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Original Article

Prevalence and Predictors of Metabolic Syndrome and Its Association with Vitamin D Deficiency in Patients with Newly Onset Type 2 Diabetes Mellitus: A Cross Sectional Study

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ABSTRACT

Introduction: Prevalence of metabolic syndrome (MS) is remarkably variable in India. There is lack of data with regard to prevalence and predictors of MS and vitamin D deficiency (VDD) from eastern part of Uttar Pradesh. We designed this study in order to know the prevalence and predictors of MS and it's association with VDD from this area. **Materials and Methods:** A cross sectional study was conducted at Varanasi. Data was collected from newly onset diabetic patients over a period of one year. **Results:** Among 309 diabetic patients, 71.84%, 73.79%, 77.02% and 83.17% were found to have MS by different criteria. Central obesity was the highest predictor of MS. This is followed by raised triglyceride, low high density lipoprotein cholesterol and hypertension. VDD was found in 59.09% and 70.21% of male and female patients respectively. VDD was more prevalent in MS patients. **Conclusion:** Prevalence of MS is very high in newly onset diabetic patients and it is strongly associated with VDD. Hence routine screening of MS and VDD in newly onset diabetic patients is essential for early diagnosis and treatment of both conditions to prevent the cardiovascular disease.
Keywords: Metabolic syndrome, Diabetes mellitus, Vitamin D deficiency, Prevalence.

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INTRODUCTION

Metabolic syndrome (MS) and Vitamin D deficiency (VDD) is highly prevalent in India and in the world.[1,2] Currently 20-25% of world's adult population is suffering from MS.[1] Globally it is estimated that nearly 1 billion people have either VDD or vitamin D insufficiency.[3] Prevalence of MS and VDD in general population is more in India than western countries.[4] In diabetic patients prevalence of each disorder is higher than in the nondiabetic population.[5] MS and VDD both are linked with increased chance of development of diabetes mellitus (DM) and cardiovascular disease (CVD).[6,7] Relevance of both in recent time has been increased because of rise in obesity and faulty life style. Obesity and overweight are a risk factor for both, MS and VDD. Prevalence of DM is increasing and so is morbidity and mortality related to DM. So, there is a need for innovative approach for management of DM. Diagnosing and treating vitamin D deficiency can be one such approach because in pathogenesis of MS, DM and CVD, VDD has been implicated and if we control VDD than we can control blood glucose effectively and prevent development of CVD.

MS is defined as clustering of cardio-metabolic risk factors namely; central obesity, insulin resistance, hypertension, atherogenic lipid profile, low grade inflammation and prothrombotic state.[7] In general MS is associated with 2-3-fold increase risk of atherosclerotic CVD and 5-fold increased risk for incident type-2 diabetes mellitus. Gami *et al.* in a meta-analysis, found that the overall relative risk for incident of death and CVD events for individual with MS was 1.78 (95% CI, 1.58-2.00).[8] A metanalysis by Ford *et al.* found that relative risk (RR) of 3.5-5.2 for incident diabetes with any MS criteria.[9] Other condition associated with MS are fatty liver, sleep apnea, polycystic ovarian disease, hypogonadism, lipodystrophy and microvascular disease.[7]

Recently role of VDD has been implicated in the pathogenesis of CVD, type 2 diabetes mellitus, hypertension, insulin resistance, dyslipidemia.[10-12] Aus-Diab study proved that VDD was associated with an increased risk of developing DM and MS at a 5 year follow up.[13] Nurse Health Study by Pittas *et al.* also found that VDD is a predisposing factor for developing DM.[14] Vitamin D act directly by stimulating the expression of insulin receptors and amplifying the glucose transport. Elevated PTH as a consequence of VDD has been shown to reduce insulin sensitivity and to inhibit insulin synthesis and secretion from β- cells.[15,16] Various cross-sectional data have reported that VDD is associated with more

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risk of CVD. Various mechanism through which Vitamin D protects against CVD are; down-regulation of RAS system, direct effect on heart, improvement of glycemic control and reduction in inflammatory cytokines. Several intervention studies shows that supplementation with Vitamin D is associated with improvement with insulin sensitivity but many did not show the positive result in prevention of DM. Conflicting results in various studies are due to different population studies, chemical formulations of Vitamin D, different dose of Vitamin D and time of supplementation.

Prevalence of MS and VDD differ in different ethnic groups due to different life style, different gene and different distribution of risk factors. High risk of morbidity and mortality associated with MS and VDD needs more studies to know the exact magnitude of problem in a particular area. There is little data available for prevalence and predictor of MS and VDD from eastern part of Uttar Pradesh. This study is aimed at to assess the prevalence and predictor of MS and VDD from this area in newly onset type 2 DM using four different criteria.[17-20] Further our aim is to explore the differences and similarities among these definitions of MS.

MATERIALS AND METHODS

To know the prevalence and predictors of MS and its association with VDD in newly diagnosed DM patients we did a cross sectional study at our endocrine clinic at Varanasi between February 2020 to January 2021 after obtaining a clearance from local ethical committee (Opal hospital). 336 recently diagnosed (duration < 1 year) type 2 diabetic patients were included in present study. 27 patients were excluded from the study as they were either Type 1 DM or suffering from chronic liver disease and/or chronic renal failure. Diagnosis of diabetes mellitus was based on ADA 2010 criteria. Data regarding age, sex, weight, height, BMI (body mass index), A1c, BP (blood pressure), and Vitamin D level were collected from patients on proforma. Weight was measured by a automated weighing machine. Height was measured by standard stadiometer with good precision. For measurement of height, patient were asked to remove footwear and stand with head kept in Frankfort position. BMI was calculated by dividing the weight (in kg) by square of height (in meter). BP was measured by digital BP machine.

8 ml venous blood was collected for A1c, FPG (fasting plasma glucose), total Vitamin D, lipid profile and creatinine. Glucose oxidase- peroxidase method was used for measurement of blood glucose. Vitamin D level was analyzed on Siemens ADVIA Centaur, standardized against ID-LC/MS/MS, as per Vitamin D standardization (thyrocare). Creatinine was analysed by creatinine enzymatic method. Lipid profile was analysed by standard enzymatic procedure. To rule out cirrhosis ultrasonography was done. Vitamin D deficiency was diagnosed, when the level was < 20 ng/ml. MS was diagnosed by four different diagnostic criteria given by IDF, Modified WHO (microalbuminuria excluded), NCEP-ATP III and Modified NCEP-ATP III.[17-20]

Statistical Analysis

The collected data were entered into a Microsoft office excel spread sheet and analyzed. Ratio and percentages were used for analysis. Excel function like mean, standard deviation and *t*-test were used. Student's *t*-test and Chi-Square test were used to determine statistical difference between variables. Results were considered significant if p value were <0.05.

RESULTS

In this study 309 patients were recruited and of this 215(69.58%) were male and 94(30.42%) were female. Male and female ratio was 2.29:1. Mean ± SD age was 46.93±10.71, 47.08±11.28 and 46.57±9.33 years for all, male and female patients respectively and it was not statistically different (p <0.679) between male and female. Mean± SD glyHbA$_{1c}$ was 9.82±2.63, 10.01±2.63 and 9.39±2.58% for all, male and female patients respectively and it was also not statistically different (p<0.0534) between the two. Metabolic Syndrome (MS) was diagnosed in 71.84%, 73.79%, 83.17% and 77.02% of all patients according to Modified WHO, NCEP-ATP III, Modified NCEP-ATP III and IDF criteria, respectively. After stratification by gender, 151 (70.23%) male and 71 (75.53%) female, 148 (68.48%) male and 80 (85.17%) female, 177(82.33%) male and 80 (85.11%) female, 161 (74.88%) male and 77 (81.91%) females, had MS according to WHO(Modified), NCEP-ATP III, NCEP-ATP III and IDF criteria, respectively. Regarding the prevalence of MS according to different criteria we find the difference in gender distribution for prevalence which is shown in Table 1. Prevalence of MS is more in female than male by all criteria but difference is statistically significant with only with NCEP-ATP III criteria.

Demographic and baseline characteristics of patients with MS versus those without MS according to MODIFIED NCEP-ATP III criteria are summarized in Table 2. Mean ± SD age, BMI, WC, SBP, DBP, GlyHbA1c, HDL, and TG in MS patients were 47.26±10.53 (Year), 27.03±4.29 (Kg/M^2), 98.78±8.71(CM), ±216.08±115.97 (mg/dl) respectively. Mean ± SD age, BMI, WC, SBP, DBP, GlyHbA1c, HDL, and TG in patients without MS were 45.31±11.56 (Year), 23.47±3.69 (Kg/M^2), 90.44±8.74 (CM), 115.69±10.73 (mm-Hg), 75.62±7.09(mm-Hg), 10.83±2.98(%), 47.65±9.42 (mg/d) l and 118±37.42 (mg/dl) respectively. All parameters (except for age) were statistically different in two groups.

Presence of various components of MS is shown in Table 3. Except for TG other components of MS wERE seen more in female as compared to men. Hypertension (≥130/85 mmHg) was present in 55.02%, 54.42% and 56.38% of all, male and female patients, respectively. Central obesity (≥90 cm in male, ≥80 cm in female) was present in 87.06%, 83.72% and 94.68% of all, male and female patients, respectively. Raised TG was seen in 61.81%, 64.65% and 55.32% of all, male and female patients, respectively. Low HDL (<40 mg/dl in male, <50 mg/dl in female) was present in 56.96%, 52.56% and 68.09% of all, male and female patients, respectively. Obesity (BMI≥30) was present in 16.83%, 15.35% and 20.21% of all, male and female patients, respectively. Central obesity and low HDL were more prevalent in female patients and it was statistically significant. Prevalence of hypertension, raised TG and obesity (BMI≥30) was not statistically significant in two groups.

According to Modified WHO criteria 42.79% were positive for 3 risk factors, 41.89% were positive for 4 risk factors and 15.32% were positive for 5 risk factors. According to NCEP-ATP III criteria 39.91% were positive for 3 risk factors, 39.91% were positive for 4 risk factors and 20.18% were positive for 5 risk factors. According to Modified NCEP-ATP III criteria 30.35% were positive for 3 risk factors, 43.19% were positive for 4 risk factors and 26.46% were positive for 5 risk factors. According to IDF criteria 27.31% were positive for 3 risk factors, 44.12% were positive for 4 risk factors and 28.57% were positive for 5 risk factors. This shows that in MS patients 4 risk factors are more prevalent than 3 risk factors in most criteria except by Modified WHO criteria.

Pie chart showing the proportion of no. of positive criteria in patients with MS according to different criteria.

Degree of agreement between different criteria is shown in Table 4. Degree of agreement between Modified WHO and NCEP-ATP III (Modified) was 88.03%. Degree of agreement between Modified WHO and IDF was 92.88% while it was 93.85% between NCEP-ATP III (Modified) and IDF. Degree of agreement was highest between NCEP-ATP III (Modified) and IDF.

Predictors of MS in present study population were shown in Table 5. We found central obesity as the highest predictor for MS with prevalence ratio of 1.86. This is followed by raised TG, low HDL and hypertension.

Table 1: Prevalence of MS according to different definition.

Parameter	Male	Female	Total	*p* value
Number	215 (69.58%)	94 (30.42%)	309 (100%)	-
Age	47.08 ±11.28	46.57 ±9.33	46.93 ±10.71	<0.679
$GlyHbA_{1c}$	10.01 ±2.64	9.38 ±2.58	9.82 ±2.63	<0.534
MS(WHO-Mod)	150 (70.23%)	71 (75.53%)	22 (71.85%)	<0.340
MS (NCEP-ATP III)	148 (68.84%)	80 (85.12%)	228 (73.79%)	<0.0027
MS (NCEP-ATP III-Mod)	177 (82.33%)	80 (85.11%)	257 (83.17%)	<0.547
MS(IDF)	161 (74.88%)	77 (81.91%)	238 (77.02%)	<0.176

Table 2: Comparison of clinical data among MS and non- MS patients by NCEP-ATP III (Modified).

Variable	Metabolic syndrome present	Metabolic syndrome absent	*p* value
Number	257 (83.17%)	52 (16.83%)	-
Age	47.26 ±10.53	45.31 ±11.56	<0.263
BMI	27.03 ±4.29	23.47 ±3.699	<0.0001
WC	98.78 ±8.71	90.44 ±8.74	<0.0001
SBP	133.1 ±17.80	115.69 ±10.73	<0.0001
DBP	85.86 ±10.495	75.62 ±7.09	<0.0001
HDL	39.87 ±9.11	47.65 ±9.42	<0.0001
TG	216.08 ±115.97	118 ±37.42	<0.0001
$GlyHbA_{1c}$	9.614 ±2.51	10.83 ±2.97	<0.007

Table 3: Distribution of various criteria for diagnosis of MS.

Variable	Male	Female	Total	*p* value
LOW HDL (M=<35, F=<39	61 (28.84%)	33 (36.17%)	94 (30.42%)	<0.236
LOW HDL (M=<40, F=<50	113 (52.56%)	63 (68.09%)	176 (56.96%)	<0.0181
High TG	139 (64.65%)	52 (55.32%)	191 (61.81%)	<0.120
BMI (≥30)	33 (15.35%)	19 (20.21%)	52 (16.83%)	<0.293
WC (M=≥102, F≥88)	79 (36.74%)	84 (89.36%)	163 (52.75%)	<0.0001
WC (M=≥90, F≥80)	180 (83.72%)	89 (94.68%)	269 (87.06%)	<0.008
BP (≥130/85)	117 (54.42%)	53 (56.38%)	170 (55.02%)	<0.749
BP (≥140/90)	93 (43.26%)	43 (45.74%)	136 (44.01%)	<0.685

Table 4: Degree of agreement between definitions.

Criteria	Percent agreement
WHO(Mod) and NCEP-ATP III (Mod)	88.03%
WHO (Mod) and IDF	92.88%
NCEP-ATP III (Mod) and IDF	93.85%

Prevalence ratio for raised TG, low HDL and hypertension in our study is 1.65, 1.476 and 1.46 respectively.

Mean± SD Vitamin D level was 19.43±10.16, 20.03±9.74 and 18.06±10.99 ng/dl for all, male and female patients, respectively. Vitamin D level in male was more than female but it was not statically significant (p <0.1357) as shown in Table 6. Vitamin D level in patients with MS were less than that in patients without MS and it was statically significant. MS defined by all four criteria shows the similar pattern. (Table 7). Prevalence of VDD (Vitamin D level <20 ng/dl) in patients with MS was 67.57%, 66.67%, 65.76% and 65.97% by Modified WHO, NCEP-ATP III, Modified NCEP-ATP III and IDF criteria, respectively. Prevalence of VDD (Vitamin D level <20 ng/dl) in patients with MS was statistically more as compared to patients without MS by all criteria (Table 8).

Table 5: Predictors of MS in present study.

Parameter	Prevalence ratio	*p* value
HYPERTENSION	1.46	<0.0001
HIGH WC	1.86	<0.0001
HIGH TG	1.65	<0.0001
LOW HDL	1.476	<0.0001

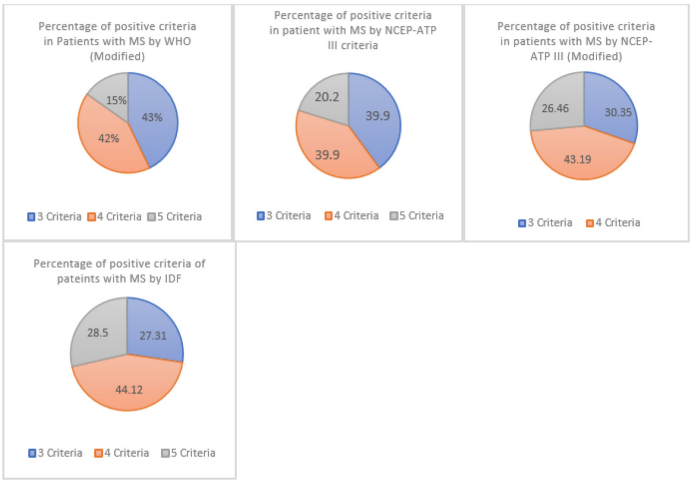

Table 6: Vitamin D level and VDD in male and female.

Parameter	Male	Female	Total	*p* value
Vit D LEVEL (ng/dL)	20.03 ±9.74	18.06 ±10.99	19.43 ±10.16	<0.135
Vit D (<20 ng/dL)	127 (59.07%)	66 (70.21%)	193 (62.46%)	<0.0627
Vit D (>20 ng/dL)	88 (40.93%)	28 (29.79%)	116 (37.54%)	

Table 7: Vitamin D level in MS and non-MS patients.

Criteria	Metabolic syndrome	Vitamin D	*p* value
WHO (Modified)	Present	18.25 ±9.35	<0.003
	Absent	22.438 ±11.51	
NCEP-ATP III	Present	18.5 ±9.75	<0.0125
	Absent	21.998 ±10.91	
NCEP-ATP III (Modified)	Present	18.79 ±9.74	<0.0346
	Absent	22.53 ±11.67	
IDF	Present	18.72 ±9.55	<0.048
	Absent	21.78 ±11.77	

Table 8: Prevalence of VDD in MS and non-MS patients.

Parameter	Metabolic Syndrome	Vitamin D (<20 ng/dl)	Vitamin D (>20 ng/ml)	*p* Value
WHO(Modified)	Present (222)	151 (68.02%)	71 (31.98%)	<0.0023
	Absent (87)	43 (49.43%)	44 (50.57%)	
NCEP-ATP III	Present (228)	152 (66.67%)	76 (33.33%)	<0.0103
	Absent (81)	41 (50.61%)	40 (49.38%)	
NCEP-ATP III(Modified)	Present (257)	169 (65.76%)	88 (34.24%)	<0.007
	Absent (52)	24 (46.15%)	28 (53.85%)	
IDF	Present (238)	157 (65.97%)	81 (34.03%)	<0.0197
	Absent (71)	36 (50.70%)	35 (49.30%)	

DISCUSSION

Prevalence of MS in present study varies from 71.84% to 83.17% by different criteria. In our study prevalence of MS was maximally shown by Modified NECP-ATP III criteria and this could due to lower BP criteria used as compared to Modified WHO criteria and lower WC criteria as compared to NCEP-ATP III criteria. High prevalence as compared to IDF criteria was due to central obesity as an essential criterion in IDF criteria and 12.94% patients in our study are not centrally obese. High prevalence of MS in diabetic patients are shown by other authors also. Surana *et al.* also found high prevalence (77.2%) of MS in urban Indian diabetic population using NCEP-ATP III criteria.[21] Prevalence of MS was present in 84.5%, 79.5% and 78% patients with diabetes by WHO, IDF and NCEP-ATP III criteria respectively by Lone *et al.* in their study from Kashmir.[22] Studies from other part of world also show a high prevalence of MS in diabetic patients. Foucan *et al.*[23] from USA, Imam *et al.*[24] from Pakistan and Bruno *et al.*[25] from USA in their study found prevalence of MS of 77%, 79.7% and 75.6% respectively. But Yadav *et al.* from India found a low prevalence in their study.[26] In their study prevalence was 45.8%, 57.7% and 28% by NCEP-ATP III, IDF and WHO criteria respectively. High prevalence of MS in present study population as compared to Yadav *et al.* is due to high BMI, high WC and low HDL seen in our study as compared to them.

In this study prevalence of MS was higher in female as compared to male. This is seen in other studies also. This may be due to lower cut off value for WC and higher cut off value for HDL in female as compared to male. Women had higher prevalence of central obesity, low HDL, and hypertension as compared to male but it is the central obesity and low HDL that is statistically significant. Prevalence of high TG is more in male as compared to female but it is not statically significant. Surana *et al.* also found the same regarding high TG. In Yadav *et al.* study high TG was seen more in females. This could be due to poor control of blood glucose in male as compared to female in our study while in study by Yadav *et al.* blood glucose was poorly controlled in female as compared to male.

Clustering of 3, 4 and 5 components of MS is seen in 42.79%, 41.89% and 15.32% of patients of MS according to Modified WHO criteria while it is 39.9%, 39.9% and 20.18% respectively with NCEP-ATP III criteria and 30.35%, 43.19% and 26.46% respectively with Modified NCEP-ATP III criteria. According to IDF criteria, clustering of 3, 4, and 5 components of MS is seen in 27.31%, 44.12% and 28.51% respectively. Suhana *et al.* also found more or less same. In their study 3, 4, and 5 risk factors are seen in 44.6%, 36.35% and 19.04% of patients, respectively by NCEP-ATP III criteria. Yadav *et al.* find 3, 4, and 5 risk factors in 62%, 26% and 12% patients with MS by NCEP-ATP III criteria. It was 57%, 34% and 9% according to IDF criteria while it was 65%, 29% and 6% according to WHO criteria. This shows that 4 or more risk factors are present in more than 60% of diabetic population in our study. So, these patients should be treated more aggressively than low risk patients to prevents the CV events.

Our present study finds, maximum agreement between NCEP-ATP III (Modified) and IDF criteria. Second best agreement was seen between WHO (Modified) and IDF and least agreement between Modified WHO and Modified NECP-ATP III. Similar pattern was seen by Lone *et al.* Yadav *et al.* also found highest agreement between ATP III and IDF and least between IDF and WHO. Many other studies have found highest agreement between NCEP and IDF criteria. In this study central obesity and high TG was the strongest predictor of MS while in study by Lone *et al.* it was the hypertension and central obesity that was the strongest predictor of MS. This difference is probably due to more aged patients and two times more obesity (BMI>30) seen in Lone *et al.* study as compared to ours. As we know that aging and obesity is linked with hypertension.

Prevalence of VDD in our study was 62.46%, 59.09% and 70.21% in all, male and female patients, respectively. Mean± SD Vitamin D level in all, male and female patients were 19.43 ng/dl, 20.03 ng/dl and 18.06% respectively. This shows a high prevalence of VDD in our study and it is more in female as compared to male. The reason of high VDD in Indian patients can be due to low intake of Vitamin D, dark colored skin, low outdoor activity, rising obesity, different clothing pattern and predominantly vegetarian diet. Various studies from India also found high prevalence of VDD in diabetic patients. Subramaniam *et al.* in their study found 85.8%, 11.9% and 2.3% of VDD, insufficiency and sufficiency, respectively.[27] Giri *et al.* found high prevalence of VDD (41.7%), insufficiency (41.7%) and sufficiency (16.6%) in their study.[28] Kumar *et al.* in their study find prevalence of VDD, insufficiency and sufficiency of 83%, 13.8% and 3.2%, respectively.[29] In youth onset DM Daga *et al.*[30] found prevalence of VDD as 94.4%. Laway *et al.* in their study find the prevalence of VDD, insufficiency and sufficiency of 66.7%, 14.7% and 18.6%, respectively.[31] But Bajaj *et al.* in their find a low prevalence of VDD (13.5%) and insufficiency (31.08%).[32] This could be due a chance finding as sample size was small. Other reason can be that in their study average age of patient was >55 year and many elderly people are getting used to of taking multivitamin tablets.[33] Studies from other part of world also shows very high prevalence of VDD in diabetic patients. The prevalence of VDD is higher in patients with MS than those without MS. Mean ±SD Vitamin D is also low in MS patients as compared to those without MS. One reason can be high BMI in MS patients as compared to those without MS. Many studies from India and abroad found high prevalence of VDD in patients with MS.

Strength of our study includes adequate sample size and relatively homogenous group of diabetic patients. Key limitation of the study is low no number of female patients, single center study and lack of availability of seasonal data for Vitamin D.

CONCLUSION

It is clear from the above study that prevalence of MS and VDD is high in newly onset type 2 diabetic patients especially female from this area. In this study central obesity was the highest predictor of MS. In this era of precision medicine this study is a small effort towards giving precise and personalized treatment. Since VDD is highly prevalent in MS patients especially females, vitamin D levels should be tested routinely in newly onset diabetic patients and treated accordingly. Patients having 4 or more components of MS should be categorized and intensively treated

as they are at high risk for CVD. In this way treatment should be tailored to individual. ADA 2021 also endorsed the same, personalization of diabetes medicine.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

MS: Metabolic syndrome; **VDD:** Vitamin D deficiency; **WC:** Waist Circumference; **DM:** Diabetes Mellitus; **CVD:** Cardiovascular Disease; **IDF:** International Diabetes Federation; **NCEP-ATP III:** National Cholesterol Education Programme Adult Treatment Panel III; **WHO:** World Health Organisation; **BP:** Blood Pressure.

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