras 2.Yoga Vasistha 3.Bhagavad Gita. The sources of study in spiritual lore are 1.Bhadranayaka Upanisad 2.Chandogya Upanisad 3.Prasna Upanisad 4. Mandukya Upanisad 5. Aksh Upanisad 6. Adhyatma Upanisad 7. Vijnana Bhairavi.

4.1.7 PRE DIABETES

Plasma glucose levels above normal range but below the clinical diabetes represent pre-diabetes. Pre-diabetes can be identified as either impaired fasting glucose (IFG) or impaired Glucose tolerance (IGT). Both are risk factors for type 2 diabetes, risk is greater when both IFG and IGT occur together. Pre diabetes commonly associates with the metabolic syndrome. For both Pre-diabetes and metabolic syndrome, the desirable approach is life style intervention, especially weight reduction and physical activity. Persons who have both IFG & IGT plus metabolic syndrome are at a greater risk for conversion to diabetes than are those with only IFG or IGT. Such persons may be better candidates for aggressive therapy to delay onset of diabetes. Major detrimental outcomes with pre diabetes are macrovascular disease and type 2 diabetes, the leading contributors to microvascular disease. Macrovascular disease occurs both before and after the onset of diabetes but microvascular disease occurs several years after conversion to diabetes.

4.2 AIMS AND OBJECTIVES OF THE STUDY

4.2.1 AIMS

To Identify EPI Parameters that draw Correlation with established Biomarkers of Diabetes Type 2 and find

Efficacy of Stop Diabetes Movement (SDM) Yoga module (developed at Yoga University, Bengaluru) through Electro Photonic Imaging (EPI)

4.2.2 OBJECTIVES

1. To study the correlation and establish relationship between Fasting Blood Sugar (FBS) and EPI parameters in type 2 diabetic population. (**constitutes study 1**)
2. To study the correlation and establish relationship between glycated hemoglobin (HbA1c) and EPI parameters in type 2 diabetic population. (**constitutes study 2**)
3. To study Diabetes type 2 through the prism of EPI in that
 - i. study the trend in normal, pre diabetic and diabetic type 2 subjects as measured by EPI technique. (**constitutes study 3**)
 - ii. to study the difference between controlled and uncontrolled diabetes through EPI parameters. (**constitutes study 4**)
 - iii. To see the effect of seven day Yoga Program (SDM) Module in diabetic type 2 patients using EPI technique. (**constitutes study 5**)

4.3 RESEARCH QUESTION

1. Can we have a mathematical model which establishes an equation between FBS and EPI parameters.
2. Can HbA1c be used as a marker for correlation with EPI parameters.
3. Do EPI parameters show a progressive change from normal to pre diabetes and diabetes.
4. Is there any difference in EPI parameters in controlled and uncontrolled diabetes type 2.
5. Can 07 day SDM Yoga program improve EPI parameters in diabetic type 2 subjects.

4.4 HYPOTHESES

Ha1: There will be a correlation between FBS and EPI parameters in normal, pre diabetics and diabetics.

Ha2: There will be a correlation between HbA1c and some EPI parameters in normal, pre diabetics and diabetics.

Ha3: There will be significant change in EPI parameters among normal, pre diabetics and diabetics.

Ha4: There will not be significant difference in EPI parameters between controlled and uncontrolled diabetic type 2 subjects.

Ha5: There will be significant improvement in EPI parameters after seven days of diabetes specific yoga Program (SDM).

4.5 NULL HYPOTHESES

Ha1: There will be no correlation between FBS and EPI parameters in normal, pre diabetics and diabetics.

Ha2: There will be no correlation between HbA1c and some EPI parameters in normal, pre diabetics and diabetics.

Ha3: There will not be significant change in EPI parameters among normal, pre diabetics and diabetics.

Ha4: There will be significant difference in EPI parameters between controlled and uncontrolled diabetic type 2 subjects.

Ha5: There will be no significant improvement in EPI parameters after seven days of diabetes specific yog program (SDM).

4.6 NEED AND SCOPE OF THE STUDIES

4.6.1 CORRELATIONAL STUDY

All the research work and practices through EPI are confined to comparing EPI parameters in various conditions. It could be a population survey, interventional study (pre-post) or observational study. The reference is EPI itself which is not yet an internationally accepted marker. If we take the case of diabetes type 2, there are accepted biomarkers for testing of diabetes e.g., FBS and HbA1c. It is very important to establish correlation between acknowledged biochemical parameters and EPI parameters to have interusability in hollistic medicine. Therefore, present study focuses on the establishment of this correlation between EPI parameters and biochemical parameters viz., FBS and HbA1c. This will enable EPI to integrate into modern medicine in case of diabetes which can be extended to other diseases as well.

4.6.2 YOGA BASED TECHNIQUE

Prevalence of stress is one of reasons for diabetes type 2. Yog is an established way of life for stress reduction. The underlying principle of Yoga practice through asanas is stimulations followed by relaxation. This reduces sympathetic activity (Vempati & Telles, 2000) and increases parasympathetic activity (Sarang & Telles, 2006). In medical connotation it is indicative of stress reduction. There are many methods to measure stress level both subjective and objective. EPI method has also been used to measure stress levels (Korotkov et al., 2012). Because of its multiple advantages, as non-invasive, objective, cost effective, time saving and easy method for quick health assessment, its clinical use could be profound.

4.6.3 DIABETES SPECIFIC YOGA MODULE (SDM)

Yoga is recognized by World Health Organization (WHO) as a practice for prevention and management of diseases. Looking at the challenges that diabetes throws at global medical community, SVYASA University has launched a Stop Diabetes Movement(SDM) campaign to educate the masses about diabetes and restrict its spread through Yogic way of life . SDM module developed has the components for aligning energies at all Pancakosa (five layer of human) levels. According to yoga philosophy, stress is a primary cause of diseases. Stress in Manomaya (mind related) Kosa level leads to imbalances in Pranamaya (energy related) Kosa level and over a period of time, it percolates to physical level manifesting in the form of diseases in energy imbalanced organs (Nagarathna & Nagendra, 2009). EPI can assess these physiological conditions of a person.This information is available through energy diagrams and parameters (Korotkov et al., 2012). EPI technique is non-invasive and a quick assessment of all physiologicalsystems can be done in a couple of minutes and no laboratory costs. Thus the EPI technique could play an important role in monitoring and prevention of diseases.