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Summer 7-1-2017

Estimated Glomerular Filtration Rate (eGFR) for Indians and effectiveness of a Disease Management Program (DMP) in controlling the progression of chronic kidney disease.

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ABSTRACT

Background

Chronic Kidney Disease is expected to increase with increasing prevalence of hypertension and diabetes in India. The common cause for Chronic Kidney Disease (CKD) is hypertension and diabetes mellitus. Annually 1,00,000 new patients with End Stage Renal Disease (ESRD) start dialysis in India (Modi & Jha, 2006). In India, diabetes and hypertension account for 40-60% cases of CKD (Rajapurkar, et al., 2012). The present research was done to find estimated Glomerular Filtration Rate (eGFR) among healthy Indian males and to assess effectiveness of a disease management program on progression of CKD. The objectives of the study were: to find the reference range of eGFR for Indian population by using Cockcroft – Gault (CG), MDRD (Modification of Diet in Renal Disease) and Chronic Kidney Disease – Epidemiology (CKD-EPI) formulae, study the extent of agreement between CG, MDRD and CKD – EPI estimated Glomerular Filtration Rate calculation formulae, and assess effectiveness of Disease Management Program (DMP) in terms of change in eGFR among participants with hypertension or diabetes or both.

Method

Quantitative approach and descriptive survey design was used for the phase I to find the reference range of eGFR and an evaluative survey design was considered in phase II since the aim was to find the effect of disease management program on eGFR. Purposive sampling technique was used for the study. The sample consisted of 1003 healthy volunteers for phase I and 103 sample with hypertension, diabetes or both for five or more years for phase II. Evaluative survey with one group pretest - posttest design was selected to determine the effectiveness of a Disease

Management Program in phase II. Phase I was Abstract iv carried out at Manipal Acunova Kasturba Hospital Clinical Research Centre and data were collected about age, gender, height, weight, serum creatinine from healthy volunteers. Estimated GFR was calculated by applying CG, MDRD and CKD – EPI formulae. The setting chosen for phase II was Udyavara, Malpe, Kadekar, Katapadi community area of Udupi district, Karnataka state. The RMCW (Rural Maternity and Child Welfare) centres in these areas were selected. In Phase II during the baseline observation (O1), data about age, height, weight were collected. Also blood for serum creatinine estimation was collected. Blood pressure and Random Blood Sugar (RBS) were also checked. After blood collection intervention given was teaching about management of Hypertension and Diabetes Mellitus. At the fourth and the eighth month after the intervention blood pressure and RBS were tested to know the status of blood pressure and blood sugar and teaching reinforced. After one year blood pressure, RBS and serum creatinine, were tested. Baseline and one year follow up blood pressure, RBS, serum creatinine and eGFR were compared to see interval changes during one year follow up.

Results

The analysis of phase I revealed that majority (96.3%) of the participants were between the age group of 18-40 years, majority (87%) of them were having serum creatinine less than 1mg/dl and 94.1% of them were having normal (18-25) Body Mass Index (BMI). Reference range of eGFR as per percentiles (2.5 & 97.5), by using CG formula was 82 to 157 ml/min/1.73 m², MDRD formula, 82 to 155 ml/min/1.73 m² and CKD- EPI formula, 88 to 135 ml/min/1.73 m², as per mean \pm 2SD eGFR for CG & MDRD was 114 ± 38 (76 to 152), CKD- EPI 115 ± 24 (91 to 139) ml/min/1.73 m², as per P30 i.e. 30% difference of mean for CG and MDRD was 80 to 148 and CKD – EPI was 81 to 150 Abstract v ml/min/1.73 m². The difference between eGFR measurement

within 30%, by using CG, MDRD and CKD –EPI formulae, showed 988 (98.5%), 990 (98.7%) and 1003 (100%) of the values are within 30% difference between CG&MDRD, CKD-EPI & CG and MDRD & CKD - EPI respectively.

Sample characteristics of phase II at baseline and at one year follow up showed 84.5% & 87.5 % of them belong to the age group of 51years and above, 50.5% & 51.1% of them were females, and 47.6% & 46.6% of them were hypertensive, 97.10% & 93.18% of them have serum creatinine level within normal limit. At baseline duration of illness was five to ten years among 75.90% of hypertensive & 77.78% of diabetics. At baseline most (69.44%) of them were having systolic blood pressure of 141-220mm of Hg, 29.78% of them were having RBS level of 201-400mg/dl. At one year follow up mean systolic blood pressure reduced by 6 mm of Hg and mean RBS by 24mg/dl. During one year follow up 40 (55%) participants remained in the same stage of systolic hypertension, whereas 25(35%) improved and 7(10%) deteriorated.

At one year follow up , according to MDRD formula 50 (57%) participants remained in the same stage of CKD, whereas 3(4%) improved and 35(40%) deteriorated, as per CKD - EPI formula 49 (56%) participants remained in the same stage of CKD, whereas 6(7%) improved and 33(37%) deteriorated, as per CG formula 53 (60%) participants remained in the same stage of CKD, whereas 3(4%) improved and 32(36%) deteriorated. Comparison of CKD stages by using CG, CKD – EPI & MDRD formulae at entry show that 25%, 9.10% % and 6.8% of participants were having CKD stage three respectively. At one year follow up 40.9%, 20.5% % and 27.30% of participants were having CKD stage three by using CG, Abstract vi CKD- EPI & MDRD formulae respectively. Agreement between MDRD, CG and CKD-EPI eGFR equations was done by using Kappa statistics. Fair agreement between CG & CKD – EPI (0.36), CG & MDRD (0.25) and a good agreement between MDRD & CKD-EPI GFR (0.78) was found.

Median, median difference, and 'Z' value of pre and post intervention eGFR of participants show significant difference in median eGFR from baseline to one year. The change in eGFR observed from pre intervention to post intervention was 16, 9 & 5 according to MDRD, CG, and CKD- EPI formulae respectively which is statistically significant ($Z= 6.370, 5.890, 5.925, P < 0.001$). Overall the intervention was not effective in decreasing the progress of CKD statistically. Hence the null hypothesis was accepted and it is inferred that disease management program was not effective. During one year follow up 45.2% (both hypertensive & diabetic), 43.8% (diabetics) and 26.8% (hypertensive) of participants showed improvement in renal function. This shows that disease management program may be effective in a subset of patients who follow it.

Conclusions

Reference range of eGFR for Indian males is 82 to 157 ml/min/1.73 m² as per MDRD and CG formulae, 88 -135 ml/min/1.73 m² as per CKD - EPI formula. Most of the participant's blood pressure (69%) and blood sugar (62%) were uncontrolled. Screening and education may aid in better control. Good agreement (Kappa – 0.78, P30 – 100%) is seen between MDRD and CKD – EPI eGFR measurement.