

ORIGINAL

Pharmacoepidemiology and Risk Factors assessment of Metabolic Syndrome in Geriatric Patients Admitted at Tertiary Care Hospital - A Cross-Sectional study

Farmacoepidemiología y evaluación de factores de riesgo del síndrome metabólico en pacientes geriátricos ingresados en un hospital de atención terciaria: un estudio transversal

Vishwas ATL¹  , Ritesh Agrawal² 

¹Pacific College of Pharmacy, Department of Pharmacy Practice. Udaipur, India.

²Pacific College of Pharmacy, Medicinal Chemistry Department. Udaipur, India.

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Corresponding Author: Vishwas ATL 

ABSTRACT

Introduction: metabolic syndrome (Mets) is the major threat factor for morbidity and mortality in geriatric patients. Cardiovascular diseases are the major complications and early detection, proper treatment, management help to improve quality of life. So, this study is to evaluate the risk components, risk behaviors, use, and effects of drugs for metabolic syndrome in the geriatric population.

Method: this was a prospective cross-sectional investigation done for a duration of 6 months. Totally, 340 both male and female patients of age above 65 were enrolled. Ethical approval was obtained from MIMS, Mandya. The south asian diagnostic criteria were used in our study. Details such as demographics, threat factors, diagnosis, lab values, past and present medical conditions, past and present medications were collected and subjected to statistical analysis.

Results: among 340 patients, male patients (57 %) are more admitted in hospital. Based on diagnostic criteria majority of patients having three components (67 %). Major threat factors are smoking (OR=27,5), family history (OR=2) and alcohol consumption (OR=1,38). Metformin, amlodipine and atorvastatin were commonly using for the management of risk components. The ANOVA results was found to be 0,00 for hyperglycaemia and 0,007 for hypertension in relation to gender wise distribution.

Conclusions: our study concludes that male patients were more suffering from metabolic syndrome. Both Modifiable and non-modifiable risk factors influencing the metabolic syndrome. Therapeutic efficacy of drugs are also depends on threat factors. So, Proper education, drug selection and healthy life style practices helps to prevent complications, improve drug efficacy and quality of life.

Keywords: Geriatrics; Hyperglycaemia; Threat Factors; Smoking; Metabolic Syndrome.

RESUMEN

Introducción: el síndrome metabólico (SMM) es el principal factor de riesgo de morbilidad y mortalidad en pacientes geriátricos. Las enfermedades cardiovasculares son las principales complicaciones, y la detección temprana, el tratamiento adecuado y el manejo adecuado contribuyen a mejorar la calidad de vida. Por lo tanto, este estudio busca evaluar los componentes de riesgo, las conductas de riesgo, el uso y los efectos de los fármacos para el síndrome metabólico en la población geriátrica.

Método: se realizó una investigación transversal prospectiva de 6 meses de duración. Se incluyeron 340 pacientes, hombres y mujeres, mayores de 65 años. Se obtuvo la aprobación ética de MIMS, Mandya. En nuestro estudio se utilizaron los criterios diagnósticos del sur de Asia. Se recopilaron datos como datos demográficos, factores de riesgo, diagnóstico, valores de laboratorio, afecciones médicas pasadas y

presentes, y medicación pasada y presente, que se sometieron a análisis estadístico.

Resultados: entre 340 pacientes, el 57 % presenta mayor ingreso hospitalario. Según los criterios diagnósticos, la mayoría de los pacientes presentan tres componentes (67 %). Los principales factores de riesgo son el tabaquismo (OR = 27,5), los antecedentes familiares (OR = 2) y el consumo de alcohol (OR = 1,38). La metformina, el amlodipino y la atorvastatina se utilizaron comúnmente para el manejo de los componentes de riesgo. El resultado del ANOVA fue de 0,00 para la hiperglucemia y de 0,007 para la hipertensión, en relación con la distribución por sexo.

Conclusiones: nuestro estudio concluye que los pacientes varones presentaron mayor prevalencia del síndrome metabólico. Tanto los factores de riesgo modificables como los no modificables influyen en el síndrome metabólico. La eficacia terapéutica de los fármacos también depende de los factores de riesgo. Por lo tanto, una educación adecuada, la selección adecuada de fármacos y un estilo de vida saludable ayudan a prevenir complicaciones, mejorar la eficacia de los fármacos y la calidad de vida.

Palabras clave: Geriátría; Hiperglucemia; Factores de Amenaza; Tabaquismo; Síndrome Metabólico.

INTRODUCTION

Mets is a serious condition that comprises a clutch of threat factors that substantially increases the risk of developing cardiovascular and cerebrovascular diseases with a high morbidity and mortality in geriatrics.

⁽¹⁾ Geriatrics represents a specialised field within general medicine. It focuses on the clinical, preventive, therapeutic, and social dimensions of health issues affecting older adults. The term 'elderly' generally refers to patients aged >65 years. ⁽²⁾ It is known that Indians have higher metabolic threat factors and greater cardiovascular risk than other populations because they are more prone to abdominal obesity along with insulin resistance. ⁽³⁾

The ubiquity of Mets ranges - 12,5 % to 31,4 % globally. ⁽⁴⁾ One-third of the urbanized population has a prevalence of 11 to 41 % in India and 33,9 % in Karnataka, respectively. ⁽⁵⁾ According to South Asian criteria, Mets is diagnosed if person consists of 3 out of 5 components, such as fasting blood glucose level (mg/dl) > 100, waist circumference (cm) > 87 in males or >82 in females, blood pressure (BP) (mm of Hg) > 130/85, triglyceride (mg/dl) > 150 and high-density lipoprotein (HDLP) (mg/dl) < 40 in males or < 50 in females. ⁽⁶⁾

The major threat factors for the development of metabolic syndrome include obesity, physical inactivity, intake of trans fats, smoking, alcohol consumption, and stress level. ⁽⁷⁾ Diagnosis challenges such as level of education, cognitive impairment, impaired hearing, and vision may decrease the capacity of clinical judgment in geriatrics. Management of diseases plays a crucial role in geriatrics due to age-related physiological changes, co-morbidities, geriatric syndromes, and reduced hepatic and renal functions. ⁽⁸⁾ Adherence to medications and diet, such as intake of fish, vegetables, and the Mediterranean diet, along with dietary methods to stop hypertension and low intake of processed and inflammatory food may reduce the risk of metabolic syndrome. ⁽⁹⁾

Pharmacoepidemiology helps to investigate whether the drug use is beneficial or harmful, drug effects to evaluate risk-benefit ratio, and the cost of the drugs in a large number of populations. So, the pharmacoepidemiologic study helps to define population, place, time, drug treatment explanations, and make estimations regarding their uses and therapeutic effects. ⁽¹⁰⁾ In geriatric patients for management of components, the following medications were preferred as fine line therapy, such as metformin and sulfonylureas for type 2 diabetes mellitus, ⁽¹¹⁾ calcium channel blockers, and beta blockers, and angiotensin-converting enzyme for hypertension, ⁽¹²⁾ and statins for dyslipidaemia. ⁽¹³⁾ Till date there is no official recommendation or guideline for obesity pharmacotherapy in geriatrics, but weight reduction by physical exercise and intake of protein and nutrients was considered in geriatrics with obesity. ⁽¹⁴⁾

Estimating the burden of metabolic syndrome, threat factors and pharmacotherapy status in the Indian geriatric population is essential to developing general public health policies and guidelines, and to develop intervention to improve the health status among the geriatric population. ⁽¹⁵⁾ In metabolic syndrome conditions, the study of pharmacoepidemiology provides information about the name of drug exposure and its effects. The threat factors are also dependent on life style practices. Hence, healthy lifestyle practices, early diagnosis, medication adherence, and rational use of drugs are essential to manage Mets, which otherwise leads to cardiovascular complications. So, this work looks to gauge the threat factors and drug usage pattern for Mets in the geriatric population.

METHOD

Study Design

This was a hospital-grounded cross-sectional study. It was done in patients admitted and received treatment for metabolic components in the department of general medicine, Mandya Institute of Medical Sciences, which

is a district tertiary care hospital in Karnataka. This work was done for a duration of 6 months from May 2022 to November 2022 based on eligibility criteria. A convenience sampling method was used in our study.

Sample Size

The sample size was gotten by utilising the Cochran's formula for cross-sectional studies.

Formula = $Z^2 p (1-p) / e^2$

$Z = 1,96$ for 5 % error, Population proportion (p) = 30 %, ⁽⁵⁾ $1-p = 70$ % and margin of error (e) = 5 %.

Calculation = $1,96 \times 0,3(1-0,3) / (0,05)^2 = 322$

The calculated minimum sample size for this study was 322 participants. Ultimately, researchers recruited 340 patients over the course of the investigation.

Inclusion Criteria

- Both male and female patients > 65 years of age.
- Patients who are admitted and received treatment for metabolic components.
- Patients who had ≥ 3 components of the metabolic syndrome according to South Asian / Indian criteria.
- Patients who gave informed consent.

Exclusion Criteria

- Patients admitted to the intensive care unit.
- Patients were referred to a higher centre for further follow-up.

Method of Data Collection (study tools)

The patients were interviewed based on the questionnaires in the pre-designed and semi- structured data collection form. The following information was collected,

- Socio-demographic details like name, age, IP number sex, and education level.
- Information regarding general threat factors such as stress, physical activity, family history, a balanced diet, alcohol consumption, smoking, and improper sleep was collected by interview method.
- Details on the constituents of the Mets according to South Asian/Indian criteria. For this criterion, the blood glucose level, and triglyceride, along with HDLP laboratory tests were performed by the hospital staff using the standard procedure. For these tests, the patients fasting blood samples were taken right at early morning and subjected to analysis. The blood pressure checkup was done by using manual mercury sphygmomanometer. The waist circumference was measured by wrapping the tape around the widest part of the patient's stomach, across the belly button. Three times measurement were taken for consistent results.
- The details of diagnosis, chief complaints, medical conditions, and past and present medications were collected from patient case sheets.

Ethical clearance and informed consent

Ethical approval was gotten straight from the institutional ethics committee, Mandya Institute of Medical Sciences, having reference number MIMS/IEC/569. Study participants delivered a voluntary written consent form for data collection and participation in our research study.

Statistical Analysis

The collected data was gauged utilising IBM 16 software. Descriptive statistics including, percentages, and frequency was calculated. Chi-square test (X^2) was applied to check the relationship across the general variables and number of threat factor components. Z- test was applied to gauge the mean difference of risk components with respect to gender distribution. Analysis of variance (ANOVA) test also applied to gauge the outcomes of oral hypoglycaemics with respect to random blood glucose level. This test also applied to assess the outcomes of different antihypertensive on blood pressure. For all the tests the confidence interval was 95 % with 5 % error. Odds ratio was calculated to gauge the threat behaviours in the development of Mets.

RESULTS

Totally, 340 participants were included inside our study per South Asian criteria for diagnosing Mets. The detailed demographic details, risk behaviors, past medical and medication history, and current medical and medication details were collected and subjected to statistical analysis.

The characteristics of the participants were collected, and they were subjected to chi-square statistical analysis with 95 % Confidence interval. It was applied to check the relationship between the variables and the number of risk components (table 1). Among the participants, 194 (57 %) of males and 146 (43 %) of females are

having metabolic syndrome. This shows that males are readier to develop metabolic syndrome than females. The p-value was found to be 0,47, and it shows there exists no statistically noteworthy association across the variables. Age-wise distribution shows that 157 (46,2 %) of participants are in the age group 65-74 years, 128 (37,6 %) of participants are in 75-84 years and 55 (16,2 %) of participants are in >85 years. The p-value was found to be 0,00 and the relationship across the variables is statistically noteworthy. Education details were obtained in that 59 (17,3 %) of participants are educated and 281 (82,7 %) of participants are uneducated. The p-value was discovered to be 0,52, and it is not statistically noteworthy across the variables. In the economic conditions of the participants, 282 (82,9 %) of participants are earning <15 000, and 58 (17,1 %) of participants are earning <15 000 per month. The p-value was discovered to be 0,17, and it is not statistically noteworthy across the variables. In the area of residence distribution 229 (67,3 %) of participants were from rural areas, and 111 (32,7 %) of participants were from urban areas. The p-value was found to be 0,00, and the relationship across the variables is statistically noteworthy.

Table 1. Relationship between characteristics and number of components among participants

Variables	Category	3 Risk Components N (%)	4 Risk Components N (%)	5 Risk Components N (%)	Total N (%)	P
Gender	Male	133(39,1)	44(13)	17(5)	194 (57)	0,47
	Female	95(28)	32(9,4)	19(5,5)	146 (43)	
Age	65-74 years	136(40)	14(4,2)	7(2)	157(46,2)	0,00*
	75-84 years	62(18,2)	45(13,2)	21(6,2)	128(37,6)	
	> 85 years	30(8,8)	17(5)	8(2,4)	55(16,2)	
Education	Educated	43(12,6)	12(3,5)	4(1,2)	59(17,3)	0,52
	Un educated	185(54,4)	64(18,8)	32(9,5)	281(82,7)	
Economic status	<15 000 rupees	192(56,4)	58(17)	32(9,5)	282(82,9)	0,17
	>15 000 rupees	36(10,5)	18(5,3)	4(1,2)	58(17,1)	
Area of Residence	Rural	176(51,8)	31(9,1)	22(6,4)	229(67,3)	0,00*
	Urban	52(15,3)	45(13,2)	14(4,2)	111(32,7)	

Note: *Statistically significant. Chi square (χ^2) test with 95 % Confidence interval

Totally, 1168 risk components are present in 340 participants. The 316 (92,9 %) of participants are having fasting hyperglycaemia, 294 (86,4 %) are having increased blood pressure, 189 (55,5 %) are having hypertriglyceridemia, 171 (50,2 %) are having low high density lipoprotein level and 198 (58,2 %) are having increased waist circumference (figure 1).

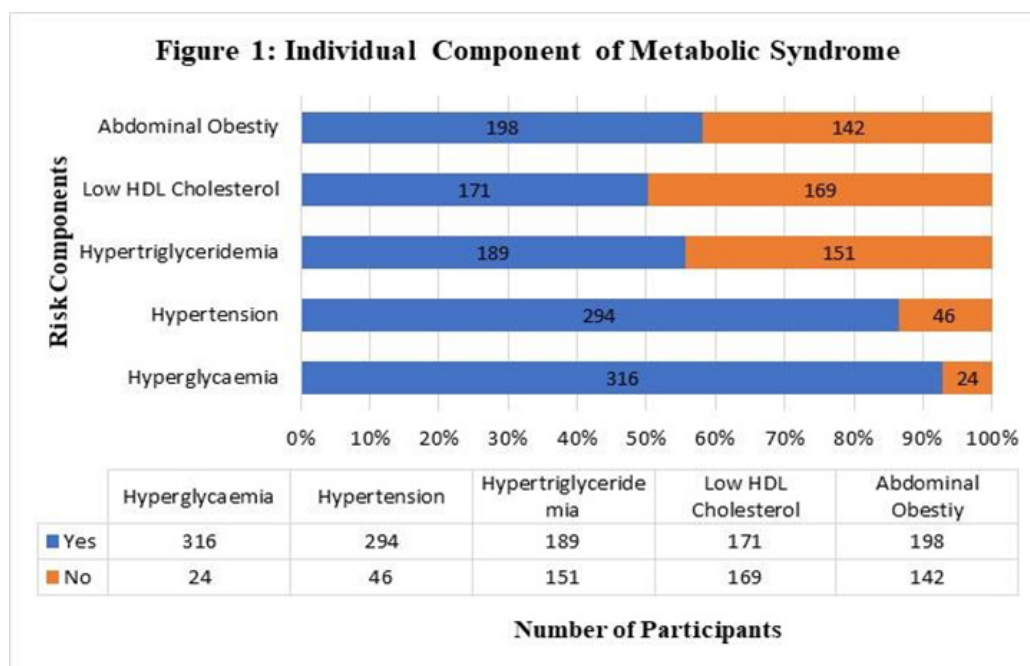


Figure 1. Individual Component of metabolic Syndrome

Based on diagnostic criteria, the risk components data were collected, and a Z- test was applied to evaluate the association between risk components and gender distribution (table 2). The mean fasting blood glucose level is 172,6 mg/dl inside males along with 186,8 mg/dl inside females, with standard deviations of 63,08 and 67,9. The p-value was found to be 0,18, and it shows there exists no statistically noteworthy association across the variables. The mean blood pressure (BP) is 151,6/91,7 mmHg in males, and 148,9/90,3 mmHg in females, with standard deviations of 25,6 and 20,8 for systolic BP and for diastolic BP was 9,2 and 7,1

The p-value was found to be 0,31 and 0,22, and the results are not statistically noteworthy. The mean triglycerides levels in males were found to be 182,4 mg/dl with standard deviation (st. dev.) 44,3 and 187,2 mg/dl with standard deviation 34 in females. The p-value was found to be 0,32, the results are not statistically significant. The mean high density lipoprotein levels in males were found to be 38,1 mg/dl with st. dev. 6,2 and 48,8 mg/dl with standard deviation 5,5 in females. The p-value was found to be 0,28, the results are not statistically significant. The mean waist circumference in males were found to be 96,2 cm with standard deviation 9,7 and 104,7 cm with st. dev. 57,6 in females. The p-value was found to be 0,17, the results are not statistically significant.

Risk Components	Male		Female		P
	Mean	Standard Deviation	Mean	Standard Deviation	
Fasting blood glucose (mg/dl)	172,6	63,08	186,8	67,9	0,18
Systolic Blood Pressure (mmHg)	151,6	25,6	148,9	20,8	0,31
Diastolic Blood Pressure (mmHg)	91,7	9,2	90,3	7,1	0,22
Triglycerides (mg/dl)	182,4	44,3	187,2	34,0	0,32
High Density Lipoprotein (mg/dl)	38,1	6,2	48,8	5,5	0,28
Waist Circumference (cm)	96,2	9,7	104,7	7,6	0,17
Note: Z test with 95 % Confidence interval					

The odds ratio was calculated to evaluate the risk behaviors and its relation to the development of Mets (table 3). In general threat factors, physical activity other than routine activities information was obtained. The 87 (25,5 %) of participants are actively involved, and 253 (74,5 %) of participants are not involved in physical activities. The odds ratio was found to be 0,11. The 69 (20,2 %) of proper and 271 (79,8 %) of participants are not having proper sleep. The odds ratio was found to be 0,2. The 74 (21,7 %) of participants are on balanced diet and 266 (78,2 %) of participants are not on balanced diet.

The odds ratio was found to be 0,07. The 138(40,5 %) of participants are having the family history of risk components, and 202 (59,5 %) of participants are not having family history. The odds ratio was found to be 2. The stress level shows that 164 (48,2 %) of participants are having stress and 176 (51,8 %) are not having stress with odds ratio 0,8. The male specific threat factors are 163 (84 %) of participants are smokers, and 31(16 %) of participants are non-smokers with an odds ratio 27,5. Another specific male threat factor was alcohol consumption 105 (54 %) of participants are alcoholic, and 89(46 %) of participants are non-alcoholic with odds ratio 1,38.

Risk Behaviors	Category	Yes N (%)	No N (%)	Odds Ratio
General	Physical Activity	87 (25,5)	253(74,5)	0,11
	Proper Sleep	69(20,2)	271(79,8)	0,2
	Balanced Diet	74(21,7)	266(78,2)	0,07
	Family History	138(40,5)	202(59,5)	2
	Stress Level	164(48,2)	176(51,8)	0,8
Males Specific	Smoking	163 (84)	31(16)	27,5
	Alcoholic	105(54)	89(46)	1,38

Among 340 participants, 289 of the participants are on medications of oral hypoglycaemic agents. In that 181 (62,3 %) of participants are taking metformin, followed by 6 (2 %) are on glimepiride, 7 (2,5 %) are on voglibose, 2 (0,7 %) are on dapagliflozin, 65 (22,5 %) are on metformin + glimepiride, 7 (2,5 %) are on metformin + glimepiride + voglibose, 13 (4,6 %) are on metformin + vildagliptin, and 8 (2,9 %) are on metformin + glimepiride + pioglitazone. The ANOVA test was applied to determine if there are statistically noteworthy

variances in random blood glucose levels among different types of oral hypoglycaemic agents. The p-value was found to be 0,00 for a 95 % confidence interval. The result was statistically significant and it suggests that the type of oral hypoglycaemic agents used has a significant impact on random blood glucose levels (table 4).

Table 4. Distribution of Hypoglycaemic Drugs and its Clinical Outcomes		
Oral Hypoglycaemic Drugs	No. of Prescription (%)	p-value
Metformin	181(62,3)	0,000*
Glimepiride	6(2)	
Voglibose	7(2,5)	
Dapagliflozin	2(0,7)	
Metformin + glimepiride	65(22,5)	
Metformin + glimepiride + voglibose	7(2,5)	
Metformin + vildagliptin	13(4,6)	
Metformin + glimepiride + pioglitazone	8(2,9)	
Note: *Statistically significant. ANOVA test with 95 % Confidence interval		

Among 340 participants, 265 of the participants are on antihypertensive drugs. In that 57 (21,5 %) of participants are on enalapril, 70 (26,4 %) are on amlodipine, 23 (8,7 %) are on atenolol, 8 (3 %) are on telmisartan, 5 (1,9 %) are on metoprolol, 40 (15,1 %) are on amlodipine + atenolol and 62(23,4 %) are on telmisartan + hydrochlorothiazide. The ANOVA test was applied to determine if there exist statistically noteworthy variances in blood pressure across different types of anti-hypertensive agents. The p-value was found to be 0,007 for a 95 % confidence interval. The result was not statistically significant, and it suggests that the type of anti-hypertensive drug used has not had a significant impact on blood pressure (table 5).

Table 5. Distribution of Hypoglycaemic Drugs and its Clinical Outcomes		
Anti-Hypertensive Drugs	No. of Prescription (%)	P
Enalapril	57(21,5)	0,007
Amlodipine	70(26,4)	
Atenolol	23(8,7)	
Telmisartan	8(3)	
Metoprolol	5(1,9)	
Amlodipine + Atenolol	40(15,1)	
Telmisartan + hydrochlorothiazide	62(23,4)	
Note: ANOVA test with 95 % Confidence interval		

DISCUSSION

Mets is a foremost and accelerating health issue in public health and clinical challenges in the developing urbanization worldwide due to increased food intake, obesity, and unhealthy lifestyle practices.⁽¹⁶⁾ In gender wise distribution both populations are having equal chances of developing disease but in our study, males are having more prevalence than females which is same in the study conducted by Marius Rus et al.⁽¹⁷⁾

Based on diagnostic criteria of South Asians maximum number of participants are having three risk components and it is similar to the study conducted by Insa Feinkohl et al.⁽¹⁸⁾. There is a relation between age and threat of Mets, our study chi-square test p-value was deemed to be 0,00, and it was statistically noteworthy. It shows that there is a relationship between the variables, and the same results were obtained by Kyung Wook Kang⁽¹⁹⁾.

Research study conducted by Dong Liu et al.⁽²⁰⁾ results show that low education levels were associated right with a decreased prevalence of Mets, and the results are the same in our study. The economic status in relation to risk components, the p-value was found to be 0,17. It demonstrates the outcomes are not statistically noteworthy. The p-value between area of residence and risk components was found to be 0,00. It demonstrates the outcomes are statistically noteworthy.

Hyperglycaemia is the most ubiquitous constituent, seen in 92,9 % participants. Also, the second most ubiquitous threat factors were hypertension seen in 55,5 % of the participants. The hypertension is a second threat factor are same in the study by Marius Rus et al.⁽¹⁷⁾. Other threat factors include, 55,5 % are having hypertriglyceridemia, 50,2 % are having low high density lipoprotein level and 58,2 % are having increased waist circumference.

The risk components mean value and standard deviation were calculated. To check the mean difference of threat factors among gender distribution, a Z-test was applied, and the results show that the p values are not

statistically significant. Hence, there is no relationship between mean risk components and gender.

Among the general threat factors, the participants actively involved in physical activity, proper sleep, stress level balanced diet are having lower risk of developing metabolic syndrome. Family history of risk components in participants is having 2 times greater risk of developing disease. These results are similar to the study done by Alice Laudiso et al.⁽²¹⁾.

Participants with the history of smoking had an odds ratio was 27,5. It shows that smokers have 27,5 times chances of developing disease than non-smokers. Among participants, alcoholics have odds ratio 1,38 times greater the chance of getting disease than non-alcoholics. the results are the same by several studies.⁽²²⁾

Among the oral hypoglycaemic drugs metformin was commonly prescribed monotherapy for the management of hyperglycaemia and it comprises of 62,3 %. Followed by metformin + glimepiride among 22,5 % of patients as dual therapy. These results are same in the study conducted by Shaimol⁽²³⁾. The p-value of ANOVA test was found to be 0,00 for a 95 % confidence interval. The result was statistically significant and it suggests that the type of oral hypoglycaemic agents used has a significant impact on random blood glucose levels.

Most commonly prescribed antihypertensive medications were found to be amlodipine (26,4 %) as monotherapy and telmisartan + hydrochlorothiazide (23,4 %) as dual therapy. The therapy was same in the study conducted by Arshad H Mohd⁽²⁴⁾. The p-value was found to be 0,007 for a 95 % confidence interval with a 5 % error. The result was not statistically significant, and it suggests that the type of anti-hypertensive drug used has not had a significant impact on blood pressure among patients.

Atorvastatin was only the hypolipidemic drug prescribed to manage increased triglyceride levels. There is no therapy was prescribed for decreased high density lipoprotein and increased waist circumference, but intervention was given to increase physical activity and healthy diet.

CONCLUSIONS

Our study results reveal that male and aging processes are the major prevalent factors, to develop Mets. Hyperglycaemia is the major threat factor, and majority of patients have three risk components. Risk behaviors of low physical activity, stress, improper sleep, imbalanced diet, family history, smoking, and alcohol consumption are having greater risks in the geriatric population. Metformin, amlodipine and atorvastatin were commonly preferred to manage the risk components. Early detection, proper intervention, specific treatment, and management of risk factors help to manage the metabolic syndrome and prevent cardiovascular complications.

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AUTHORSHIP CONTRIBUTION

Conceptualization: Vishwas ATL.

Data curation: Ritesh Agrawal.

Formal analysis: Vishwas ATL, Ritesh Agrawal.

Research: Vishwas ATL, Ritesh Agrawal.

Methodology: Vishwas ATL.

Project management: Ritesh Agrawal.

Resources: Vishwas ATL, Ritesh Agrawal.

Software: Vishwas ATL.

Supervision: Ritesh Agrawal.

Validation: Vishwas ATL, Ritesh Agrawal.

Display: Vishwas ATL, Ritesh Agrawal.

Drafting - original draft: Vishwas ATL, Ritesh Agrawal.

Writing - proofreading and editing: Vishwas ATL, Ritesh Agrawal.