## **Original Research Article**

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## Analysis of cost of medical therapy in patients of metabolic syndrome: an observational study

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#### ABSTRACT

**Background:** The objective of the study was to analyze cost of medical therapy in patients of Metabolic syndrome. **Methods:** This was an observational study. The study was conducted by enrolling patients of the outpatient department of Medicine of Rajindra Hospital, Government Medical College, Patiala, Punjab. A total of 100 patients diagnosed with Metabolic syndrome were enrolled in the study. The total daily cost of the therapy was calculated by adding the direct cost of individual drugs taking in consideration the frequency of the drug. The daily cost of therapy was then extrapolated to calculate the monthly as well as annual cost of therapy.

**Results:** The mean age of patients was  $58.27\pm10.32$  years. Out of a total of 100 patients, there were 57 female and 43 male patients, indicating a female preponderance of the disease. The average individual daily cost of medical therapy is INR 44.56 which upon extrapolation gives monthly and annual cost of INR 1336.90 and INR 16264.40 respectively. The cost of treatment in males is costlier than females (INR 50.09 in males versus INR 40.22 in females). The cost of treatment of age 31-40 years is INR 27.90 while it INR 36.97, 48.16 and 50.75 for age groups 41-50, 51-60 and 61-70 years. The various components of metabolic syndrome viz. diabetes mellitus, hypertension and dyslipidemia contribute differently to the cost of therapy. Daily cost of medical therapy for diabetes mellitus is INR 18.57 while for hypertension and dyslipidemia are INR 10.25 and INR 6.13 respectively.

**Conclusions:** Chronic diseases like metabolic syndrome have a huge share of the healthcare budget. Given the fact that it is a lifestyle disease, its prevalence is likely to swell in the coming decades. Hence, formulation of preventive and innovative treatment guidelines is of utmost importance.

Keywords: Cost of Medical therapy, Diabetes mellitus, Hypertension, Metabolic syndrome, Pharmacoeconomics

### **INTRODUCTION**

The concomitant occurrence of metabolic disorders like diabetes mellitus, hypertension, dyslipidemia and obesity is often clubbed together as "metabolic syndrome".<sup>1</sup> The chronic nature of the syndrome puts a huge financial burden and affects the quality of life of the patients.<sup>2,3</sup> This burden in turns reflects on the compliance and adherence to the therapy which further leads to complications. Although nation-wide data on the prevalence of metabolic syndrome is lacking, the various

regional studies have reported prevalence of metabolic syndrome ranging from 10%-40%.<sup>4-12</sup>

According to the National Institute of Health, direct cost is defined as "those costs borne by the healthcare system, community and patients' families in addressing the illness". Direct costs to individuals and their families include medical care, drugs, and other supplies.<sup>13</sup> Pharmacoeconomic analysis in the management of a disease serves as a tool in formulation of sustainable treatment guidelines. At present, Indian studies dedicated to estimation of financial burden on patients of metabolic syndrome are quite limited. This study is aimed at estimation of cost of medical therapy in the patients of metabolic syndrome.

#### **METHODS**

#### Study design

This study was a cross sectional and observational study. The duration of the study was one year.

#### Source of data

Patients enrolled in the study were recruited from the department of Medicine, Rajindra hospital, Government Medical College, Patiala. 100 patients diagnosed with Metabolic syndrome were used for cost of therapy analysis.

#### Inclusion criteria

All patients aged >18 years and <80 years who fulfilled the diagnostic criteria according to the IDF definition of metabolic syndrome were included in the study. The permission to use the definition was taken from the concerned authorities. According to IDF, metabolic syndrome is defined as central obesity (based on race and gender specific waist cut offs) plus any two of the four parameters:

- Raised triglycerides: >150 mg/dl or history of specific treatment for this lipid abnormality
- Reduced HDL cholesterol: <40 mg/dl in males and <50 mg/dl in females or history of specific treatment for this lipid abnormality.
- Raised blood pressure: systolic BP ≥130 mm Hg or diastolic BP ≥85 mm Hg or on treatment for previously diagnosed hypertension
- Raised Fasting Plasma Glucose (FPG) ≥100 mg/dl or previously diagnosed type 2 diabetes mellitus.<sup>14</sup>

# Table 1: Definition of central obesity (based on race and gender specific waist cut offs).

Country/ ethnic	Waist circumference cutoff (cms)		
group	Male	Female	
Europoids	≥94 cm	≥80 cm	
South Asians Based on a Chinese, Malay, and Asian Indian population	≥90 cm	≥80 cm	
Chinese	≥90 cm	≥80 cm	
Japanese	≥90 cm	≥80 cm	
Ethnic South and Central Americans	Use South Asian recommen until more specific data are	ndations available	
Sub- Saharan Africans	Use European recommendations until more specific data are available		
Eastern Mediterranean and Middle East (Arab) Populations	Use European recommendations until more specific data are available		

#### Exclusion criteria

- Pregnant and lactating women
- Patients with secondary causes of obesity
- Malignancy
- Thyroid disorders
- Severe hepatic or renal diseases
- Patients unwilling or unable to comply with study proceedings.

#### Study sequence

The patients of metabolic syndrome coming to the department of medicine were enrolled in the study. Patients of either sex with age group between 18-80 years were included in this study. All the patients were informed about the study in layman language and written informed consent was taken. The number and type of anti-diabetic, anti-hypertensive, lipid lowering, anti-oxidant drugs, and any other drug (anti-platelet drug) per prescription, their dosage and frequency of administration was noted. Data from the prescriptions was entered into case record form.

The maximum retail price (MRP) of all the prescribed drugs was noted in terms of Indian National Rupees (INR). The cost of the medications was calculated on the basis of maximum retail price (MRP) mentioned in the CIMS/ MIMS (2015).<sup>15</sup>

The total daily cost of the therapy was calculated by adding the direct cost of individual drugs taking in consideration the frequency of the drug. The daily cost of therapy was then extrapolated to calculate the monthly as well as annual cost of therapy. Statistical analysis was performed using Statistical Program for Social Sciences (SPSS) software version 20.0 Chicago, Illinois, USA.

#### RESULTS

In this observational study, a total of 100 patients of metabolic syndrome were enrolled. The mean age of patients was  $58.27\pm10.32$  years. The maximum number of patients belong to the age-group of 51-60 years (33%) followed by 61-70 years, 41-50 years and >71 years (Table 2).

#### Table 2: Distribution of patients according to age.

Age	Frequency	Percentage
31-40	6	6%
41-50	20	20%
51-60	33	33%
61-70	30	30%
>71	11	11%
Total	100	100%
Mean Age± SD	58.27±10.32	
Range	32-78	



#### Figure 1: Distribution of patients according to gender.

Out of a total of 100 patients, there were 57 female and 43 male patients, indicating a female preponderance of the disease. Hence, prevalence of metabolic syndrome was more in females (57%) as compared to males (43%) (Figure 1).

Analysis of prescriptions found that the average individual daily cost of medical therapy is INR 44.56 which upon extrapolation gives monthly and annual cost of INR 1336.90 and INR 16264.40 respectively (Table 3).

#### Table 3: Cost of medical therapy per prescription (individual and gender differences).

Average cost per prescription	Individual	Males	Females
Daily	Rs. 44.56	Rs. 50.09	Rs. 40.22
Monthly	Rs.	Rs.	Rs.
	1336.90	1502.7	1206.56
Annual	Rs.	Rs.	Rs.
	16264.40	18282.85	14680.30

The cost of treatment in males is costlier than females (INR 50.09 in males versus INR 40.22 in females). Upon extrapolation, monthly and annual cost of therapy in males is INR 1502.7 and INR 18282.85 respectively while in females, these figures are INR 1206.56 and INR 14680.30 respectively. Hence, there is an annual gender difference of INR 3602.55 between males and females.

The differences in the cost of treatment are also present based on age differences. The cost of treatment of age 31-40 years is INR 27.90 while it INR 36.97, 48.16 and 50.75 for age groups 41-50, 51-60 and 61-70 years. The Age-wise increment in the cost of treatment is present till the age of 70 years after which a dip in the cost of treatment is noted. For patients of age group more than 70 years, the daily cost of therapy is INR 37.18 (Table 4).

Table 4:	Cost of 1	nedical	therapy	analysis	(age-wise
		differ	rences).		

Age	Daily	Monthly	Annual
31-40	27.90	837.50	10183.50
41-50	36.97	1109.13	13494.05
51-60	48.16	1444.85	17578.40
61-70	50.75	1522.50	18523.75
>71	37.18	1115.55	13570.70

The annual cost of treatment escalated from INR 10183.50 for age group 31-40 years to almost doubling to INR 18523.75 for age group 61-70 years; after which it dips to INR 13570.70 for patients above 70 years.

The various components of metabolic syndrome viz. diabetes mellitus, hypertension and dyslipidemia contribute differently to the cost of therapy. Daily cost of medical therapy for diabetes mellitus is INR 18.57 while for hypertension and dyslipidemia are INR 10.25 and INR 6.13 respectively. Rest of cost (i.e. INR 15.69/ day) was due to medicines for treatment of other complications associated with metabolic syndrome.

# Table 5: Cost of medical therapy analysis (component-wise differences).

Component	Daily	Monthly	Annual
Diabetes mellitus	18.57	557.10	6778.05
Hypertension	10.25	307.50	3741.25
Dyslipidemia	6.13	183.90	2237.45
Miscellaneous	15.69	470.70	5726.85

#### DISCUSSION

Chronic diseases lead to a sustained financial burden on the healthcare budget of family as well as country at large.<sup>16</sup> Metabolic syndrome is such a chronic disease which not only increases the financial burden but also has severe impact upon the quality of life.<sup>3</sup>

Healthcare costs can be direct costs, indirect costs and other costs. Direct costs can be either variable or fixed costs. Variable cost includes cost for drug, hospital charges and physician fees while fixed costs include capital costs of hospital building, equipment and staff salaries. Indirect costs include travel costs and wages lost due to treatment or wages.<sup>17</sup>

In this study, the prescriptions were analyzed for the cost of medical therapy as per prescription. The individual average cost of medical therapy per prescription was found to be INR 44.56. Upon extrapolation, this value yields a monthly and annual value of cost of therapy as INR 1336.90 and INR 16,264.40 respectively. The daily cost of therapy was higher in males (50.09 INR) as compared to females (40.22 INR). Shah SN et al in 2008 reported that the cost of treating hypertension, diabetes, obesity and dyslipidemia to be around 15,700 INR- Rs. 28,200 INR per year.<sup>18</sup>

Our study found that diabetic component of metabolic requires an annual cost of INR 6778.05 for its medical therapy. Kumar A et al reported that the average annual total cost of type 2 diabetes was INR 6212.4 (USD 143.14) in 2005, of which more than half were drug costs (INR 3324).<sup>19</sup>

Our study found that hypertensive component of metabolic requires an annual cost of INR 3741.25 for its medical therapy.

Curtis LH et al found that the total costs to medical care were 20% higher among patients of metabolic syndrome (\$40,873 vs. \$33,010).<sup>20</sup> Nicoholas GA et al found that annualized age- and sex-adjusted medical costs incurred rose in direct proportion to addition of each metabolic syndrome component. This study also reported higher annual costs for hypertension (\$550), obesity (\$366), low high-density lipoprotein (HDL) (\$363), and high triglycerides (\$317).<sup>21</sup>

Country-wise differences in the cost of medical therapy can be due to the differences in the cost of medicines in different countries. In Republic of Seychelles, Bovet et al (2004) estimated direct costs of metabolic syndrome components. The study found that the cost for medications amounted to US \$45.6. Out of this amount, \$11.2 was for hypertension, \$3.8 for diabetes, and \$30.6 for dyslipidemia.<sup>22</sup> Boudreau DM et al compared costs of health utilization for patients with and without metabolic syndrome. Average annual total costs between subjects with metabolic syndrome versus no metabolic syndrome differed by a magnitude of 1.6 (\$5,732 vs. \$3,581).<sup>2</sup>

Currently the majority (around 50%) of the Indian population belongs to younger age groups (below 25 years).<sup>23</sup> Hence, as the population will age, the healthcare demands of older population is likely to present as a huge economic burden on both domestic as well as national health budget.

The GDP per capita of India for 2014-15 (period of this study) was INR 98,993.<sup>24</sup> This amount to about 16% of family income may be devoted to treatment of metabolic syndrome. It should be noted that this figure is only the cost of medical therapy i.e. cost of medicines. It does not take into account either the indirect cost of treatment or the management of complications which requires inpatient care.

Several limitations deserve note. First of all, the duration of the study was short with small sample size. Another limitation was the region-specific nature of the research data. So, the results cannot be generalized to other population groups. By only calculating cost of medical therapy of metabolic syndrome, there might be an underestimation of total medical costs.

Further studies with a larger sample size and longer duration are, therefore, warranted. Patient enrollment

should be extended beyond the outpatient department so as to improve external validity in the general population and different settings. The studies with a multicentric patient enrollment will help in the generalization of data to larger populations.

#### CONCLUSION

The healthcare needs of a country pose a huge burden on country's economy. This burden becomes magnified in a developing economy like India. Chronic diseases have a huge share of the healthcare budget. Metabolic syndrome is one such disease. Given the fact that it is a lifestyle disease, its prevalence is likely to swell in the coming decades. Hence, formulation of preventive and innovative treatment guidelines is of utmost importance. The limited resources of developing economies can thereby utilized in a more judicious manner.

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#### Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee GMC Patiala. The trial was registered at the Clinical Trial Registry- India (CTRI.nic.in identifier: CTRI/2016/06/007002) and the World Health Organization (Universal Trial Number: U111111654868).

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