Assessment of 10-Year Risk of Developing a Major Cardiovascular Event in Type-2 Diabetes Patients Attending a Hospital in Davangere, Karnataka

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ABSTRACT

Background: Diabetes increases the risk of cardiovascular disease (CVD). The aim of this study was to assess the 10-year risk of fatal or non-fatal major cardiovascular events (myocardial infarction or stroke) in type-2 diabetes mellitus patients attending a tertiary care centre in Davangere-Karnataka.

Methods: A cross-sectional study was conducted among diabetics coming to OPD of a tertiary level hospital in Davangere between September 2015-February 2016. 10-year risk of developing a major (fatal or non-fatal) cardiovascular event was assessed using WHO-ISH risk prediction charts.

Results: Of the 311 subjects, 181 (58.2%) were females. 139 (44.69%) had low risk ie.< 10%. 93 (29.9%) and 41 (13.81%) had 10-<20% and 20-< 30 % risks respectively. 16 (5.14%) subjects had 30-<40% risk while 22 (7.07%) had ≥40 % risk. Age more than 60 years, smoking and hypertension were significantly associated with a 10-year cardiovascular risk of ≥20%. Those with prehypertension were at significantly higher risk than those with stage II hypertension.

Conclusion: WHO-ISH charts can help in identifying diabetics at high-risk of CVD and could serve as a tool in planning suitable strategies for the estimated CVD burden in the hospital in near future.

Keywords: Cardiovascular disease, diabetes, WHO-ISH charts

INTRODUCTION

WHO estimates that more than 422 million people worldwide have diabetes.[1] India was estimated to have 69,188 diabetics in 2015, accounting to a prevalence of 8.7%.[2] It was also the largest contributor to regional mortality with 1,065,052 deaths caused due to diabetes 2013.[3] WHO projects that diabetes will be the 7th leading cause of death in 2030. 50% of people with diabetes die of cardiovascular disease (primarily heart disease and stroke).[1]

Studies indicate that morbidity and mortality due to cardiovascular diseases can be minimized by primary and secondary prevention strategies.[4-6] In patients already having diabetes, a non-fatal major cardiovascular event can further deteriorate the quality of life of patients and burden the financial resources of the households in dealing with the resultant cardiovascular complication.[7-9] Therefore, a tool that quantifies the risk of such cardiovascular events in diabetes patients can be of immense value to plan individualized treatment goals, to test efficacy of treatment and health promoting interventions and in order to aid planning, programming and budgeting of future health policies and programs considering the burden that is likely to be anticipated on the health system if the current risk-trend continues.

There is a paucity of such studies in Indian settings despite India bearing a major burden of morbidity

and mortality due to diabetes in the world. Hence, this study is undertaken with the aim of assessing 10-year risk of developing a major (fatal or non-fatal) cardiovascular event i.e. myocardial infarction or stroke, in patients with type-2 diabetes mellitus attending a tertiary level hospital.

METHODS

A cross sectional study was conducted among patients with type 2 diabetes mellitus coming to the general medicine OPD of a tertiary level hospital attached to J.J.M. Medical College, Davangere-Karnataka between the period September 2015-February 2016. All patients who fulfil the inclusion criteria of age 40-80 years, having type 2 diabetes (defined as those taking oral hypoglycemic agents (OHAs) or those with FPG >126 mg/dl or PPPG > 200 mg/dl) were included in the study after obtaining an informed consent. The age limits were fixed based on the age-groups included in the WHO/ISH charts.[10] Patients with severe physical or cognitive impairments, those with past or present history of a major cardiovascular event (MI or stroke) and pregnant women with diabetes were excluded.

10-year risk assessment for fatal or non-fatal major cardiovascular event (myocardial infarction or stroke) was done using the WHO/ISH risk estimation charts.[10] These charts are designed according to age, sex, blood pressure, smoking status, total blood cholesterol and presence or absence of diabetes mellitus for 14 WHO epidemiological sub-regions. India is classified under the SEAR-D sub-region. SEAR-D specific charts for males and females with diabetes were used for the purpose of this study.[10] As cholesterol measurements were not available with many patients, the charts that do not require cholesterol values were used for uniformity.[11] Current smokers and those who quit smoking less than 1 year before the assessment were classified as smokers for this study. Blood pressure of the individual participants was measured 2 times in sitting position using automated blood pressure measuring instrument (OMRON®) and the average systolic BP of the two readings was plotted in the WHO/ISH charts.[10] Hypertension was classified as per JNC-7 criteria.[12] Ethical clearance was obtained from the Institutional Ethical Review Board of J.J.M. Medical College.

STATISTICS: Data was entered in Microsoft Excel 2013 and analysed using SPSS version 19. 10-year risk of developing a major cardiovascular event (fatal or non-fatal) were described in 5 categories viz. <10% risk, 10- < 20% risk, 20- < 30% risk, 30-< 40% risk and ≥ 40% risk as identified by different colours in the WHO/ISH charts.[10] Descriptive sta-

tistics were used to present cardiovascular risk assessment. To test the relative strengths of each of the independent variables namely age, sex, smoking status and systolic BP, the dependent variable that is cardiovascular risk was classified into risk < 30% and ≥ 30% as risk more than 30% is classified as high risk. Pearson's chi square test was used to find association between the variables. P value < 0.05 was considered significant.

RESULTS

A total of 311 subjects were recruited for the study. Of these, 130 (41.8%) were males and 181 (58.2%) were females. The mean age of males was 58.80 years (SD: ± 9.62) and the mean age of females was 57.46 years (SD: ± 9.34). Of all the males, 28 (21.5%) were smokers and the mean age of smokers was 55.2 years (SD: ± 7.98). None of the females in the study were smokers. The mean systolic BP in males was 135.46 mm Hg (SD: ± 18.60) and that in females was 133.80 mm Hg (SD: ± 17.11).

Table 1: 10-year risk of major (fatal or non-fatal) cardiovascular event in the total study population

Risk Categories	Subjects (n=311) (%)
<10 %	139 (44.69)
10- < 20%	93 (29.90)
20- <30%	41 (13.18)
30- <40%	16 (5.14)
≥ 40 %	22 (7.07)

Cardiovascular risk assessment in the total study population (Table 1) showed that majority, i.e. 139 (44.69%) patients belonged to the lowest risk category, with 10-year risk of having a major CVD of <10 %. 93 (29.9%) and 41 (13.81%) belonged to 10-<20% and 20-<30% risk categories respectively. The least number of patients, i.e. 16 (5.14%) was seen in 30- <40% risk category while 2 (7.07%) belonged to ≥ 40 % risk category. Majority of both males (42%) and females (46%) belonged to < 10% risk categories.

Table 2 and 3 show 10-year risk of major (fatal or non-fatal) cardiovascular event in and males females respectively according to age-groups. While the study population in 4th and 5th decades in both sexes essentially belonged to low risk categories in our study, those in 6th decade showed a medium risk. While the males in the 7th decade were spread across all risk categories, the females in the corresponding decade belonged mainly to higher risk categories.

In this study, age more than 60 years, smoking status and hypertension were significantly associated with a 10-year cardiovascular risk of ≥ 20%. Al-

though the males had 1.23 odds of having high risk as compared to females, the association was not found to be statistically significant (P= 0.432). As compared to those with stage II hypertension, those with prehypertension had higher risk (OR= 36.93, C.I.= 13.93- 97.85) of having a high 10-year cardiovascular risk than those with stage II hypertension and this association was statistically significant (P < 0.001).

Table 2: 10-year risk of major (fatal or non-fatal) cardiovascular event in males according to age-groups

10-year cardiovascular risk	Age in completed years (column %)				
	40-49	50-59	60-69	70-79	Total
<10 %	24 (100.0)	31 (77.5)	0 (0)	0 (0)	55 (42.3)
10- < 20%	0 (0)	7 (17.5)	22 (47.8)	10 (50.0)	39 (30.0)
20- <30%	0 (0)	0 (0)	11 (23.9)	7 (35.0)	18 (13.8)
30- <40%	0 (0)	0 (0)	6 (13.0)	0 (0)	6 (4.6)
≥ 40 %	0 (0)	2 (5.0)	7 (15.2)	3 (15.0)	12 (9.2)
Total	**24**	**40**	**46**	**20**	**130**

Table 3: 10-year risk of major (fatal or non-fatal) cardiovascular event in females according to age

10-year cardiovascular risk	Age in completed years (column %)				
	40-49	50-59	60-69	70-79	Total
<10 %	38 (95)	46 (95.8)	0 (0)	0 (0)	84 (46.4)
10- < 20%	1 (2.5)	0 (0)	53 (72.6)	0 (0)	54 (29.8)
20- <30%	0 (0)	0 (0)	14 (19.2)	9 (45)	23 (12.8)
30- <40%	0 (0)	0 (0)	0 (0)	10 (50)	10 (5.5)
≥ 40 %	1 (2.5)	2 (4.2)	6 (8.2)	1 (5)	10 (5.5)
Total	**40**	**48**	**73**	**20**	**181**

Table 4: Univariate Analysis of risk predictors in WHO/ISH chart with 10 year risk of having a major (fatal or non-fatal) cardiovascular event

Variable	Risk ≥20% (%)	Risk <20% (%)	P value	OR (95% C.I.)
Sex				
Males	36 (27.69)	94 (72.31)	0.432	1.23 (0.74-2.06)
Females	43 (23.76)	138 (76.24)		
Age in years				
More than 60	63 (50.81)	61 (49.19)	**< 0.001**	11.04 (5.93-20.55)
Less than 60	16 (8.56)	171 (91.44)		
Smoking				
Smokers	13 (46.43)	15 (53.57)	**0.012**	2.85 (1.29-6.29)
Non-smokers	66 (23.32)	217 (76.68)		
SBP in mm Hg				
120-139 (Prehypertension)	14 (6.93)	188 (93.07)	**< 0.001**	36.93 (13.93- 97.85)
140-159 (Stage I HTN)	43 (54.43)	36 (45.57)		2.30 (0.92-5.79)
160 and above (Stage II HTN)	22 (73.33)	8 (26.67)		1

DISCUSSION:

A G Ghorpade et al[13], in their study done in the rural field practice area of a medical college in South India reported that 83% individuals had low risk (<10%). 6.8% and 10.2% subjects had moderate (10%–20%) and high risk (≥20%) of CVD-related outcome respectively. The study was done in the community and among both diabetics as well as non-diabetics. In a study done by Priya Bansal et al[14] in a rural health training centre in North India, CVD risk (≥10%) was found to be higher in females (59.3%) as compared to males (40.7%). This is in contradiction to the finding in the present study. 56% participants had risk less than 10 % as compared to 44.69% in the present study. Only 27.1% participants in this study were diabetics. Savitharani BB et al[15], in their study done among support staff of a tertiary hospital in Mysuru reported that 98.3% of participants had a 10-year risk of <10%. The fact that only 3.3% of participants in this study had hypertension and 2.2% were known cases of diabetes mellitus on treatment could have contributed to the large percentage under low cardiovascular risk.

Aswin K et al[16], in their study done in JIPMER Pondicherry reported that 3.7% subjects had >10% risk of developing cardiovascular disease in next 10 years. On the other hand, a study done by Shrivastava et al[17] in rural Puducherry reported that the prevalence of low, moderate and high CVD risk in the men was 82.7%, 12.8% and 4.5%, as compared to 88.8%, 5.9% and 5.3% in women respectively. A study done by Fatema K et al[18] in rural population of Bangladesh reported that 78.5 %

of males and 82.7% of females had low risk (<10%). While the percentage of males decreased with successive risk categories from low to very high, the least percentage of females (1.6%) was reported to have 20- <30% risk. The percentage increased to 5.2% in very high risk (≥ 30% risk) category. Only 2.7% of the participants in the study had diabetes, while 75.8% were smokers as compared to 9% in the present study. Khanal MK et al[19] reported that in their study done in rural Nepal, 86.4% had low 10-year CVD risk. Moderate and high risk were seen in 9.3% and 4.3%, respectively. More female (10.5%) than male (7.8%) had moderate risk. 4.5% men and 4.2% women were at high CVD risk.

Due to paucity of published studies assessing 10-year cardiovascular risk among diabetics, the findings of this study cannot be compared with the studies that are done in general population having a relatively smaller percentage of diabetics. This study attempts to provide risk assessment incorporating diabetes as a risk factor for cardiovascular disease in hospital patients so that suitable strategies can be planned to handle the increasing burden of the disease on the health system.

CONCLUSION

In this study, 139 (44.69%) patients belonged to the lowest risk category (<10% risk) while 93 (29.9%) and 41 (13.81%) belonged to 10- < 20% and 20-<30% risk categories respectively. The least number of patients, i.e. 16 (5.14%) was seen in 30- <40% risk category while 22 (7.07%) belonged to ≥ 40 % risk category. An age-sex wise analysis showed that majority of the patients in high risk categories were females in 6th and 7th decades. Age more than 60 years, smoking status and hypertension were significantly associated with a 10-year cardiovascular risk of ≥ 20%. Those with prehypertension had significantly higher risk of having a high 10-year cardiovascular risk than those with stage II hypertension.

RECOMMENDATIONS

Recent research suggests the use of a total risk approach to guide treatment decisions in cardiovascular disease patients. As the study showed that 44.69 % of the total patients coming to the OPD of our hospital belonged to a low 10-year risk i.e less than 10%, there is ample scope for implementing secondary prevention strategies in these patients. As the WHO-ISH charts yield useful information, these can be used by the doctors in the OPD not only to plan treatment goals for the patients but also to educate patients about their risk status. On the other hand, these charts can be of immense use

to the institution to estimate the number of major cardiovascular events averted over a period of time and the kind of services the hospital needs to be equipped with in the near future.

LIMITATIONS

The WHO/ ISH charts lack external validation in the Indian subcontinent and paucity of such studies limits the predictive value of these charts. As the WHO/ ISH charts used in this study use a combination of only 5 risk factors to predict the patient's cardiovascular risk, the predicted risk is an under-estimation, as other risk factors such as family history, dyslipidemia, sedentary lifestyle, etc. are not considered. Though the study uses charts designed for diabetic patients, these WHO/ ISH charts do not factor in glycemic control status of diabetics.

REFERENCES:

1. Global report on diabetes. Geneva: World Health Organization; 2016.

2. India. International Diabetes Federation. Available from: http://www.idf.org/membership/sea/india Accessed on 07-04-2017

3. IDF Diabetes Atlas. 7th edition. Brussels: International Diabetes Federation; 2015. Available from http://www. diabetesatlas.org/ Accessed on 07-04-2017

4. Taylor F, Huffman MD, Macedo AF, Moore TH, Burke M, Davey Smith G, et al. Statins for the primary prevention of cardiovascular disease. Cochrane Database of Systematic Reviews. 2013; 1: CD004816. Available from: http://doi. wiley.com/10.1002/14651858.CD004816.pub5 Accessed on 06-04-2017

5. Halvorsen S, Andreotti F, Ten Berg JM, Cattaneo M, Coccheri S, Marchioli R, et al. Aspirin Therapy in Primary Cardiovascular Disease Prevention. Journal of the American College of Cardiology. 2014;64(3):319–27.

6. Akesson A, Larsson SC, Discacciati A, Wolk A. Low-Risk Diet and Lifestyle Habits in the Primary Prevention of Myocardial Infarction in Men. Journal of the American College of Cardiology. 2014;64(13):1299–306

7. Impact of Intensive Lifestyle Intervention on Depression and Health-Related Quality of Life in Type 2 Diabetes: The Look AHEAD Trial. Diabetes Care. 2014;37(6):1544–53.

8. Chauhan AS, Mukherjee K. Economic burden of coronary heart disease in North India. Int J Non–Commun Dis 2016;1:18–25.

9. Jan S, Lee SW-L, Sawhney JP, Ong TK, Chin CT, Kim H-S, et al. Catastrophic health expenditure on acute coronary events in Asia: a prospective study. Bulletin of the World Health Organization. 2016;94(3):193–200.

10. WHO/ISH risk prediction charts for 14 WHO epidemiological sub-regions. Available on http://ish-world.com/

downloads/activities/colour_charts_24_Aug_07.pdf   Accessed on 07-04-2017

11. Otgontuya D, Oum S, Buckley B, Bonita R. Assessment of total cardiovascular risk using WHO/ISH risk prediction charts in three low and middle income countries in Asia. BMC Public Health. 2013;13(1):539. doi: 10.1186/1471-2458-13-539.

12. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Bethesda: NHLBI Health Information Center; 2004. Available on https://www.nhlbi.nih.gov/files/docs/guidelines/jnc7full.pdf Accessed on 07-04-2017

13. Ghorpade AG, Shrivastava SR, Kar SS, Sarkar S, Majgi SM, Roy G. Estimation of the cardiovascular risk using World Health Organization/International Society of Hypertension (WHO/ISH) risk prediction charts in a rural population of South India. Int J Health Policy Manag. 2015;4(8):531–6.

14. Bansal P, Chaudhary A, Wander P, Satija M, Sharma S, Girdhar S, et al. Cardiovascular Risk Assessment Using WHO/ISH Risk Prediction Charts In a Rural Area of North India. Journal of Research in Medical and Dental Science. 2016; 4(2):127-31.

15. Savitharani BB, Madhu B, Renuka M, Sridevi, Ashok NC. Utilization of WHO-ISH 10-year CVD risk prediction chart as a screening tool among supporting staff of a tertiary care hospital, Mysuru, India. Heart India 2016;4:13-6.

16. Aswin K, Arun GG, Sitanshu S K, Ganesh K. Cardiovascular disease risk factor profiling of group C employees in Jipmer, Puducherry, Journal of family medicine and primary care, 2014; 3(3):255-9.

17. Shrivastava SR, Ghorpade AG, Shrivastava PS. A Community-based Cross-sectional Study of Cardiovascular Risk in a Rural Community of Puducherry. Heart Views. 2015; 16(4): 131-6.

18. Fatema K, Zwar NA,Milton AH,et al. Application of two versions of the WHO/international society of hypertension absolute cardiovascular risk assessment tools in a rural Bangladeshi population. BMJ Open 2015;5:e008140. Available on http://bmjopen.bmj.com/ Accessed on 30-10-2016

19. Khanal MK, Ahmed MSAM, Moniruzzaman M, Banik PC, Dhungana RR, Bhandari P, et al. Total cardiovascular risk for next 10 years among rural population of Nepal using WHO/ISH risk prediction chart. BMC Research Notes. 2017;10(1). doi: 10.1186/s13104-017-2436-9