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ASSESSING THE RISK FACTORS AND COMPLICATIONS RELATED TO METABOLIC SYNDROME IN DIABETIC PATIENTS: A RETROSPECTIVE ANALYSIS FROM METABESITY MANAGEMENT CLINICS.

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Abstract

Objective: This study aimed to assess the risk factors and complications related to Metabolic Syndrome in Type 2 Diabetes Mellitus (T2DM) patients presented at the Metabesity Management Clinics.

Methods: A retrospective cross-sectional study was conducted at two tertiary care centers over two years, including type 2 diabetic patients aged 18 and above. Patients with specific conditions or critical illnesses were excluded. Data, encompassing medical history, demographics, and various clinical measurements, were collected from medical records using Healthwire software.

Results: The analysis revealed hypertension (53.3%) as the predominant risk factor associated with MetS among T2DM patients. Furthermore, Diabetic Peripheral Neuropathy (40.0%) emerged as the most prevalent microvascular complication in this population. Lower extremity vascular health, assessed by DFA-TBPI (0.80 ± 0.19), demonstrated consistent results, while DFA-ABPI (1.06 ± 0.06) indicated stable blood flow. Neurological assessments revealed moderate sensory perception in both right (12.15) and left (12.97) feet, with notable variability. A significant proportion (33.2%) reported mild depression based on PHQ-9 outcomes. The categorical distribution based on the FIB-4 score indicated a high level in 1.0% of respondents, with 15.9% at an intermediate stage. Conversely, the NFS score demonstrated that 0.1% exhibited high fibrosis advancement, while 53.4% were at an intermediate level.

Conclusion: Hypertension was identified as the most prevalent risk factor and peripheral neuropathy as the most common microvascular complications associated with MetS among type 2 diabetes patients.

Keywords: Type 2 Diabetes Mellitus (T2DM), Metabolic Syndrome (MetS), Risk Factors, Complications, Metabesity Management Clinics.

Introduction

According to the International Diabetes Federation (IDF), there are approximately 33 million adults in Pakistan who are thought to have diabetes, which equates to a prevalence rate of 26.7%. It is significant to highlight that this estimate probably understates the true number of instances since it ignores cases that are unreported, misdiagnosed, and untreated.[1] Diabetes has remarkably risen over the last 20 years to rank among the top 10 global killers, with a startling 70% increase in fatality rates. A noteworthy surge of 1.5 million deaths resulted from this in 2019.[2] Besides contributing to these dismal numbers, diabetes also increases the risk of blindness, depression, heart illness, renal failure, blindness, and, unfortunately, even suicide.[3] Patients are severely affected by this confluence of health problems, which has a negative impact on their quality of life, prognoses, treatment costs, and adherence and eventually results in premature deaths.[4]

As a result of endocrine abnormalities linked to essential enzymes, metabolic diseases typically start with an accumulation of some metabolites or a deficiency in others.[5] The Metabolic Syndrome (MetS), which is characterized by a collection of cardio-metabolic risk factors and comorbidities, markedly increases the risk of both cardiovascular illnesses and type 2 diabetes.[6] Insulin resistance and abnormalities in fatty acid metabolism are two of the most well-known causes of MetS.[7] The term "metabesity" broadly refers to metabolic disorders having inflammatory origins, including heart disease, dementia, obesity, metabolic syndrome, diabetes, non-alcoholic fatty liver disease (NAFLD), and premature ageing.[8,9]

T2DM is frequently accompanied by obesity, which worsens the prognosis and increases risks for renal disease, liver problems, and CVD. There is apparent consensus about the relationships between obesity, MetS, NAFLD, and diabetes complications.[9] The WHO reports significant obesity rates. However, there is little data on diabetic patients in Pakistan.[10] The risk of mortality is doubled for overweight and obese diabetics as obesity increases metabolic problems.[11] These challenges worsen due to limited awareness, slow diagnosis, and genetics. South Asians are more likely to develop diabetes complications, and T2DM has a large economic burden.[12] Age, obesity, and type 2 diabetes all play a role in cognitive deterioration and possibly dementia. Additionally, conditions associated with stress and obesity may deteriorate cognitive performance. Conversely, NAFLD risk factors include obesity and diabetes.[13]

Considering the knowledge gaps in this part of the world, the Metabesity Project was initiated to develop a healthcare framework to combat the increasing burden of Metabesity. In pursuit of this mission, comprehensive Metabesity guidelines[14] were meticulously developed and subsequently disseminated. In line with these guidelines, data from clinics specializing in Metabesity management was systematically collected, providing insights into the risk factors and complications associated with MetS among individuals diagnosed with T2DM. This initiative represents a stride in deepening our understanding of the complex dynamics surrounding Metabesity within our community.

Methodology:

Study Design

The retrospective study was designed to analyze data from the Metabesity Management Clinics. The study spanned a two-year period, from January 1, 2021, to December 31, 2022.

Participant selection

- Inclusion Criteria: The study included type 2 diabetic patients aged 18 years or above, irrespective of gender, treated at the selected clinics.

- Exclusion Criteria: Patients with specific conditions (e.g., underweight, congenital diseases, CVA, acute infections) and those with critical illnesses that might affect health outcomes were excluded.

Data Collection

Data were collected from the hospital medical records of eligible patients. The Healthwire software, an electronic data capture system, was used to collect and integrate the data. Various data variables were collected, including medical history, demographics, physical examinations, and laboratory tests (e.g., blood tests, lipid profiles, and glucose levels). Additional assessments included Doppler Foot Assessment, neurothesiometer readings, and Fibrosis advancement through the FIB-4 index and NAFLD Fibrosis score (NFS).

The TBPI > 0.7 was considered normal, indicating no arterial disease, 0.64 - 0.7 as borderline Peripheral arterial diseases (PAD), and TBPI < 0.64 was considered abnormal, while ABPI >1.4 indicated calcification, >1.0 depicts probably no arterial disease, 0.81–1.00 no significant arterial disease, or mild/insignificant disease, 0.5–0.80 moderate disease, <0.5 severe disease and <0.3 critical ischemia.

The FIB-4 score was calculated using the formula: Age (years)×AST (U/L)/[PLT(109/L)×ALT1/2 (U/L)] and for NFS score the following formula was used: -1.675 + 0.037 × age (years) + 0.094 × BMI (kg/m2) + 1.13 × IFG/diabetes (yes = 1, no = 0) + 0.99 × AST/ALT ratio – 0.013 × platelet (×109/l) – 0.66 × albumin (g/dl).

Depression status was assessed using the Patient Health Questionnaire (PHQ-9), where the total score ranges from 0 to 27 (scores of 5–9 are classified as mild depression; 10–14 as moderate depression; 15–19 as moderately severe depression; ≥ 20 as severe depression.

Ethical Approval

Ethical approval was obtained from an Independent ethics committee (Reference# ERC/S20/P-018; Dated December 9th, 2022). The study adhered to ethical principles based on the Declaration of Helsinki and relevant regulatory requirements.

Statistical Analysis

Statistical analysis was conducted using SPSS version 22. Continuous data were reported as mean and standard deviation, while categorical variables were characterized using frequencies and percentages. Pearson correlation was applied to assess the relationship between the studied variables.

Results

The sociodemographic characteristics of the study participants are summarized in table 1. The average age is approximately 49.80 years, with an even gender distribution. Most are employed (52%) and non-smokers (79.8%), while the majority are married (97.9%).

On average, participants had diabetes for approximately 6.87 ± 6.15 years, with some variability as shown in table 2. Vascular health of the lower extremities, as indicated by the DFA-TBPI (0.80 ± 0.19), showed relatively consistent results. DFA-ABPI (1.06 ± 0.06) suggested stable blood flow in the lower limbs. Neurological assessments indicated moderate sensory perception in both right (12.15) and left (12.97) feet, with notable variability. The data from the Patient Health Questionnaire (PHQ) classification reveals the distribution of depression levels among the respondents. The majority of respondents, constituting 33.2%, reported experiencing mild depression. A smaller proportion, 4.1%, reported experiencing moderate depression, while an even smaller percentage, just 0.1%, reported moderately severe or severe depression. The FIB-4 score indicated a high probability of fibrosis advancement in 1.0% of respondents, with 15.9% showing intermediate advancement. In contrast, the

NFS score revealed that 0.1% exhibited high fibrosis advancement, while 53.4% fell into the intermediate category.

The risk factors and complications related to Metabolic Syndrome among T2DM patients are presented in table 3. HTN (53.3%) was identified as the most prevalent risk factor, and Diabetic Peripheral Neuropathy (40.0%) was the most prevalent complication.

The correlation analysis revealed significant associations between various metabolic parameters among Type 2 Diabetes Mellitus (T2DM) patients. Positive correlations were observed between total Cholesterol, LDL, and triglycerides, reflecting dyslipidemia. Additionally, negative correlations were identified between HDL and several factors, indicating an inverse relationship. Liver function markers (ALT, AST, ALP) exhibited positive correlations with certain metabolic indicators. The study also explored relationships with neuropathy markers, with NT-VPT showing significant correlations. Furthermore, the Doppler Foot Assessment parameters (ABPI, TBPI) demonstrated associations with specific metabolic factors, emphasizing the interconnectedness of metabolic and vascular health in T2DM patients.

Discussion

Our study identified hypertension (HTN) as the most prevalent risk factor associated with MetS, closely followed by obesity. These findings are also supported by existing literature confirming MetS is characterized by the clustering of obesity, hypertension, dyslipidemia, and insulin resistance.[15] In diabetic patients, factors associated with hypertension include age, body mass index (BMI), and high triglyceride levels, while dyslipidemia is linked to diabetes duration.[16] MetS is also associated with other risk factors such as waist-to-hip ratio, HDL dysfunction, and prothrombotic factors.[17,18]

The metabolic syndrome (MetS) is associated with increased risk of complications in diabetic patients. Studies have shown that MetS is an independent indicator of both macro- and microvascular complications in type 1 and type 2 diabetes.[19] In the current study, Diabetic Peripheral Neuropathy (DPN) emerged as the most frequent (40.0%) complication among the study participants. Cardiovascular Disease (CVD) was the second most frequent complication, affecting a notable proportion of patients. The presence of CVD in individuals with T2DM is concerning, as it significantly increases the risk of heart attacks, strokes, and other cardiovascular events. Katsiki et al., also reported significant link between MetS and microvascular complications such as diabetic kidney disease, retinopathy, and neuropathy.[18] Non-alcoholic fatty liver disease, a hepatic manifestation of MetS, may also be associated with these complications.[18]

Although the frequency of nephropathy was relatively low in our study, it remains a significant concern in diabetes care. Diabetic nephropathy can progress to chronic kidney disease (CKD) and ultimately lead to kidney failure, necessitating dialysis or transplantation. Regular monitoring of kidney function and early intervention are essential to prevent the progression of nephropathy in individuals with diabetes. Retinopathy, observed in 2.5% of cases, is another common microvascular complication of diabetes. The interaction between obesity, hypertension, and other components of MetS contributes to the progression of renal disease, even independent of diabetes.[20] Patients with MetS have a 4.45 times higher risk of developing DN compared to those without MetS.[21]

The consistency in these findings underscores the importance of ongoing efforts to raise awareness about diabetes complications, implement regular screening protocols, and provide appropriate medical care and interventions. Managing these complications is essential not only for improving the quality of life for individuals with T2DM but also for reducing the economic and healthcare burden associated with diabetes-related complications. Despite these critical objectives, unmet goals persist in the face of limited healthcare access, socioeconomic disparities, low health literacy, cultural dietary

influences, inadequate diabetes education, stigma, social support gaps, limited specialized care, and challenges related to continuous monitoring and medication affordability.[22] Overcoming these hurdles necessitates a holistic approach, including initiatives to improve healthcare accessibility, enhance health literacy through culturally tailored practices, promote physical activity, and address medication affordability.

Considering the prevalence of hypertension, dyslipidemia, and obesity, which significantly elevate the CKD and CVD risk, the development of the Clinical Practice Guideline for the Management of Metabesity in Pakistan is a crucial initiative.[14] However, to maximize its impact, it is imperative to reinforce these guidelines within routine clinical practices. This involves ensuring healthcare practitioners are well-versed in the guidelines, integrating them into standard operating procedures, fostering interdisciplinary collaboration, educating and empowering patients, conducting regular audits, and leveraging technology for seamless implementation. By actively reinforcing these guidelines, healthcare systems can better address the complex web of metabolic factors associated with Metabesity, ultimately mitigating the risks of CKD and CVD and improving patient outcomes.

Limitations

Firstly, the research was conducted exclusively within specific healthcare facilities situated in a particular geographic region. This confined geographic focus may constrain the applicability of the findings to more extensive populations or diverse healthcare environments. Secondly, due to its retrospective nature, the study heavily relies on historical data retrieved from medical records. Consequently, this design is susceptible to constraints related to data precision, comprehensiveness, and possible irregularities in record-keeping during the two-year period under review. These limitations emphasize the need for further research encompassing broader populations and employing prospective study designs to validate and expand our findings. Additionally, efforts to improve the accuracy and consistency of medical record-keeping practices are essential for enhancing the quality of data available for future research and clinical decision-making.

Conclusion

Our study identifies hypertension as the predominant risk factor linked to Metabolic Syndrome (MetS) in individuals with T2DM. Additionally, we found that Diabetic Peripheral Neuropathy stands out as the most prevalent microvascular complication associated with diabetes. By advocating for early detection and intervention through MetS screening and health education, the potential to prevent or delay diabetes-related complications is significantly enhanced, ultimately contributing to an improvement in overall quality of life. The holistic strategy outlined in Metabesity guidelines not only contributes to an improved overall quality of life but also plays a crucial role in mitigating the burden of disability-adjusted life years.

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Author contributions

(1) SAR, MH, SS substantial contributions to conception and design of the study, acquisition of data, or analysis and interpretation of data;
(2) MH, SS, MAR drafting the article or making critical revisions related to important intellectual content of the manuscript; and
(3) MH, SS, SAR, FAR final approval of the version of the article to be published.

Disclosure

Collaboration with Pakistan's medical societies, including the Pakistan Endocrine Society (PES), Pakistan Cardiac Society (PCS), Pakistan Nephrology Society (PNS), Pakistan Society of Gastroenterology (PSG), and Pakistan Neurology Society (PSN), was secured for the development and endorsement of guidelines. The guidelines were published in the Journal of the Pakistan Medical Association (JPMA), volume 71, No.5, supplement 3, May 2021.

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Table 1: Sociodemographic characteristics of the study population.

Variables		**N(%)**
Age (Years); Mean±SD		49.80±12.08
Gender	Female	965(52.7)
	Male	866(47.3)
Occupation	Working	952(52)
	Non-working	879(48)
Smoking	Non-smoker	1461(79.8)
	Current smoker	277(15.1)
	Ex-smoker	93(5.1)
Marital Status	Married	1792(97.9)
	Single	39(2.1)

Table 2: Clinical assessment of enrolled T2DM patients.

Variables			**Mean±SD**
General Characteristics	**Duration of DM (years)**		6.87±6.15
	Age of diabetes [n(%)]	≤ 1 year	399(21.8)
		2 to 5 years	570(31.1)
		6 to 15 years	702(38.3)
		≥ 16 years	160(8.7)
	Height(inches)		64.54±2.91
	Weight (kg)		78.61±12.29
	BMI (kg/m^2)		29.26±4.67
	Categories [n(%)]	Underweight	9(0.5)
		Normal Weight	117(6.4)
		Overweight	191(10.4)
		Obese 1	756(41.3)
		Obese 2	589(32.2)

		Obese 3	169(9.2)
	Temp (°F)		98.02±2.32
	Heart Rate (Beats Per Minute)		84.42±13.02
	Respiratory Rate (Breaths per minute)		16.54±1.20
	Systolic Blood Pressure (mmHg)		126.61±14.83
	Diastolic Blood Pressure (mmHg)		82.23±9.78
Glucose testing	**HbA1c**		8.86±1.812
	FBS (mg/dL)		189.41±64.41
	RBS (mg/dL)		252.72±110.23
Renal Function Test	**Cr (mg/dL)**		0.87±0.53
	eGFR (mL/min/1.73m2)		93.03±24.96
Electrolytes & microalbumin	**Na (mEq/L)**		138.78±3.03
	Cl (mEq/L)		99.64±2.43
	K (mmol/L)		4.75±2.745
	Ca (mg/dL)		9.20±3.36
	Microalbumin (mg)		23.15±19.416
Lipid profile	**Total Cholesterol (mg/dL)**		194.17±45.30
	LDL (mg/dL)		120.17±36.25
	HDL (mg/dL)		44.42±9.20
	Triglycerides (mg/dL)		197.79±100.54
LFT	**ALT (IU/L)**		30.36±20.32
	AST (IU/L)		28.26±17.75
	ALP (IU/L)		109.26±48.36
	Albumin (g/dL)		4.02±0.35
CBC	**Hb (g/dl)**		13.29±1.53
	WBC (10^3/µL)		8.55±2.14
	RBC (10^6/µL)		4.86±.607
	HCT (%)		40.57±4.657
	MCV (fL)		80.89±5.547
	Platelets (10^3/µL)		259.57±64.218
Doppler Foot Assessment	**DFA-TBPI (n=1637)**		0.80±0.19
	Categories [n(%)]	Abnormal indicating PAD	106(5.8)
		Borderline	139(7.6)
		Normal indicating no arterial disease	1392(76.0)
	DFA-ABPI (n=1618)		1.06±.069
	Categories [n(%)]	Moderate disease	13(.7)
		No significant arterial disease or mild/insignificant disease	516(28.2)
		Probably no arterial disease	1089(59.5)
Neurothesiometer	**NT-VPT (rt)**		12.15±5.62
	Categories [n(%)]	None	1162(63.5)
		Mild	403(22.0)
		Moderate	32(1.7)
		Severe	41(2.2)

	NT-VPT (lt)		12.97±8.11
	Categories [n(%)]	None	1003(54.8)
		Mild	535(29.2)
		Moderate	56(3.1)
		Severe	44(2.4)
Fibrosis Advancement	**FIB-4 Score (n=1717)**		1.10±0.83
	Categories [n(%)]	Low Probability	1406(76.8)
		Intermediate Probability	292(15.9)
		High Probability	19(1.0)
	NAFLD Score (n=1460)		-1.01±1.19
	Categories [n(%)]	Low Probability	481(26.3)
		Intermediate Probability	977(53.4)
		High Probability	2(0.1)
Depression Assessment	**PHQ-9**		6.08±2.73
	Categories [n(%)]	Mild Depression	608(33.2)
		Moderate Depression	75(4.1)
		Moderately Severe Depression	2(0.1)
		Severe Depression	1(0.1)

Table 3: Risk factors and complications related to MetS among diabetic patients.

Variables		**N(%)**
Risk Factors	Hypertension (HTN)	976(53.3)
	Dyslipidemia (DLD)	470(25.7)
	Obesity	668(36.5)
Complications	Cardiovascular Disease/Arterial Disease (CVD/AD)	142(7.8)
	Non-Alcoholic Fatty Liver Disease (NAFLD)	146(8.0)
	Diabetic Peripheral Neuropathy (DPN)	732(40.0)
	Nephropathy	10(0.5)
	Retinopathy	45(2.5)
	Peptic Ulcer Disease/Gastroesophageal Reflux Disease (PUD/GERD)	70(3.8)
	Chronic Kidney Disease (CKD)	62(3.4)