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ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH

The need for uniform ethical guidelines for research on human subjects is universally recognised. It has acquired a new sense of urgency as the critical issues in the area of biogenetic research involving human subjects have become acute. Apart from the mandatory *clinical trails on new drugs, a number of diagnostic procedures, therapeutic interventions and prevention measures* including the use of vaccines, are being introduced which involve human subjects. Further the advent of *new medical devices and radio-active materials* and therapeutic benefits of *recombinant DNA products* have added a new dimension to the ethical issues that need to be considered before evaluating these for their efficacy, utility and safety.

Any research using the human beings as subjects shall bear in

mind the following principles of : i) **essentiality**, (ii) **voluntariness**, **informed consent**, (iii) **non exploitation**, (iv) **privacy and confidentiality**, (v) **precaution and risk minimisation**, (vi) **professional competence**, (vii) **accountability & transparency**, (viii) **maximisation of public interest and distributive justice** (ix) **institutional arrangements** (x) **public domain** (xi) **totality of responsibility** and (xii) **compliance**.

Recent advances in the field of **Assisted Reproductive technologies, organ transplantation, Human genome analysis, and gene therapy** promise unquestionable benefits to mankind. At the same time, they raise many questions of law and ethics, stimulating public interest and concern.

(Source : ICMR Publication 2000)

Literature Review

Compiled by Dr. PD Gulati

Decline of renal function is associated with proteinuria and systolic blood pressure in the morning in diabetic nephropathy. Suzuki H, Kanno Y, Nakamoto H, Okada H, Sugahara S. *Clin Exp Hypertens.* 2005 27(2-3):129-38.

The aim of this study was to investigate a significance of increased proteinuria in the morning and the effects of antihypertensive treatment on proteinuria and arterial blood pressure in the progression of chronic renal insufficiency in type 2 diabetic patients with hypertension and nephropathy. In three 24-hr urine samples and blood pressure monitoring, separated into a night- and daytime and spot urine in the morning, variation in protein-creatinine ratio (g/g) and blood pressure were assessed in 24 (58 ± 3years old; M/F: 17/7) diabetic patients with hypertension and nephropathy. Furthermore, the effects of antihypertensive therapy of combinations of angiotensin converting enzyme (ACE) inhibitor, calcium antagonists, diuretics, and alpha blocker were evaluated in 3 years. Home blood pressure measurement was carried out every month and 24-hr urine was collected every 2 months. The baseline urine excretion of protein-creatinine ratio and blood pressure were (1.22 ± 0.13 g/g creatinine: 154/96 ± 6/5 mmHg) in daytime and (1.39 ± 0.13: 168/88 ± 15/7) in the morning. At the end of the study, significant associations among a decline of 24-hr creatinine clearance and both of the urine excretion of protein-creatinine ratio (r=0.47, p<.01) and the levels of systolic blood pressure (r=0.46, P<.01) and between the levels of systolic blood pressure and the urine excretion of protein-creatinine ratio in the morning (r=0.57, p<.001) were demonstrated. However, there were no significant associations among other variables. Analysis of patients who had systolic blood pressure in the morning less than 140 mmHg revealed that 65% of these patients received doxazosin-averaged

doses of 4.8 ± 1.5mg daily. The levels of both blood pressure and proteinuria-creatinine ratio in the morning mainly associate with progression of renal function in diabetic patients with hypertension and nephropathy.

Why Are Indian More Prone to Diabetes. V. Mohan. *JAPI.* 2003; 780-781.

Diabetes, a global public health problem, is now emerging as a pandemic and by the year 2025, three-quarters of the world's 300 million adults with diabetes will be in non-industrialized countries and almost a third in India and China alone. There is evidence from several studies that the prevalence of Type 2 diabetes is increasing in migrant Indians. Today, the prevalence of diabetes in the urban metros of India is approaching the figures reported in the affluent migrant Indians. Environmental and lifestyle changes resulting from industrialization and migration to urban environment from rural settings may be responsible to a large extent, for this epidemic of Type 2 diabetes in Indians. Obesity, especially central obesity and increased visceral fat due to physical inactivity, and consumption of a high-calorie/high-fat and high sugar diets are major contributing factors. There is also strong evidence that Indians have a greater degree of insulin resistance and a stronger genetic predisposition to diabetes. As several of the factors associated with diabetes are potentially modifiable, the epidemic of diabetes can be curbed if proper measures are taken to increase physical activity and reduce obesity rates in adults, and most importantly, in children. In addition, strategies to achieve healthy fetal and infant growth and encouraging the use of traditional diets rich in fibre are also important steps. Such interventions should be attempted in those who are genetically predisposed to diabetes in order to tackle explosion of, and thereby reduce the burden due to, diabetes within the Indian subcontinent.