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Journal of
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Original Article

Effects of segmental muscle vibration on upper limb function in subacute poststroke patients

Irum Farooq [a], Shoaib Aziz [a], Aamir Sohail Saddozai [b], Yar Wali [a], Mohammad Nashit Saeed [a], Imran Amjad [c,*]

[a] Department of Physical Therapy, Gomal University, Dera Ismail Khan, Pakistan
[b] SAHARA Voluntary Social Welfare Agency for Persons with Disability, Dera Ismail Khan, Pakistan
[c] Department of Physical Therapy, Riphah International University, Islamabad, Pakistan

* Correspondence: imran.amjad@riphah.edu.pk

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Abstract

Stroke-related upper limb dysfunction and spasticity are main causes of long-term disability which affect functional independence and quality of life notably among patients. Segmental muscle vibration (SMV) has arisen as a promising rehabilitation approach to improve motor recovery and reducing spasticity in poststroke patients. This study aimed to compare the effects of the SMV on upper limb function and spasticity in subacute poststroke patients treated with two vibration frequencies (i.e., 60 Hz and 120 Hz) with those of patients treated with traditional therapy alone. Twenty-eight participants (N = 28) were randomized into three groups including two experimental groups that received extra SMV at 60 Hz and 120 Hz, and a control group that received conventional physiotherapy. The interventions were provided twice a week for eight weeks. The study employed Fugl-Meyer Assessment for Upper Extremes (FMA-UE), Modified Ashworth Scale (MAS) and Motor Assessment Scale were used to measure the outcomes. Upper limb function showed significant improvements across all groups and a decrease in spasticity at baseline ($p < 0.05$). Nevertheless, the postintervention between-group results were not significantly different between two SMV and control groups ($p > 0.05$). SMV in combination with traditional therapy is effective, but there was no difference in the benefits of 60 Hz versus 120 Hz in patients with subacute stroke treated with conventional therapy alone.

Keywords

Physical therapy modalities; Muscle spasticity; Recovery of function; Segmental muscle vibration; Stroke rehabilitation; Upper extremity

1. Introduction

Stroke is among the leading causes of long-term disability and mortality globally and is defined by the National Institute of Neurological Disorders and Stroke (NINDS) as a temporary or permanent impairment of cerebral function due to ischemia or bleeding of selected areas of the brain [1]. WHO defines stroke as the rapid development of neurological symptoms that remain for > 24 hours or cause death, with no clinically visible cause other than vascular origin [2]. Although healthcare has improved globally, stroke remains a socioeconomic burden, especially in developing countries where rehabilitation facilities are underdeveloped [3].

In major burden-of-disease studies, ischemic stroke is the most commonly reported type, while the remainder comprises intracerebral and subarachnoid hemorrhage [4]. Hemorrhagic stroke is less frequent but tends to be more severe and is commonly caused by ruptured aneurysms in the circle of Willis [5]. Impairment of the upper limbs after stroke is typical, and up to 80% of stroke survivors require rehabilitation to restore func-

tional independence [6]. Spasticity is a significant cause of disability, which is a velocity-dependent surge in muscle tone because of upper motor neuron lesions, causing impaired movement, contractures, and restriction of daily activities [7].

Traditional rehabilitation is instrumental in the process of motor recovery, but a considerable number of patients still display chronic upper limb deficits after therapy [8]. Different methods of rehabilitation, e.g., constraint-induced movement therapy, robotics, mirror therapy, and functional electrical stimulation have been proposed to increase neuroplasticity and improve functional outcomes [9]. Over recent years, vibrational therapy has shown potential as a promising modality that can result in reducing spasticity and improving motor performance following stroke.

Segmental muscle vibration (SMV) activates muscle spindle Ia afferents and modulates corticospinal excitability, leading to improved muscle activation, proprioceptive stimulation, and potential reorganization of cortical pathways [10]. Studies have demonstrated that vibrational frequencies ranging from 30 Hz to 120 Hz may reduce spasticity, improve coordination, and enhance motor recovery in poststroke individuals [11,12]. However, the evidence remains inconsistent, and appropriate parameters, including frequency, amplitude, as well as duration have yet to be established.

Several randomized and pilot trials on segmental or local muscle vibration have predominantly recruited chronic stroke patients, e.g., SMV, to improve reaching or gait in chronic stroke cohorts [13]. A recent systematic review of vibration therapy for post-stroke spasticity revealed that most included randomized controlled trials were in chronic or mixed chronic/subacute populations and that the protocols (including frequency) used were heterogeneous, with no clear consensus on optimal frequencies [14]. The existing evidence underscores the need for standardized vibration protocols and targeted trials in acute and subacute stroke patients to establish clearer therapeutic guidelines. We hypothesized that the addition of the SMV technique would prove to be more effective than conventional rehabilitation therapy alone for improving upper limb function and reducing spasticity among stroke patients.

2. Methods

2.1. Sample size and study design

The initial estimate of sample size was made using G*Power with Fugl–Meyer scores as the outcome variable, and 100 participants were needed. Owing to COVID-19 restrictions, the final sample included 30 participants, with 10 patients in each group. Two participants from the control group dropped out because of death, and the final analysis included twenty-eight participants (N = 28).

This randomized controlled trial was carried out to determine the effects of SMV on upper limb function among patients with subacute poststroke. Three groups were formed: a control group receiving only conventional physiotherapy and two experimental groups receiving conventional therapy combined with SMV at two different frequencies, one at 60 Hz and one at 120 Hz.

2.2. Study duration and setting

This study was conducted in Cure Medical Complex, Islamabad, between February 2020 and October 2020. All the participants had a treatment period of 8 weeks (2 sessions per week).

2.3. Ethics approval

The study was approved by the Research Ethical Committee (REC), Riphah College of Rehabilitation Sciences, Riphah International University, Islamabad (No. Riphah/RCRS/REC/00654), followed by the approval from Board of Advanced Studies and Research (BASR). This study was not registered as a clinical trial prospectively owing to the development of an intervention protocol based on previously published as well as established methodologies, and our study procedures adhere to these published protocols [10,12,14,15,16].

2.4. Sampling method and randomization

The participants were selected through purposive sampling according to specific inclusion criteria. Both types of patients (Ischemic and Hemorrhagic) were included. The three study groups were randomized by means of a sealed-envelope technique. Study included subacute poststroke patients of both genders (males and females) who were between 35 and 65 years of age and who had modified Ashworth scale (MAS) scores of less than three (≤ 3). However, patients with other neurological disorders, diabetic ulcers, limb infections, or amputations, severe cardiovascular disease (CVD) or unstable angina, orthopedic complications, and chronic medical instability were not recruited. The following validated instruments were used for assessment at baseline and after 16 treatment sessions: the Fugl-Meyer Assessment for Upper Extremes (FMA-UE), which measures motor recovery, sensation, coordination, and joint integrity (reliability = 0.88), and the MAS, which measures muscle tone on a 6-point scale (reliability = 0.567). Motor Assessment Scale: This scale consists of eight tasks that determine functional motor performance, with each task rated on a scale of 0–6.

2.5. Intervention and vibration device

The treatment adopted was conventional therapy along with SMV for ischemic and hemorrhagic patients. The control group (A) received 40 minutes of conventional physiotherapy, including active and passive range-of-motion (ROM) exercises along with stretching, strengthening, and balance training, adjusted tailored to the participant's needs. The experimental group (B) received the same conventional therapy plus 10 minutes of SMV at 60 Hz applied to the biceps brachii (BB) and extensor carpi radialis longus (ECRL) applied to the entire muscle from origin to insertion. The experimental group (C) received conventional therapy plus 10 minutes of vibration at 120 Hz applied to the same muscles. SMVs were delivered from the origin to the insertion using the Myovolt vibration system, a wearable nonelectrical device that generates localized mechanical vibration. The machine has a 10-minute cyclic duration of operation (fixed on the muscle using a belt so it can be stationary when vibrating at the target location) and can provide safe, controlled vibrational stimulation for use in neuromuscular applications. Medications for ischemic stroke included alteplase, antiplatelets, and anticoagulants, whereas medications for hemorrhagic stroke included labetalol, protamine, anticonvulsants, and mannitol.

The CONSORT flow chart for the recruitment, allocation, and follow-up of participants is shown in Figure 1.

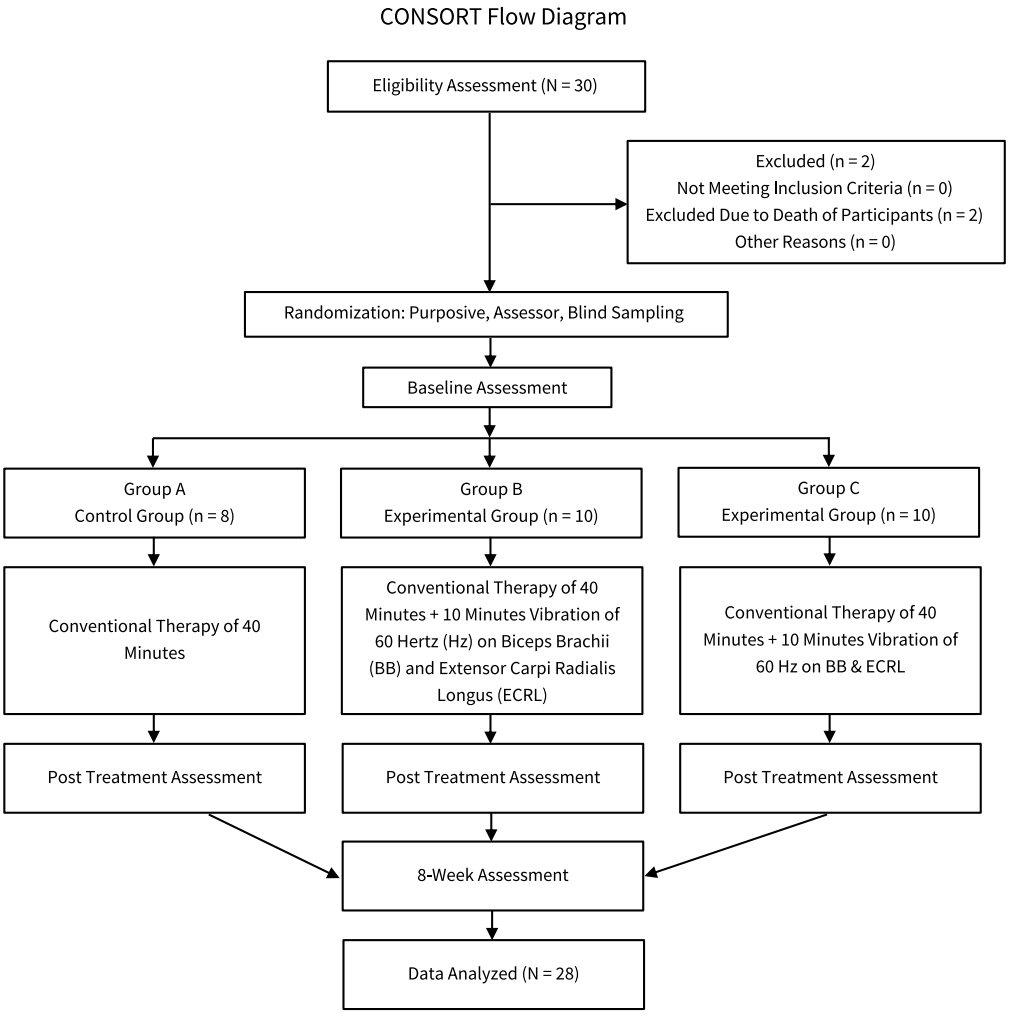


Figure 1. This is a figure. Schemes follow the same formatting.

2.6. Data analysis

Statistical analysis was performed using SPSS (v.23.0). In addition to descriptive statistics, Wilcoxon signed-rank test was used to compare within-group pre- and postintervention measurements, whereas differences between groups were compared by the Mann–Whitney U test and Kruskal–Wallis H test. Statistical significance was assessed using p values (i.e., $p < 0.05$).

3. Results

Initially, 30 subacute stroke patients were randomly selected. An 8-week intervention was conducted, and finally 28 patients completed follow-up after the death of two participants in Group A (the control group). The participants were divided into the following groups: a control group (Group A, n = 8), who underwent conventional therapy only, and two experimental groups [Group B and Group C (n = 10, each group)], which received conventional therapy in addition to SMV at frequencies of 60 Hz and 120 Hz, respectively.

Table 1 delineates the demographic as well as clinical attributes of the patients. Baseline analysis confirmed that the three groups were alike at the start of the study, and

no significant differences existed in terms of age, gender distribution, FMA-UE scores, MAS scores of the BB or ECRL, as well as Motor Assessment Scale scores (all $p > 0.05$).

Table 1. Baseline attributes of the study participants (N = 28).

Patients' Characteristics		Group A (Control) (n = 8)	Group B (Segmental Muscle Vibration 60 Hertz) (n = 10)	Group C (Segmental Muscle Vibration 120 Hertz) (n = 10)	*p* Value
		Median (IQR)	Median (IQR)	Median (IQR)	
Age (years), Mean ± SD		51.87 ± 4.88	54.40 ± 10.64	51.50 ± 3.95	-
Gender	Male, n (%)	7.00 (87.50)	7.00 (70.00)	8 (80.00)	-
	Female, n (%)	1.00 (12.50)	3.00 (30.00)	2 (20.00)	
Fugl-Meyer Assessment for upper extremity (Sec A)		29.00 (21.00)	28.00 (8.00)	27.00 (12.00)	0.831
Modified Ashworth Scale (biceps brachii)		2.00 (3.00)	4.00 (2.00)	4.00 (2.00)	0.455
Modified Ashworth Scale (extensor carpi radialis longus)		2.00 (3.00)	2.00 (4.00)	4.00 (2.00)	0.062
Motor Assessment Scale		39.00 (12.00)	39.00 (26.00)	40.00 (10.00)	0.684

[*] Statistical test: Wilcoxon signed-rank test.

Table 2 presents the baseline-to-postintervention changes within each group. Within-group analyses revealed statistically significant improvements between baseline and postintervention in all three intervention protocols. Significant improvements in upper limb motor function were observed in the FMA-UE and the Motor Assessment Scale (all p values < 0.05). Moreover, MAS scores revealed that spasticity was greatly decreased in the BB and ECRL across all groups (all p values < 0.05).

Table 2. Within-group differences in outcome measures between baseline and postintervention.

Outcome Measures	Baseline	Post-Intervention	*p* Value
	Median (IQR)	Median (IQR)	
Group A (Control)			
Fugl-Meyer Assessment for upper extremity (Sec A)	29.00 (21.00)	34.00 (14.00)	0.012 [**]
Modified Ashworth Scale (biceps brachii)	2.00 (3.00)	1.00 (3.00)	0.007 [**]
Modified Ashworth Scale (extensor carpi radialis longus)	2.00 (3.00)	1.00 (3.00)	0.007 [**]
Motor Assessment Scale	39.00 (12.00)	45.00 (8.00)	0.011 [**]
Group B (Segmental Muscle Vibration 60 Hertz)			
Fugl-Meyer Assessment for upper extremity (Sec A)	28.00 (8.00)	33.00 (8.00)	0.005 [**]
Modified Ashworth Scale (biceps brachii)	4.00 (2.00)	1.00 (1.00)	0.005 [**]
Modified Ashworth Scale (extensor carpi radialis longus)	2.00 (4.00)	1.00 (1.00)	0.004 [**]
Motor Assessment Scale	39.00 (26.00)	44.00 (30.00)	0.018 [**]
Group C (Segmental Muscle Vibration 120 Hertz)			
Fugl-Meyer Assessment for upper extremity (Sec A)	27.00 (12.00)	30.00 (7.00)	0.005 [**]
Modified Ashworth Scale (biceps brachii)	4.00 (2.00)	2.00 (2.00)	0.003 [**]
Modified Ashworth Scale (extensor carpi radialis longus)	4.00 (2.00)	2.00 (2.00)	0.003 [**]
Motor Assessment Scale	40.00 (10.00)	45.00 (6.00)	0.005 [**]

[*] Statistical test: Mann–Whitney U test. [**] $p < 0.05$, statistically significant.

Table 3 shows the postintervention comparisons between groups. Comparisons of postintervention results revealed no statistically significant differences between the groups. Postintervention FMA-UE ($p = 0.774$), MAS (BB) ($p = 0.737$), MAS (ECRL) ($p = 0.096$) and Motor Assessment Scale ($p = 0.583$) scores did not significantly differ between the control group and the two SMV groups.

Table 3. Comparisons of postintervention outcomes among the study groups.

Outcome Measures	Group A (Control)	Group B (Segmental Muscle Vibration 60 Hertz)	Group C (Segmental Muscle Vibration 120 Hertz)	*p* Value
	Median (IQR)	Median (IQR)	Median (IQR)	
Fugl-Meyer Assessment for upper extremity (Sec A)	34.00 (14.00)	33.00 (8.00)	30.00 (7.00)	0.774
Modified Ashworth Scale (biceps brachii)	1.00 (5.00)	1.00 (1.00)	2.00 (2.00)	0.737
Modified Ashworth Scale (extensor carpi radialis longus)	1.00 (5.00)	1.00 (1.00)	2.00 (2.00)	0.096
Motor Assessment Scale	45.00 (8.00)	44.00 (30.00)	45.00 (6.00)	0.583

[*] Statistical test: Kruskal–Wallis H test.

4. Discussion

SMV is a well-tolerated and safe intervention that has been investigated for its potential to increase motor recovery as well as neuroplasticity after stroke. However, there is a dearth of literature regarding its effectiveness during the subacute stage of stroke. In the present study, Group A received conventional rehabilitation therapy alone, Group B received conventional rehabilitation therapy with 60 Hz SMV, and Group C received conventional therapy with 120 Hz SMV. MAS evaluation revealed that participants in all three groups experienced similar reductions in spasticity. Motor Assessment Scale results revealed similar improvements: 39 to 45 for Group A, 39 to 44 for Group B and 40 to 45 for Group C. Our study revealed improved functional levels in patients with subacute stroke following the invention period. Improvements were confirmed by MAS, motor assessment scores, and Fugl–Meyer assessment scores. Moreover, our evaluation revealed that all three groups showed comparable improvements at the functional level, as measured by the Fugl–Meyer Assessment and Motor Assessment Scale, with significant reductions in spasticity observed via the MAS.

Consistent with our study results, Noma et al reported improvements in functional level when MAS was used after vibration therapy was applied to spastic muscles, especially when it was combined with conventional therapy [17,18]. Another study using focal muscle vibration and neurokinetic facilitation measured MAS outcomes in three groups of patients, with *p* values of 0.027, 0.026 and 0.042, respectively. These results highlight that vibrational therapy alone significantly reduces spasticity, likely through effects on inhibitory circuits at both the cortical and the spinal level [9].

The results of the current study revealed that a vibrational session before conventional therapy reduces spasticity and relaxes muscles for further exercise. Similarly, a study conducted in 2017 by Park et al. applied 20 minutes of vibration before therapy in children suffering from cerebral palsy and reported improved spasticity reduction compared with conventional therapy alone [19]. Costantino et al evaluated MAS and FMA-UE in patients receiving vibrational therapy versus those receiving sham therapy and reported improvements in FMA-UE mean scores from 82.82 (SD = 20.04) to 94.24 (SD = 19.40) for Group A and from 83.33 (SD = 17.81) to 84.27 (SD = 17.25) for Group B ($p < 0.05$) [20].

The available data show that much remains to be understood about the parameters of vibration, especially since most of the studies focus on chronic or mixed stroke populations. Not all frequency-specific protocols are the same, which makes the clarity of clinical recommendations complicated because of the absence of consensus. Hence, well-structured, focused, and standardized controlled trials in acute and subacute stroke patients are needed to describe more specific treatment guidelines and improve clinical practice. This study has several limitations. First, data collection was affected by the

COVID-19 pandemic, allowing us to recruit fewer patients, ultimately limiting the generalizability of the findings. Second, patients were assessed only at baseline and then after an eight-week follow-up; however, shorter-term follow-ups may provide a more accurate evaluation of SMV effects.

5. Conclusions

This study revealed that vibration therapy, along with conventional therapy, effectively reduced spasticity and upper limb function. No differences were observed among the three groups; all the groups showed similar improvements. Further research is recommended to evaluate the effects of vibrational therapy on improving functional outcomes and reducing spasticity, which are common sensorimotor impairments after stroke.

Author contributions: Conceptualization, IF, and SA; methodology, IF, SA, ASS, YW, MNS and IA; software, SS, YW, and MNS; validation, SS, YW, and MNS; formal analysis, SS, YW, and MNS; investigation, SS, YW, and MNS; resources, IA; data curation, SS, YW, and MNS; writing—original draft preparation, IF, SA, ASS, YW, and MNS; writing—review and editing, IA; visualization, SS, YW, and MNS; supervision, IA; project administration, IA. All authors have read and agreed to the published version of the manuscript.

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Consent to publication: Not applicable.

Data availability: The data supporting this study's findings are available from the corresponding author, Imran Amjad, upon reasonable request.

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Original Article

Association of HbA1c with lipid profile in patients with type 2 diabetes mellitus and cardiovascular disease

Gul Zareen Asifa *, Uswa Manzoor, Sana, Zunaira Shahzadi, Danish Irfan, Shaima Maqbool, Muhammad Huzaifa Khan

Niazi Medical & Dental College, Sargodha, Pakistan

* Correspondence: gulzareen09@gmail.com

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Abstract

Cardiovascular diseases (CVDs) are major causes of increased mortality and disability across the globe. Effective management of diabetes mellitus (DM) in CVD patients requires the integration of monitoring of glycemic status (HbA1c) and lipid metabolism. This cross-sectional analytical study included 121 patients and 80 control subjects to analyze the association of HbA1c levels with lipid profiles. Serum biochemical analyses of the lipid profile [total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C) and triglycerides] were performed with an Agilent 8453 UV-Visible spectrophotometer (Agilent Technologies, USA), and HbA1c was measured on an A1C EZ 2.0 glycohemoglobin analyzer. Comparisons of characteristics between the groups were performed using chi square or Fisher's exact tests and unpaired Student's t tests, and the relationships between HbA1c and other variables were determined by correlation and linear regression analyses. The cohort exhibited evidence of poor glycemic control (mean HbA1c of 8.23%) and was associated with increasing age (mean 50.7 years) and weight (mean 70.61 kg). Low levels of HDL-C and a positive family history are associated with disease. Increased age and high body weight, systolic blood pressure (SBP), diastolic blood pressure (DBP) and fasting blood glucose levels were associated with high HbA1c levels (≥ 6.5 %), whereas HDL-C levels were inversely associated with HbA1c. Key correlations included significant positive associations of age, weight, SBP, and DBP with HbA1c (all $p < 0.05$). HDL-C was negatively correlated with HbA1c ($p = 0.04$). The association of HbA1c with dyslipidemia confirms interlinked nature of risk factors for CVD and glycemic control. Our findings support integrated clinical management that addresses blood pressure alongside glycemic and lipid targets to help mitigate long-term cardiovascular risk in diabetic patients.

Keywords

Diabetes mellitus; Glycated hemoglobin; Cardiovascular diseases; Cholesterol, LDL; Triglycerides; Dyslipidemias

1. Introduction

Cardiovascular disease (CVD) is an umbrella term comprising various cardiac and vascular conditions [1]. Diabetes mellitus (DM), a metabolic disorder, is a potential risk factor for CVDs as well as strongly connected with CVDs being the major determinant of health complications and diabetes-related mortality. Type 2 diabetes mellitus (T2DM) patients are predisposed to a greater risk of mortality from CVDs including heart failure, myocardial infarction (MI), and stroke. Cardiovascular risks in diabetic patients are linked with multiple factors, including hyperglycemia, dyslipidemia, insulin resistance,

inflammation, obesity, high blood pressure, along with that diabetes complications such as nephropathy and retinopathy [2,3].

Obesity has damaging effects on cardiac health through its effects on established risk determinants, including glucose intolerance, dyslipidemia, hypertension, obstructive sleep apnea and hypoventilation, systemic inflammation, and a prothrombotic state, as well as through potential mechanisms that remain incompletely understood [4]. Thus, obesity markedly predisposes individuals to a wide variety of cardiovascular complications, including coronary artery disease, cardiac arrest, and heart failure due to its persistent impact on cardiovascular system of a patient [5].

The formation of glycosylated hemoglobin (Hb) is a progressive, continuous, and irreversible non enzymatic process. HbA1c levels are mainly affected by long-term blood glucose levels over approximately 2–3 months rather than short-term fluctuations caused by factors such as insulin therapy or immediate oral glucose administration [6]. HbA1c is a reliable biomarker that reflects long-term glycemic control and helps predict risk factors associated with diabetes-related complications in individuals with T2DM, however, the prognostic value of HbA1c in patients with underlying CVD, especially coronary heart disease, remains unclear owing to conflicting as well as scarce evidence. Notwithstanding its clinical importance, there is a dearth of literature assessing the correlation of HbA1c levels with lipid profiles, especially among South Asian populations, with a focus on Pakistan.

There is a dire need to determine the relationship between HbA1c and lipid profile in the South Asian population, given the substantial burden of T2DM and CVD in the region. Compared to the West, South Asians usually experience earlier onset and rapid progression of diseases and are particularly prone to metabolic abnormalities, including obesity, resistance to insulin, and an atherogenic lipid pattern characterized by increased triglycerides (TG), decreased high-density lipoprotein cholesterol (HDL-C), and elevated low-density lipoprotein cholesterol (LDL-C). This amalgamation of metabolic disturbances contributes significantly to their increased vulnerability to cardiovascular complications. Furthermore, genetic susceptibility, carbohydrate-rich dietary patterns, and sedentary lifestyles increase risk, with premature cardiovascular mortality being disproportionately high in South Asian population. However, research is required to determine exact predictive value of HbA1c for dyslipidemia and CVD risk in this cohort.

Our hypothesis suggests that in patients with T2DM and established CVD, higher HbA1c levels are significantly associated with adverse lipid profile changes, characterized by elevated TC, LDL C, and triglyceride levels and reduced HDL C levels.

The aim of our research is to comprehensively investigate the relationship between glycemic control (as measured by HbA1c) and lipid profiles in a Pakistani population characterized by a high incidence of both diabetes and CVD.

2. Methods

2.1. Study setting, ethics, and approval

The study was conducted in hospitals/medical centers located in Punjab Province. Samples were collected after approval from the Ethical Review Committee (ERC) Ref. No. (NMDC-ERC/CER/13/25) & Institutional Research Advisory Committee (IRAC) Ref. No. (RAC/0017/25-APR), Niazi Medical & Dental College and Niazi Welfare Foundation Teaching Hospital, Sargodha, followed by the approval of Heads (Medical Superintendents) of the respective hospitals/medical centre (Tayyab Hospital Sargodha, Niazi Welfare Foundation Teaching Hospital Sargodha, Mubarak Hospital Sargodha, Shazia Zahid Medical Centre Lahore, New Mahar Medical Hospital Silanwali, Noshani Hospital Sandhiliwali, Mughees Haris Surgical Complex Joharabad).

2.2. Sample size

The sample size for the study was calculated using Cohen's guidelines (r = 0.2; α = 0.05; power = 80%). The minimum required sample size was approximately 194; a total of 201 participants (121 patients and 80 controls) were enrolled.

2.3. Sampling method

Eligible participants were recruited by using non-probability convenience sampling technique, and selection was based on predefined inclusion and exclusion criteria.

2.4. Study design

This is a cross-sectional analytical study, and we carried out it over a period of six months from April to September 2025.

2.5. Target population

Adult patients with a confirmed T2DM diagnosis and/or established CVD.

2.6. Selection criteria

We recruited participants aged ≥ 18 years who had a confirmed T2DM diagnosis for at least one year, established CVD (defined as MI or unstable angina) and provided written informed consent. Patients were excluded if they had type 1 diabetes mellitus (T1DM), were pregnant, or had acute infections or other severe systemic illnesses that could acutely influence blood glucose or lipid levels, as well as individuals with known or suspected secondary causes of dyslipidemia, such as hypothyroidism or nephrotic syndrome, or those with conditions affecting HbA1c measurement, including severe anemia or hemoglobinopathies.

2.7. Study subjects

This study included 80 unrelated, healthy control subjects and 121 sporadic diabetic CVD patients. The patients (67 males, 54 females) were diagnosed with either MI or unstable angina. The initial diagnosis of CVD was established using electrocardiographic evidence of cardiac abnormalities, followed by confirmation with coronary angiography.

DM was diagnosed using standardized biochemical criteria. According to American Diabetes Association (ADA), a diagnosis is established by an HbA1c level of ≥ 6.5%, a fasting plasma glucose concentration of ≥ 126 mg/dL, or a random plasma glucose concentration of ≥ 200 mg/dL in individuals who present with classic symptoms of hyperglycemia. These criteria offer a consistent and reproducible mechanism to identify individuals at increased risk of microvascular and macrovascular complications.

The control participants group, comprised of unrelated 45 males and 35 females, recruited from similar geographical area who belonged to same ethnic group as study group with no prior diagnosis of CVD or diabetes, as well as absence of clinical evidence of other atherosclerotic vascular disorders with normal electrocardiography findings. We defined arterial hypertension as a systolic blood pressure (SBP) of ≥ 140 mmHg or a diastolic blood pressure (DBP) of ≥ 90 mmHg. Smoking status was assessed based on tobacco use history, with participants classified as smokers if they reported current or previous tobacco use and as nonsmokers if they had no history of tobacco exposure. Overweight and obesity were determined per the World Health Organization Western Pacific Region (WPRO) criteria for Asian populations, based on body mass index (BMI) cut-off values for overweight (≥ 23.0 kg/m^2) and obesity (≥ 25.0 kg/m^2) [7,8].

2.8. Data collection

Participants provided information for completion of the questionnaire. Personal information (name, sex, age), family history, socio-behavioral risk factor data (smoking status), physical measurements (weight, height, blood pressure), and medical history, including disease profile and clinical symptoms, were collected. The questionnaires were carefully completed according to the information and data provided by patients and their consulting physicians. BMI was calculated by the standard formula. The clinical histories of the control subjects were also obtained through an interview.

2.9. Sample collection

After an overnight fast of at least 8 hours, peripheral venous blood samples were collected from patients and controls using sterilized syringes. For biochemical analysis, 2.5 mL blood was collected into sterile plain serum tubes and allowed to clot before centrifugation at 4000 rpm for 5 minutes to separate the serum. The resulting serum supernatant was carefully transferred into microcentrifuge tubes in 0.5 mL aliquots and preserved at −20°C for further analysis.

2.10. Biochemical analysis

Biochemical parameters were analyzed employing an Agilent 8453 UV-Visible spectrophotometer (USA). The levels of serum TC, TG, and glucose were determined through enzymatic colorimetric analysis using commercially available gCHEM SERIES reagents (gCHEM, Italy). HDL-C levels were determined using enzymatic colorimetric assays with commercially available kits (Erba Lachema, Brno, Czech Republic). LDL-C concentrations were estimated using the Friedewald equation based on the measured values of TC, TG, and HDL-C; because LDL-C was derived using this equation, all samples were fasting and cases with triglycerides > 400 mg/dL were excluded from LDL-C estimation. HbA1c was measured on an A1C EZ 2.0 glycohemoglobin analyzer. The glucose value used in all analyses was fasting plasma glucose.

All biochemical analyses were performed under strict quality control measures, and all instruments were calibrated daily with help of standard references, while assay precision was determined by intra- and inter-assay coefficients. Reproducibility was confirmed by a duplicate analysis of randomly selected samples, ensuring reliability and consistency of results.

2.11. Statistical analysis

Frequencies (n) and percentages (%) were calculated for the baseline variable, whereas means ± standard deviations (SD) were calculated for biochemical and clinical parameters. Pearson chi-square test/Fisher's exact test was used to determine associations between categorical variables and to compare their distribution across patient and control groups. Continuous variables, including age, blood pressure, BMI, and lipid profile, were compared between the study groups using an unpaired Student’s t-test. Correlation as well as linear regression were performed to determine the relationship between HbA1c levels and relevant clinical variables. Statistical analyses using SPSS, version 26.0, were performed. Statistical significance was set at $p \leq 0.05$.

Levene's test was rendered to determine homogeneity of variance prior to conducting parametric tests. Regression diagnostics included the assessment of residual plots, and residuals’ normality. Residuals were approximately normally distributed, indicating the validity of the regression model.

3. Results

3.1. Characteristics of patients and control subjects

The study cohort consisted of 80 control subjects and 121 patients (Table 1). The proportion of participants aged > 45 years was significantly higher among the patient group compared to the control group ($p = 0.010$). As presented in Table 1, patient group included 54 (45%) females and 67 (55%) males, whereas control group consisted of 35 (44%) females and 45 (56%) males. Compared to control group, common risk factors such as high blood pressure and family history were observed at significantly higher frequencies among patients ($p < 0.0001$).

Table 1. Baseline profile of study participants by group.

Characteristics		Study Groups		*p* Values
		Controls n = 80	Patients n = 121	
		n (%)	n (%)	
Age	≤ 45 years	48 (60)	51 (42)	0.010 ***
	> 45 years	32 (40)	70 (58)	
Gender	Female	35 (44)	54 (45)	0.902
	Male	45 (56)	67 (55)	
Body mass index (BMI)	Normal	35 (44)	45 (37)	0.605
	Overweight/obese	45 (56)	76 (63)	
Hypertension	Normal	50 (62.5)	42 (35)	< 0.0001 ***
	Yes	30 (37.5)	79 (65)	
Smoking status	Non-smokers	53 (66)	76 (63)	0.619
	Smokers	27 (34)	45 (37)	
Family history	No family history	80 (100)	50 (41)	< 0.0001 ***
	Family history	0 (0)	71 (59)	

* The table presents a column-wise comparison of each characteristic between control participants and patient groups. ** Data are expressed as absolute numbers and corresponding percentages. *** Significant at $p \leq 0.05$.

3.2. Clinical and biochemical characteristics

Clinical and biochemical variables such as age, weight, blood pressure (BP), anthropometric measures (BMI), glycemic indices (blood glucose and HbA1c), and lipid parameters were compared between patients and controls (Table 2). The patients were significantly older (50.7 ± 12.7 years) than the control subjects were (42.9 ± 13.1 years), showing significant difference between the groups ($p < 0.001$). Patients had a significantly greater mean weight (70.61 ± 8.59 kg) than control subjects did (65.75 ± 12.86 kg; $p = 0.002$). The two groups did not differ significantly with respect to BMI ($p = 0.59$), possibly because of variability in height. The SBP was greater among patients (129.21 ± 10.8 mm Hg) than among control subjects (124.06 ± 10.73 mm Hg; $p = 0.001$). Table 2 further delineates that DBP was significantly greater in patients (89.01 ± 12.35 mm Hg) than in control subjects (82.44 ± 10.67 mm Hg; $p < 0.0001$).

Analysis showed a significant difference between study groups regarding the average blood glucose and HbA1c levels (228.1 ± 50.5 mg/dL; 8.23 ± 1.75 %) and the control group (114.49 ± 17.3 mg/dL; 5.06 ± 0.68 %) ($p < 0.0001$). The mean concentrations of TC and LDL-C were higher in patients than in control subjects, whereas triglyceride and VLDL-C levels were somewhat higher in the control group relative to patients, though these differences were not statistically significant. In contrast, the mean HDL-C levels were significantly greater among the controls than among the patients ($p = 0.008$).

Table 2. Differences in clinical and biochemical parameters between study groups.

Parameters	Study Groups		95% Confidence Intervals (CI)	*p* Values
	Controls (n = 80)	Patients (n = 121)		
	Mean ± SD	Mean ± SD		
Age (years)	42.94 ± 13.10	50.74 ± 12.70	4.14–11.47	< 0.0001 **
Weight (kg)	65.75 ± 12.86	70.61 ± 8.59	1.87–7.84	0.002 **
Body mass index (BMI) (kg/m^2)	24.32 ± 5.30	24.01 ± 2.96	-1.46–0.83	0.590
Systolic blood pressure (SBP) (mm Hg)	124.06 ± 10.73	129.21 ± 10.80	2.09–8.21	0.001 **
Diastolic blood pressure (DBP) (mm Hg)	82.44 ± 10.67	89.01 ± 12.35	3.23–9.90	< 0.0001 **
Fasting blood glucose (mg/dL)	114.49 ± 17.31	228.11 ± 50.51	102.05–125.18	< 0.0001 **
HbA1c	5.06 ± 0.68	8.23 ± 1.75	2.76–3.57	< 0.0001 **
Cholesterol (mg/dL)	187.10 ± 40.26	193.17 ± 45.80	-6.34–18.48	0.330
Triglycerides (mg/dL)	197.30 ± 114.93	184.44 ± 70.75	-38.69–12.96	0.320
Low-density lipoprotein cholesterol (LDL-C) (mg/dL)	104.86 ± 31.77	109.96 ± 36.48	-4.76–14.95	0.300
High-density lipoprotein cholesterol (HDL-C) (mg/dL)	47.39 ± 14.92	42.70 ± 10.03	-8.15–-1.21	0.008 **
Very Low-density lipoprotein cholesterol (VLDL-C) (mg/dL)	38.68 ± 20.81	37.15 ± 15.04	-6.54–3.48	0.540

* The table presents a column-wise comparison of each characteristic using unpaired Student's t test between study groups. ** Significant at $p \leq 0.05$.

3.3. Differences in clinical and biochemical characteristics by HbA1c status

Table 3 summarizes the characteristics of our study population in terms of comparisons between subjects with normal HbA1c (< 6.5%; n = 92, comprising all 80 controls and 12 patients) and those with high HbA1c (≥ 6.5%; n = 109, all patients) using t tests. Subjects with high HbA1c levels were significantly older (51.14 ± 12.88 years) than those with normal HbA1c levels were (43.49 ± 12.92 years). Analysis revealed significant variation in this parameter ($p < 0.0001$).

High-HbA1c group had a greater average body weight (70.71 ± 8.84 kg) than those in the normal-HbA1c group (66.27 ± 12.25 kg) did ($p = 0.003$). Similarly, SBP was observed to be greater in the high HbA1c group (129.40 ± 10.68 mm Hg) than in the normal HbA1c group (124.51 ± 10.92 mm Hg) ($p = 0.002$). Similarly, DBP was markedly elevated in the high-HbA1c group (89.18 ± 12.29 mm Hg) compared with that in the normal-HbA1c group (83.02 ± 11.07 mm Hg), indicating significant association ($p < 0.0001$). The mean blood glucose level was markedly greater in the high-HbA1c group (234.64 ± 45.39 mg/dL) than in the normal-HbA1c group (121.57 ± 31.65 mg/dL), underscoring the strong link between increased HbA1c and hyperglycemia ($p < 0.0001$). Furthermore, patients in the high-HbA1c group had lower HDL-C levels (42.95 ± 9.98 mg/dL) than those in the normal-HbA1c group did (46.48 ± 14.58 mg/dL; $p = 0.04$). However, comparison between the two groups showed no significant differences in BMI or lipid profile.

Table 3. Comparison of clinical and biochemical profiles according to HbA1c status.

Parameters	Subjects with Normal HbA1c (n = 92)	Subjects with High HbA1c (n = 109)	95% Confidence Intervals (CI)	*p* Values
	Mean ± SD	Mean ± SD		
Age (Years)	43.49 ± 12.92	51.14 ± 12.88	4.04–11.25	< 0.0001 **
Weight (kg)	66.27 ± 12.25	70.71 ± 8.84	1.49–7.37	0.003 **
Body mass index (BMI) (kg/m^2)	24.13 ± 5.03	24.13 ± 3.00	-1.14–1.12	0.990
Systolic blood pressure (SBP) (mm Hg)	124.51 ± 10.92	129.40 ± 10.68	1.87–7.90	0.002 **
Diastolic blood pressure (DBP) (mm Hg)	83.02 ± 11.07	89.18 ± 12.29	2.87–9.45	< 0.0001 **

Parameters	Subjects with Normal HbA1c (n = 92)	Subjects with High HbA1c (n = 109)	95% Confidence Intervals (CI)	*p* Values
	Mean ± SD	Mean ± SD		
Fasting blood glucose (mg/dL)	121.57 ± 31.65	234.64 ± 45.39	101.99–124.16	< 0.0001 **
Cholesterol (mg/dL)	185.76 ± 39.18	194.97 ± 46.91	-2.94–21.37	0.130
Triglycerides (mg/dL)	192.30 ± 109.79	187.24 ± 71.61	-30.49–20.37	0.700
Low-density lipoprotein cholesterol (LDL-C) (mg/dL)	105.75 ± 33.84	109.77 ± 35.45	-5.67–13.71	0.410
High-density lipoprotein cholesterol (HDL-C) (mg/dL)	46.48 ± 14.58	42.95 ± 9.98	-6.96–-0.10	0.040 **
Very Low-density lipoprotein cholesterol (VLDL-C) (mg/dL)	38.48 ± 21.93	37.46 ± 14.35	-6.10–4.06	0.690

* The table shows a column-wise comparison of each characteristic using unpaired Student's t test among the study population based on HbA1c status. ** Significant at $p \leq 0.05$.

3.4. Pearson correlation analysis of HbA1c with other parameters

Pearson correlation analysis results are summarized in Table 4, highlighting relationships between HbA1c and independent parameters. Elevated HbA1c levels were strongly and positively linked to blood glucose levels ($p < 0.0001$). Weak but statistically significant positive associations were identified between HbA1c levels and age, body weight, SBP and DBP (all, $p < 0.05$). Conversely, HbA1c was weakly, negatively, and significantly related to HDL-C ($p = 0.04$). No significant relationship was recorded between HbA1c levels and other evaluated parameters, including BMI, and cholesterol levels ($p > 0.05$).

Table 4. Correlation analysis of HbA1c and related parameters.

Variables	Correlation Coefficient (r)	*p* Values
Age (years)	0.19	0.005 *
Weight (kg)	0.23	0.001 *
Body mass index (BMI) (kg/m2)	0.07	0.270
Systolic blood pressure SBP (mm Hg)	0.19	0.005 *
Diastolic blood pressure (DBP) (mm Hg)	0.17	0.010 *
Fasting blood glucose (mg/dL)	0.75	< 0.0001 *
Cholesterol (mg/dL)	0.10	0.120
Triglycerides (mg/dL)	-0.01	0.850
Low-density lipoprotein cholesterol (LDL-C) (mg/dL)	0.05	0.420
High-density lipoprotein cholesterol (HDL-C) (mg/dL)	-0.14	0.040 *
Very low-density lipoprotein cholesterol (VLDL-C) (mg/dL)	-0.01	0.850

* Significant at $p \leq 0.05$.

3.5. Linear regression analysis of HbA1c with other parameters

Regression analysis results for HbA1c levels and age, weight, BMI, SBP, DBP, and blood glucose and lipid parameters are presented in Table 5. Regression model accounted for 56% of the variability in HbA1c levels ($R^2 = 0.56$), and the model assumptions were adequately met. The residuals were normally distributed. Blood glucose and HDL-C were the only parameters that were significantly related to HbA1c. After controlling for other variables, the regression coefficient (b = 0.023) revealed that a 1 mg/dL increase in blood glucose corresponded to a 0.023-unit increase in HbA1c. Among the evaluated parameters, blood glucose exhibited the strongest association with HbA1c ($p < 0.0001$). Table 5 further corroborates that HDL-C is inversely associated with HbA1c. The regression coefficient (b = −0.027) indicates that each 1 mg/dL increase in HDL-C is associated with a 0.027-unit reduction in HbA1c after controlling for other variables ($p = 0.030$).

Table 5. Regression analysis of factors associated with HbA1c levels.

Parameters	Unstandardized Coefficient (b)	Standardized Coefficient (β)	*p* Values
Age (Years)	-0.000	-0.050	0.300
Weight (kg)	0.010	0.090	0.110
Body mass index (BMI) (kg/m^2)	0.010	0.020	0.590
Systolic blood pressure (SBP) (mm Hg)	-0.000	-0.000	0.960
Diastolic blood pressure (DBP) (mm Hg)	0.000	0.040	0.500
Fasting blood glucose (mg/dL)	0.023	0.740	< 0.0001 **
Cholesterol (mg/dL)	0.000	0.100	0.160
Triglycerides (mg/dL)	-0.030	-1.430	0.800
Low-density lipoprotein cholesterol (LDL-C) (mg/dL)	0.000	0.040	0.530
High-density lipoprotein cholesterol (HDL-C) (mg/dL)	-0.027	-0.150	0.030 **
Very Low-density lipoprotein cholesterol (VLDL-C) (mg/dL)	0.160	1.420	0.800

* Dependent variable: HbA1c. ** Significant at $p \leq 0.05$.

4. Discussion

Our study shows HbA1c levels and key cardiovascular risk factors relationship among patients with diabetes. Baseline parameters like age > 45 years, hypertension and positive family history were significantly linked to disease ($p < 0.05$). Consistent results have been documented in previous studies [9,10,11]. Our results show that among the major risk factors, including weight, blood pressure were higher among patient groups than in control group. Previous studies have shown excess body weight and visceral obesity to be contributing risk factors in development of hypertension and cardiovascular disease [12]. Biochemical analysis revealed that patients had numerically higher cholesterol and LDL-C levels than healthy control subjects did, although this difference was not statistically significant. Comparable outcomes have been documented in prior studies, likewise, indicating no significant correlations between these variables [10]. These results are not in agreement with those of multiple prior studies, which reported significant correlations between HbA1c and both TC and LDL-C levels [13]. However, no significant associations were detected for TC, LDL-C, TG, or VLDL-C. Our results indicated that patients have lower HDL-C levels than control subjects do. These findings reveal a positive effect of HDL-C on health. A previous population survey similarly documented a high burden of lipid abnormalities in a comparable adult population [14].

We divided our study population on the basis of the cutoff value for HbA1c according to the ADA criteria. Study participants were categorized into a group of subjects with normal HbA1c levels (< 6.5) and individuals with higher levels of HbA1c (≥ 6.5 %). High HbA1c levels were associated with increasing age, blood pressure, body weight, and blood glucose levels, whereas HDL-C had a negative correlation with HbA1c, as per the findings of current study. Similar nature associations between glycemic status and cardiovascular risk factors have been reported by previous studies [13,15].

Pearson correlation analysis indicated a strong positive association of HbA1c with age, weight, SBP, DBP and glucose levels. Findings of current study align with previously conducted studies reporting significant and positive correlations between HbA1c levels, increased SBP, and family history [11]. Our results are in agreement with those of a number of studies that documented a significant inverse relationship between HbA1c levels and HDL-C levels [16,17].

The observed positive association between SBP, HbA1c, and fasting glucose levels is consistent with previous studies, highlighting relationship between impaired glycemic control and cardiovascular risk factors [9,18]. These findings highlight importance of

maintaining optimal blood pressure, as persistent hyperglycemia has been linked to vascular alterations such as arterial stiffness and impaired endothelial function, potentially contributing to increased SBP. Effective control of glycemia and blood pressure is essential for reducing cardiovascular risk among patients with diabetes.

A negative association for HbA1c and HDL-C levels was observed, which is in agreement with findings of Madhuri and Shet, revealing a negative correlation between these variables [19]. LDL-C was not significantly correlated with HbA1c, as reported by present study, which differs from findings of Vergès et al., who observed either no association or a positive relationship between these parameters [20]. These differences may reflect variations in metabolic profiles, genetic predispositions, lifestyle patterns, and clinical factors across populations, which can affect lipid parameters beyond glycemic status.

Insulin resistance reduces hepatic LDL receptor expression, resulting in impaired LDL clearance from circulation. Furthermore, increased influx of free fatty acids into liver promotes production of VLDL, resulting in hypercholesterolemia [20].

A study from Pakistan by Shahid et al. assessed HbA1c levels and fasting lipid profiles relationship among local diabetic population and showed that TC, and other parameters of lipid profile were positively correlated with HbA1c levels; however, LDL-C levels were negatively correlated [21]. Similarly, an Arabian study assessed HbA1c levels and lipid profiles relationship and revealed significant linkage between the levels of both TC and triglyceride levels and between the levels of these two variables in T2DM patients [22]. A recent Indonesian study similarly examined the relationship between HbA1c and the lipid profile in patients with T2DM [23].

Absence of a significant relationship between TC and glycemic indices in current study contrasts with findings from other scientific studies [24]. While previous studies have linked hypercholesterolemia with poor glycemic control, observations made by current study highlighted metabolic alterations in diabetes are heterogeneous, with individual lipid fractions revealing different associations with glycemic indices.

The variation in findings of current study and other earlier studies may highlight differences in underlying population characteristics. South Asian populations, including nondiabetic individuals, are reported to have a high baseline incidence of dyslipidemia, influencing HbA1c and lipid profile relationship. A key strength is the use of complete biochemical profiles of patients, which enabled comprehensive assessment through comparative, correlation, and regression analyses. However, the use of a cross-sectional study design, sample size, and lack of information on dietary habits, lifestyle patterns, duration of diabetes, and regular physical activity may be limitations to this study. Because the correlation and regression analyses were performed on the combined sample of patients and controls, the observed associations partly reflect between-group (case–control) differences and may not represent within-patient relationships. Furthermore, unmeasured confounding factors may have affected the observed associations; therefore, comprehensive clinical management strategies combining strict glycemic control with lipid-lowering agents are important for complications risk reduction.

5. Conclusions

The study identified a significant association between diabetes and several risk factors, including older age, hypertension, and family history. High levels of HbA1c were positively associated with age, blood pressure, body weight, and, most strongly, blood glucose levels, reflecting complex metabolic alterations associated with diabetes. The observed negative relationship between HbA1c and HDL-C highlights that reduced levels of protective lipoprotein may be associated with worsening glycemic status in diabetic patients. Although patients showed numerically higher TC and LDL-C than controls, these

differences were not statistically significant and were not associated with HbA1c levels, highlighting possible metabolic differences within the South Asian population.

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Original Article

Beyond the prescription: self-management practices and their sociodemographic determinants among type 2 diabetes patients visiting physicians

Ayesha Tahir [a,*], Kashmala Khan [a], Mohammed Khudhair Hasan [b], Hadia Jamil [c], Talha Jamil [d], Shaiza Hakeem [e]

[a] Department of Community Medicine, Rai Foundation Medical College, Sargodha, Pakistan
[b] Ibn Khaldun University College, Baghdad, Iraq
[c] Niazi Welfare Hospital, Sargodha, Pakistan
[d] Wah Medical College, Wah Cantt, Pakistan
[e] Niazi Medical & Dental College, Sargodha, Pakistan

* Correspondence: ayeshadrtahir@gmail.com

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Abstract

The prevalence of type 2 diabetes mellitus (T2DM) is rising steeply across South Asia, and day-to-day self-management largely determines whether patients avoid complications. However, local evidence on which patients struggle most remains limited. This exploratory study examined the pattern and determinants of self-management among adults with T2DM visiting physicians in Sargodha, Punjab, Pakistan. Between July and August 2025, 483 eligible patients were recruited by consecutive sampling across five outpatient clinics and hospital-linked pharmacies. A structured, interviewer-administered questionnaire adapted from a previously published regional instrument captured nine recommended self-care practices and sociodemographic and clinical characteristics; each interview lasted approximately ten minutes. The proportion of patients reporting each practice was summarized with Wilson confidence intervals (CIs), and a practice-count index (0–9) was derived. Because the internal consistency of the nine items was low (Kuder–Richardson 20 = −0.11; mean interitem ϕ = 0.08; Kaiser–Meyer–Olkin [KMO] = 0.56), practices were analyzed individually, and adequate self-management was defined a priori as adherence to at least five of nine practices. Associations were tested using chi-square tests, t tests and multivariable binary logistic regression, with Poisson regression as a sensitivity analysis. Adherence was highest for home and periodic blood glucose monitoring (68.1% and 67.3%, respectively) and lowest for three-monthly glycated hemoglobin (HbA1c) testing (26.5%) and stress-management techniques (45.5%). Overall, 70.8% achieved adequate self-management. In the adjusted analysis, younger age (adjusted odds ratio [aOR] 0.96 per year; 95% CI 0.94–0.98) and being married rather than unmarried (unmarried aOR 0.37; 95% CI 0.20–0.67) independently predicted adequate self-management (likelihood ratio $\chi^2 = 28.8$, $p = 0.001$; area under the curve 0.66). Education, income, family system, disease duration, family history and smoking status were not independent predictors. Diabetes self-care in this setting is uneven, with striking underuse of laboratory monitoring and stress management. Older and unmarried patients warrant targeted support.

Keywords

Diabetes mellitus, type 2; Glycated hemoglobin; Pakistan; Primary health care; Self care; Self-management; Sociodemographic factors

1. Introduction

Diabetes mellitus has become one of the defining chronic disease challenges of the present era. Global estimates indicate that approximately 537 million adults were living with diabetes in 2021, a figure projected to reach 783 million by 2045, with the sharpest increases concentrated in low- and middle-income countries [1]. Pakistan now has one of the heaviest burdens in the world, ranking among the top three countries in terms of the absolute number of affected adults, and type 2 diabetes mellitus (T2DM) accounts for the overwhelming majority of these cases [1,2]. The World Health Organization (WHO) continues to identify diabetes as a leading driver of blindness, kidney failure, myocardial infarction, stroke and lower-limb amputation, most of which are preventable when the disease is well controlled [2].

Unlike acute illness, T2DM is managed largely by the patient rather than the clinician. The everyday behaviors that determine outcomes—taking medicines as prescribed, following an appropriate diet, being physically active, monitoring blood glucose, examining the feet, attending laboratory tests and coping with psychological strain—unfold at home and between clinic visits and are strongly shaped by the social and economic conditions in which patients live [3,4,5,6]. These behaviors, collectively termed diabetes self-management, are the practical expression of the recommendations set out in contemporary standards of care and in national standards for diabetes self-management education and support [5,6]. Their importance is not merely theoretical: structured self-monitoring of blood glucose, regular physical activity and systematic foot care each has a demonstrable effect on glycemic control and on the risk of complications [7,8,9].

Where patients obtain their medicines and advice also matters. In much of South Asia, care is fragmented across physicians in outpatient clinics and pharmacists in community and hospital-linked settings, and a growing body of trial evidence shows that interventions delivered by either professional group can improve glycemic control, blood pressure and medication adherence [10,11,12,13,14]. An earlier exploratory study from Lahore compared self-management among patients who were attending physicians with those who were attending pharmacists and reported meaningful gaps in several practices, most notably laboratory monitoring [15]. That work supplied the questionnaire and conceptual starting point for the present study, but it did not model patient-level factors that might explain why some patients manage their condition well and others do not.

Internationally, self-care behavior varies with sociodemographic circumstances. Age, sex, marital status, educational attainment, household income, family structure and disease duration have been linked to self-management in studies from Jordan, Ghana, India, Portugal and elsewhere, although the direction and strength of these associations vary considerably across settings [16,17,18,19]. Psychological factors, particularly diabetes-related distress, further shape whether patients sustain healthy routines [20,21]. In Pakistan specifically, qualitative work suggests that barriers differ by educational level and that structured, patient-centered programs can improve self-efficacy and behavior [22,23]. What is largely missing is a quantitative, determinant-focused analysis of self-management among patients as they actually present for care.

This study was therefore designed with two aims. First, we aimed to describe the proportion of patients reporting each of nine recommended self-management practices among adults with T2DM who visit physicians at outpatient clinics and hospital-linked pharmacies in Sargodha, Punjab, Pakistan. Second, we sought to identify the sociodemographic and clinical characteristics independently associated with adequate self-management. Given the descriptive and hypothesis-generating character of the work, we framed it as an exploratory study and report it in accordance with STROBE recommendations for observational research [24].

2. Materials and methods

2.1. Study design and setting

We conducted an exploratory study over an eight-week period from July to August 2025. Data were collected at five sites in Sargodha, Punjab, Pakistan: outpatient clinics and hospital-linked pharmacies at which people with T2DM commonly present to purchase antidiabetic medicines, to undergo diabetes-related laboratory testing and to consult a physician about their condition. Sites were selected purposively to include settings that had a prescribing physician onsite and that together served patients drawn from a range of socioeconomic backgrounds, so that the sample would reflect the mixed clientele typical of urban and peri-urban diabetes care in the region.

2.2. Sample size

Because the number of people with T2DM attending these sites over the study window could not be determined (no register of patients attending the five sites was available) and was therefore treated as unknown and very large, the sample size was estimated using the Cochran formula for an unknown or very large population, $n_0 = Z^2p(1-p)/e^2$ [25,26]. With a 95% confidence level (Z = 1.96), an expected proportion of 0.50 and a 5% absolute margin of error (e = 0.05), the minimum required sample size was 384. The most conservative value, $p = 0.50$, was used because no reliable local estimate of overall adherence was available and the nine practices were expected to vary widely in frequency. To allow for up to 20% incomplete or unusable questionnaires, the recruitment target was inflated to 480 (384/0.8), and 483 complete interviews were obtained. This calculation served the primary, descriptive objective of estimating the proportion of patients reporting each practice. Its adequacy for the secondary, analytical objective was checked separately: with 141 patients in the smaller outcome category and 10 parameters in the multivariable model, there were approximately 14 outcome events per parameter, above the commonly used minimum of 10, although this rule of thumb is only a rough guide [27].

2.3. Sampling and recruitment

Participants were enrolled by consecutive sampling. During prearranged data-collection sessions at each site, every patient presenting for diabetes-related medicines, testing or consultation was screened for eligibility, and all those who met the criteria and consented were interviewed in the order in which they presented until the target across sites was reached. This walk-in, consecutive approach is well suited to the exploratory objective and to the flow of patients through pharmacy and clinic settings; its nonprobability nature is acknowledged among the study limitations.

2.4. Eligibility criteria

Adults aged 18 years or older with a physician-confirmed diagnosis of T2DM of at least two years' duration who were attending one of the five study sites in person during the study period and who were willing to provide written informed consent were eligible. Patients with type 1 or gestational diabetes, those newly diagnosed (less than two years), pregnant women and individuals with a psychiatric or cognitive condition that precluded a reliable interview were excluded. These criteria are consistent with those of the source study and with the observed data, in which all participants were adults and reported a disease duration of two years or more [15].

2.5. Questionnaire development

The instrument was adapted from the previously published regional questionnaire used by Malik and colleagues, which was informed by established self-care measures [15]. It comprised two sections. The first recorded sociodemographic and clinical characteristics: sex, age, marital status, years of formal education, monthly household income, family system, duration of T2DM and family history of diabetes. The second captured self-management using ten dichotomous (yes/no) items: cigarette smoking (a risk behavior) and nine recommended practices, namely daily feet checking, daily medication use, exercising for at least 20–30 minutes on at least five days per week, eating a well-balanced planned diet, checking random blood glucose at least once every three months, checking home blood sugars according to physician advice, checking glycated hemoglobin (HbA1c) every three months, using stress-management techniques, and regular random blood pressure monitoring. The content was reviewed by a physician and a pharmacist for clarity and local relevance, the instrument was translated into Urdu and back-translated to confirm fidelity, and it was pretested on a small group of patients who were not included in the final sample. Minor wording revisions followed the pilot test.

2.6. Data collection

Trained interviewers administered the questionnaire face-to-face in a private area at each site. Each interview lasted approximately ten minutes and was conducted separately from any clinical or dispensing encounter so that the responses were not influenced by the consultation itself. Interviewers recorded responses directly, and completed forms were checked for completeness on the same day, which is reflected in the absence of missing values in the final dataset.

2.7. Variables and outcome definition

The nine recommended practices were analyzed both individually and as a summed practice-count index ranging from 0 to 9. Because diabetes self-care behaviors are known to be only weakly intercorrelated, we first examined the internal structure of the nine items. Internal consistency was low (Kuder–Richardson 20 = −0.11), the mean absolute interitem phi coefficient was 0.08, and the Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy was 0.56, indicating that the items did not form a unidimensional scale. We therefore treated the practices primarily as distinct behaviors and retained the count only as a descriptive summary. For determinant modeling, adequate self-management was defined a priori as adherence to at least five of the nine practices (that is, a majority of recommended behaviors), in line with the common convention of classifying self-care as good when at least half of the maximum possible score is attained [28]; this cutoff also coincided with the median practice count in the sample. Patients below this threshold were classified as having inadequate self-management. Cigarette smoking was treated as an explanatory clinical/behavioral characteristic rather than as a self-care practice.

2.8. Statistical analysis

Continuous variables were summarized as mean and standard deviation or median and interquartile range, and categorical variables were summarized as frequencies and percentages. The proportion of patients reporting each practice was reported with 95% Wilson confidence intervals (CIs). Bivariate associations between patient characteristics and adequate self-management were tested using the chi-square test (with Cramér's V as an effect size) for categorical variables and the independent-samples t test (with Cohen's d) for continuous variables; the Mann–Whitney U test was used as a robustness check for

skewed continuous variables. All characteristics were then entered simultaneously into a multivariable binary logistic regression model with adequate self-management as the outcome, and adjusted odds ratios (aORs) with 95% CIs were derived. Model performance was assessed using the likelihood ratio test, the Nagelkerke pseudo-R^2, the Hosmer–Lemeshow goodness-of-fit test and the area under the receiver operating characteristic curve (AUC). As a sensitivity analysis, a Poisson regression model was fitted to the practice-count index. Given the exploratory design, no adjustments were made for multiple comparisons, and associations were interpreted as hypothesis-generating. A two-sided p value ≤ 0.05 was considered statistically significant. Analyses were performed in Python 3 using the statsmodels (version 0.14) and SciPy (version 1.17) libraries.

2.9. Ethical considerations

The study protocol was reviewed and approved by the Ethical Review Committee, Rai Foundation Medical College (a project of Rai Institute of Medical Sciences), Sargodha, Pakistan (No. RFMC/IRAB/Protocol/No.2025-005). All participants provided written informed consent before enrollment, participation was voluntary, no personally identifying information was recorded, and the data were analyzed in anonymized form. The study conformed to the principles of the Declaration of Helsinki.

3. Results

3.1. Sample characteristics

A total of 483 adults with T2DM completed the interview. Their characteristics are summarized in Table 1. Just under two-thirds were men (64.4%), and the mean age was 44.8 ± 10.5 years, ranging from 18 to 76 years. Most were married (73.3%) and lived within a joint family system (75.2%). Formal education was limited: 42.7% had received no formal schooling, and the mean duration of formal education was 6.5 ± 6.2 years. The median monthly household income was PKR 51,000 (interquartile range 39,500–70,000). The mean duration of diagnosed T2DM was 7.2 ± 2.6 years; almost two-thirds reported a family history of diabetes (63.6%), and 41.0% were current cigarette smokers.

Table 1. Sociodemographic and clinical characteristics of the study participants (N = 483).

Characteristic		Value
Sex	Male	311 (64.4)
	Female	172 (35.6)
Age (years), mean ± SD		44.8 ± 10.5
Age	18–39 years	165 (34.2)
	40–49 years	206 (42.7)
	≥ 50 years	112 (23.2)
Marital status	Married	354 (73.3)
	Unmarried	101 (20.9)
	Widowed/separated/divorced	28 (5.8)
Education	No formal education	206 (42.7)
	1–10 years	99 (20.5)
	> 10 years	178 (36.9)
Monthly household income (PKR), median (IQR)		51,000 (39,500–70,000)
Family system	Joint	363 (75.2)
	Nuclear	120 (24.8)
Duration of type 2 diabetes mellitus (years), mean ± SD		7.2 ± 2.6
Family history of diabetes	Yes	307 (63.6)

Characteristic		Value
Cigarette smoking	Yes	198 (41.0)

Abbreviations: SD, standard deviation; IQR, interquartile range; PKR, Pakistani rupees.

3.2. Self-management practices

Adherence to the individual practices is presented in Table 2. Blood glucose monitoring was the most commonly reported behavior: 68.1% of the participants checked home blood sugars in line with physician advice, and 67.3% had a random blood glucose check at least once every three months. A well-balanced planned diet (66.5%), daily medication use (65.8%) and regular exercise (62.3%) were also reported by approximately two-thirds of the patients. Blood pressure monitoring (60.0%) and daily feet checking (58.0%) were somewhat less common. The two conspicuous gaps were the use of stress-management techniques, reported by fewer than half (45.5%), and three-monthly HbA1c testing, reported by only approximately one-quarter of patients (26.5%)—by a wide margin the least-practiced behavior in the cohort.

Table 2. Self-management practices reported by participants, with 95% Wilson confidence intervals (N = 483).

Self-Management Practice	Yes, n (%)	95% CI
Checking home blood sugars (per physician advice)	329 (68.1)	63.8–72.1
Random blood glucose (≥ once/3 months)	325 (67.3)	63.0–71.3
Eating a well-balanced, planned diet	321 (66.5)	62.1–70.5
Daily medication use	318 (65.8)	61.5–69.9
Exercising ≥ 20–30 min, ≥ 5 days/week	301 (62.3)	57.9–66.5
Regular blood pressure monitoring	290 (60.0)	55.6–64.3
Daily feet checking	280 (58.0)	53.5–62.3
Using stress-management techniques	220 (45.5)	41.2–50.0
Checking HbA1c every 3 months	128 (26.5)	22.8–30.6

CI, confidence interval (Wilson method).

3.3. Practice-count index and its internal structure

Patients adhered to a mean of 5.20 ± 1.37 of the nine practices (median 5, interquartile range 4–6); the distribution is shown in Figure 1. Using the prespecified threshold, 342 patients (70.8%) achieved adequate self-management (≥ 5 of 9). Consistent with the broader literature, the nine practices largely behaved as independent behaviors rather than as facets of a single construct: internal consistency was low (Kuder–Richardson 20 = −0.11), the mean absolute interitem correlation was 0.08, and only one pair—daily feet checking and HbA1c testing—showed a moderate association ($\phi = 0.37$; Figure 2). This pattern justified analyzing the practices individually and interpreting the count purely descriptively.

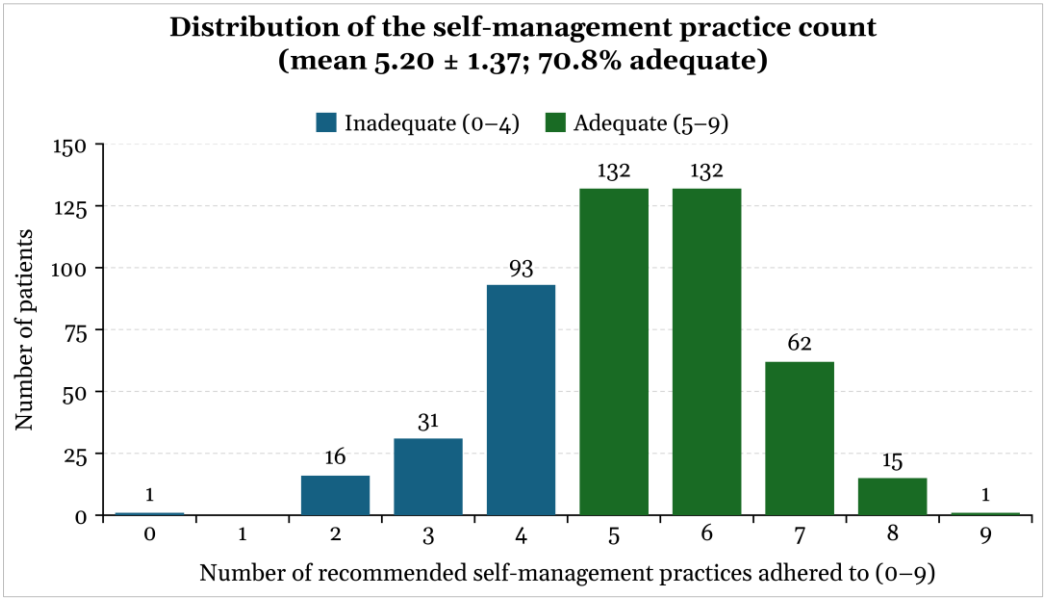


Figure 1. Distribution of the self-management practice-count index (0–9). The bars at or above the prespecified adequacy threshold (≥ 5) are shaded green.

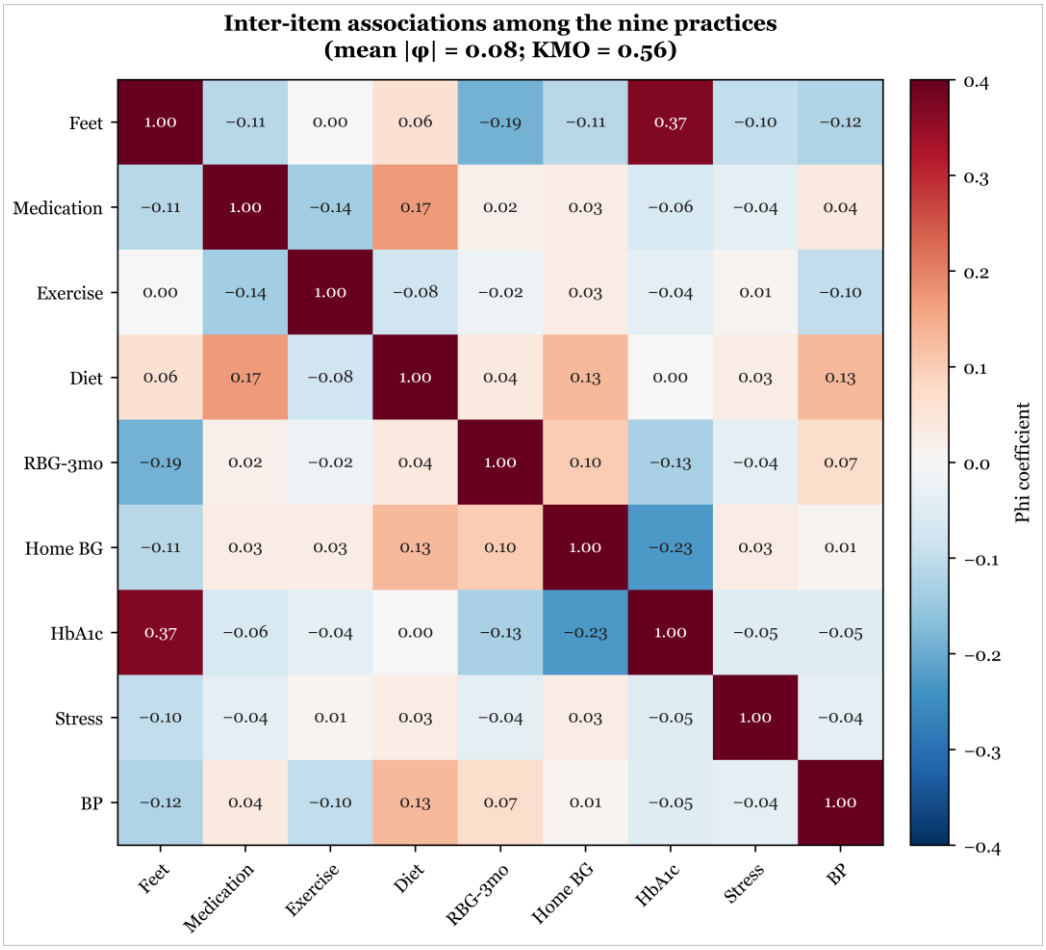


Figure 2. Interitem associations (phi coefficients) among the nine practices. The generally weak associations (mean |φ| = 0.08) and a Kaiser–Meyer–Olkin value of 0.56 indicate that the items do not form a unidimensional scale.

3.4. Factors associated with adequate self-management

Bivariate associations are shown in Table 3. Adequate self-management was significantly related to age, both as a continuous variable (44.0 ± 10.0 years in the adequate group versus 46.7 ± 11.3 years in the inadequate group; $p = 0.011$) and across age groups, decreasing from 75.2% among those aged 18–39 years to 61.6% among those aged 50 years or older ($p = 0.042$). It also varied by marital status ($p = 0.035$): married and widowed/separated/divorced patients were more likely to manage adequately (73.4% and 75.0%, respectively) than unmarried patients were (60.4%). A greater percentage of men than women achieved adequacy (74.0% versus 65.1%), a difference of borderline significance ($p = 0.052$). Education, income, family system, family history, disease duration and smoking showed no significant bivariate association with adequate self-management. At the level of individual practices, several behaviors differed by patient characteristics—for example, three-monthly random blood glucose checking differed by sex ($\chi^2 = 13.6$, $p < 0.001$) and blood pressure monitoring by smoking status ($\chi^2 = 11.1$, $p = 0.001$)—but these isolated associations should be read cautiously in light of multiple testing.

Table 3. Bivariate association of patient characteristics with adequate self-management (≥ 5 of 9 practices).

Characteristic		Adequate (n = 342) n (%)	Inadequate (n = 141) n (%)	Test (t/ χ^2/ Cohen's d)	*p* Value
Age (years), mean ± SD		44.0 ± 10.0	46.7 ± 11.3	d = 0.26, t = 2.56	0.011 ***
Age (years)	18–39	124 (75.2)	41 (24.8)	$\chi^2 = 6.32$	0.042 ***
	40–49	149 (72.3)	57 (27.7)		
	≥ 50	69 (61.6)	43 (38.4)		
Sex	Male	230 (74.0)	81 (26.0)	$\chi^2 = 3.77$	0.052
	Female	112 (65.1)	60 (34.9)		
Marital status	Married	260 (73.4)	94 (26.6)	$\chi^2 = 6.73$	0.035 ***
	Unmarried	61 (60.4)	40 (39.6)		
	Widowed/separated/divorced	21 (75.0)	7 (25.0)		
Education	None	147 (71.4)	59 (28.6)	$\chi^2 = 0.27$	0.873
	1–10 years	68 (68.7)	31 (31.3)		
	> 10 years	127 (71.3)	51 (28.7)		
Income (PKR), mean ± SD ($\times 10^3$)		52.2 ± 17.1	52.5 ± 17.9	t = 0.14	0.892
Family system, nuclear		89 (74.2)	31 (25.8)	$\chi^2 = 0.67$	0.413
Duration (years), mean ± SD		7.1 ± 2.5	7.5 ± 2.9	t = 1.31	0.191
Family history, yes		210 (68.4)	97 (31.6)	$\chi^2 = 2.05$	0.153
Smoking, yes		143 (72.2)	55 (27.8)	$\chi^2 = 0.22$	0.640

* Percentages for categorical variables are row percentages (proportion adequate versus inadequate within each level). ** Abbreviation: d, Cohen's d. *** Statistically significant at $p \leq 0.05$.

In the multivariable logistic regression (Table 4), two factors remained independently associated with adequate self-management. Each additional year of age reduced the odds of adequacy by approximately 4% (aOR 0.96, 95% CI 0.94–0.98; $p < 0.001$), and unmarried patients had markedly lower odds than married patients did (aOR 0.37, 95% CI 0.20–0.67; $p = 0.001$). The widowed/separated/divorced group did not differ significantly from the married reference group (aOR 1.87, 95% CI 0.72–4.83). Sex, education, income, disease duration, family system, family history and smoking status were not independent predictors. The model was statistically significant overall (likelihood ratio $\chi^2 = 28.8$, $p = 0.001$), showed acceptable calibration (Hosmer–Lemeshow $p = 0.086$) and modest discrimination (AUC = 0.66), and explained a limited share of the variance

(Nagelkerke R^2 = 0.083). A Poisson sensitivity model fitted to the practice count reproduced the age effect (incidence-rate ratio 0.995 per year, 95% CI 0.991–0.999; p = 0.020), supporting the robustness of the main finding.

Table 4. Multivariable binary logistic regression for adequate self-management (≥ 5 of 9 practices) (N = 483).

Predictor	aOR	95% CI	*p* Value
Age (per year)	0.96	0.94–0.98	< 0.001 ***
Male (versus female)	1.14	0.70–1.86	0.599
Unmarried (versus married)	0.37	0.20–0.67	0.001 ***
Widowed/separated/divorced (versus married)	1.87	0.72–4.83	0.199
Education (per year)	0.99	0.96–1.02	0.554
Income (per 10,000 PKR)	1.00	0.89–1.13	0.986
Duration of type 2 diabetes mellitus (per year)	0.94	0.87–1.02	0.135
Nuclear family (versus joint)	1.32	0.81–2.16	0.266
Family history (yes versus no)	0.76	0.49–1.17	0.212
Smoking (yes versus no)	1.07	0.70–1.65	0.746

* Abbreviations: aOR, adjusted odds ratio; CI, confidence interval. ** Model: likelihood ratio χ^2 = 28.8, p = 0.001; Nagelkerke R^2 = 0.083; Hosmer–Lemeshow p = 0.086; AUC = 0.66. *** Statistically significant at $p \leq 0.05$.

4. Discussion

This exploratory study of 483 adults with T2DM who presented to physicians in Sargodha, Punjab, describes a pattern of self-management that is broadly moderate but distinctly uneven. Between three-fifths and two-thirds of patients reported adhering to most recommended behaviors, and 70.8% met our threshold for adequate self-management. Two behaviors, however, stood out for their low uptake: three-monthly HbA1c testing, reported by only 26.5% of patients, and the use of stress-management techniques, reported by 45.5%. Multivariable analysis showed that younger age and being married were the factors independently associated with adequate self-management, whereas the more commonly cited socioeconomic markers of education and income were not.

The proportions observed here align closely with those in the source study from Lahore, which used the same instrument and reported that HbA1c testing was the least-practiced behavior among physician-attending patients, with diet and stress management at levels very similar to ours [15]. This concordance across independent samples lends face validity to the present findings. Compared with pooled regional estimates for South Asia, where blood glucose monitoring, medication use, physical activity, diet and foot care have been reported at approximately 65%, 64%, 53%, 48% and 42%, respectively, our cohort reported somewhat higher adherence to diet and foot care in particular [29]. The persistent shortfall in laboratory-based monitoring is nonetheless consistent with regional evidence and is plausibly driven by the out-of-pocket cost of HbA1c testing, limited laboratory access and incomplete patient understanding of why periodic testing matters [30,31].

The low uptake of HbA1c testing deserves particular emphasis because it is not merely one behavior among nine; it is the objective yardstick by which glycemic control is judged and treatment intensified [32,33]. Its underuse suggests that a substantial proportion of patients are being managed without the very measurement that current standards of care place at the center of monitoring [34]. Structured self-monitoring of blood glucose and periodic laboratory assessments together support timely treatment adjustment and better outcomes, and the gap identified here points to a concrete, addressable

target for clinics and hospital-linked pharmacies—for example, opportunistic point-of-care testing or reminder systems at the point of medicine collection [35,36,37].

Equally striking is the modest use of stress-management techniques. Diabetes-related distress and associated psychological strain are increasingly recognized as barriers to sustained self-care, and interventions that address the emotional burden of the disease can improve both distress and glycemic outcomes [38,39]. The fact that fewer than half of our patients engaged in any form of stress management indicates that the psychological dimension of diabetes care remains largely unaddressed in this setting, despite being a low-cost and scalable avenue for support [40].

The independent association of younger age with better self-management, which is robust across both the logistic and Poisson models, runs counter to a common assumption that older patients—with longer disease experience—necessarily self-manage better [41]. This finding is, however, consistent with reports that advancing age can result in physical limitations, competing comorbidities and reduced engagement with newer monitoring practices, and with syntheses identifying older age among the determinants of poorer control in similar populations [3,17]. The strong protective association of marriage and the correspondingly lower odds among unmarried patients echo the substantial literature on the role of social and spousal support in chronic disease self-management, in which a partner often facilitates medication routines, dietary change and clinic attendance [18,19,42]. Together, these findings suggest that structured support should be prioritized for older and unmarried patients, who may lack the informal scaffolding that helps others sustain daily self-care.

The near absence of an education or income gradient is noteworthy and contrasts with the findings of some international studies [16,19,43]. One interpretation is that, in a setting where a large share of patients have no formal schooling, the more decisive influences on self-care are practical and relational—cost, access, and the presence of a supportive household—rather than years of education per se. Qualitative work from urban Pakistan similarly revealed that the nature of barriers, more than educational level alone, shapes self-management [44]. This finding reinforces the case for interventions that are practical and support-oriented rather than purely educational.

Our findings also speak to the delivery of care. Trial evidence shows that professional-led interventions, whether delivered by pharmacists or by nurse-led teams, can improve glycemic control, blood pressure, medication adherence and diabetes-related distress [10,11,12,13,14,21,22]. Because patients in this study were recruited precisely at the points where they collect medicines and seek testing, these same touchpoints offer a natural platform for brief, structured interventions targeting the specific gaps identified here, most obviously HbA1c monitoring, foot care and psychological coping [9,45].

The strengths of this study include a sample that comfortably exceeds the calculated minimum, complete data, recruitment at real points of care across five sites, and an analytical approach that goes beyond simple description to model determinants while transparently testing and reporting the weak internal structure of the practice items. Several limitations temper the conclusions. First, the single-time-point design precludes causal inference; the associations with age and marital status are hypothesis-generating. Second, self-reported behavior is subject to recall and social desirability bias, which may inflate reported adherence. Third, consecutive sampling at purposively selected sites limits generalizability beyond comparable urban and peri-urban settings, and patients who do not attend for care are unrepresented. Fourth, the questionnaire captured practices dichotomously and did not measure glycemic control (HbA1c values), quality of the practices, or important contextual variables such as insulin use, comorbidity and health literacy. Fifth, the modest model R^2 indicates that most of the variation in self-manage-

ment is explained by factors not captured here, and the exploratory analyses were not corrected for multiple comparisons. Future work would benefit from a more analytical design (for example, a prospective cohort or case–control study), objective glycemic measures and a richer set of psychosocial predictors.

5. Conclusions

Among adults with T2DM visiting physicians in Sargodha, Punjab, self-management was moderate overall but marked by two clear deficits: very low uptake of three-monthly HbA1c testing and limited use of stress-management techniques. Younger and married patients were independently more likely to manage their condition adequately, whereas education and income were not. These results point to practical, equity-oriented priorities—expanding access to and awareness of laboratory monitoring, integrating psychological support into routine diabetes care, and directing structured, support-based interventions toward older and unmarried patients—that could be delivered at the clinics and hospital-linked pharmacies where patients already present for care.

Abbreviations: aOR, Adjusted odds ratio; AUC, Area under the receiver operating characteristic curve; BG, Blood glucose; BP, Blood pressure; CI, Confidence interval; HbA1c, Glycated hemoglobin; IQR, Interquartile range; KMO, Kaiser–Meyer–Olkin; PKR, Pakistani rupees; RBG, Random blood glucose; SD, Standard deviation; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology; T2DM, Type 2 diabetes mellitus; WHO, World Health Organization.

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Original Article

Health-risk knowledge of cigarette smoking and attitudes toward pack warning labels among adult smokers and nonsmokers in Punjab, Pakistan: a comparative cross-sectional study

Muneeb Ghumman [a,*], Ambreen Salman [b], Niaz Ali Khan [c], Khadija [d], Sadaf Zehra [e], Muhammad Abdullah Ahmad [f]

[a] Department of Public Health, University of Health Sciences, Pakistan
[b] School of Creative Arts, The University of Lahore, Pakistan
[c] World Health Organization, Pakistan
[d] Semnan University of Medical Sciences, Iran
[e] Liaquat National Hospital and Medical College, Pakistan
[f] University College of Medicine and Dentistry, Pakistan

* Correspondence: muneebghuman4499@gmail.com

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Abstract

Cigarette smoking is a leading preventable cause of death in Pakistan, yet adults' knowledge of its specific harms and attitudes toward pack warning labels are incompletely characterized. We conducted a comparative cross-sectional survey of 406 adults (260 smokers and 146 nonsmokers) in Ichhra, a densely populated locality of Lahore, Punjab. An interviewer-administered questionnaire adapted from a validated instrument captured sociodemographic characteristics, smoking behavior, a 14-item health-risk knowledge battery, and warning-label attitudes. Knowledge scores were classified by the modified Bloom cutoff, and internal consistency was assessed using the Kuder–Richardson 20 (KR-20) and Cronbach's alpha coefficients. Categorical characteristics were compared with the chi-square test, weight with the t test, and the knowledge score with the Mann–Whitney U test, applying a Bonferroni correction across the 14 item comparisons. Independent predictors were modeled with binary and ordinal logistic regression, and dimensionality (whether each scale measures one or more distinct constructs) was examined by exploratory factor analysis. The sample was predominantly male (97.8%); smokers consumed 7.6 (SD 3.9) cigarettes daily for 6.2 (SD 4.8) years, and 52.7% had attempted to quit. The knowledge and warning-label scales showed acceptable reliability (KR-20 = 0.71 and 0.72), and the quit-barrier scale had good reliability (Cronbach's alpha = 0.84). Nonsmokers knew more than smokers did; six items remained significant after the Bonferroni correction, all favoring nonsmokers. Good knowledge was more common among nonsmokers (72.6% versus 53.1%; $p = 0.001$). After adjustment, smoking (adjusted odds ratio [aOR] 0.42, 95% confidence interval 0.26 to 0.68), a rural background (0.45, 0.28 to 0.71) and lower personal income independently predicted poorer knowledge, whereas a graduate education level predicted being a smoker (3.48, 2.13 to 5.68). Among smokers, feeling concerned about smoking predicted quitting attempts (2.13, 1.26 to 3.60). Health messaging should prioritize smokers and people with a rural background and should address sex-specific harms.

Keywords

Cigarette smoking; Cross-sectional studies; Health knowledge; Nonsmokers; Pakistan; Smokers; Warning labels

1. Introduction

Tobacco use is among the greatest preventable causes of premature death worldwide, killing more than seven million people each year, including over 1.6 million nonsmokers who are exposed to second-hand smoke [1]. The overwhelming majority of the world's tobacco users live in low- and middle-income countries, where health systems are least prepared to absorb the resulting burden of cardiovascular disease, chronic respiratory disease and cancer [1,2]. Cigarette smoke contains thousands of chemical constituents, and causal links between smoking and ischemic heart disease, chronic obstructive pulmonary disease, and cancers of the lung, larynx, pharynx, esophagus, oral cavity and stomach have been firmly established [2].

Pakistan bears a heavy and unequal share of this burden. National survey data indicate a high prevalence of smoking among men, a strong urban–rural gradient in household smoke exposure, and important sex differences in tobacco use and its determinants [3,4]. Recent Pakistani studies of smokers and the general population confirm that combustible cigarettes remain the dominant product and that knowledge, attitudes and practices vary widely across regions and social groups [5,6,7]. Understanding what people know about the specific harms of smoking is central to tobacco control because accurate risk perception underpins both the decision not to start smoking and the motivation to quit [8].

Health warnings on cigarette packaging are among the most cost-effective instruments available to communicate these harms, and Pakistan, as a party to the World Health Organization Framework Convention on Tobacco Control, has implemented pictorial and text warnings under the MPOWER package. A growing evidence base shows that stronger warnings increase perceived harm, quitting intentions and quitting attempts, especially when they are large and graphic [9,10]. However, the effect of warnings depends on how they are received, and public knowledge and the endorsement of warning content are rarely measured together in the same population, particularly among community-dwelling adults rather than students.

An earlier comparative study of university students in Pakistan applied a 14-item knowledge battery and the modified Bloom classification and revealed that knowledge did not differ between smokers and nonsmokers, that smoking was more common among rural students and that sex-specific harms were poorly understood; this study relied mainly on descriptive statistics, the chi-square test and the Mann–Whitney U test, and it did not report the reliability of its instrument, quantify effect sizes, adjust for confounding, or examine attitudes toward warning labels [8]. Whether its conclusions extend to the wider adult community, which differs from that of students in terms of age, education and occupation, is unknown. Comparable international work using knowledge indices has since shown that former smokers and more advantaged groups often know more than current smokers do and that knowledge is associated with concern about personal risk [11,12,13].

We therefore studied a community sample of adult smokers and nonsmokers in Punjab with three objectives: first, to quantify and compare health-risk knowledge between smokers and nonsmokers at the item level and overall; second, to establish the reliability and dimensionality of the knowledge, warning-label and quit-barrier scales; and third, to identify the independent sociodemographic determinants of knowledge, smoking status, and quit attempts using multivariable models. By adding reliability testing, effect sizes, correction for multiple comparisons and regression modeling to the earlier descriptive framework, the study aims to provide a more robust and policy-relevant account of what adults in this setting know and believe about cigarette smoking.

2. Methods

2.1. Study design and setting

This was a comparative, community-based cross-sectional study conducted over one month, from March 2025 to April 2025, in Ichhra, a densely populated residential and commercial locality of Lahore, Punjab, Pakistan. Ichhra is an old part of the city, with a mix of long-standing buildings and later flats, and is well known for Ichhra Bazaar, one of the more economical markets of Lahore. The locality houses both families who have lived there for generations and a large number of tenants who have moved from other parts of Pakistan and rent rooms or flats while working in the surrounding residential and commercial areas; this mix made Ichhra a practical setting in which to reach adults of varied backgrounds in a short period.

2.2. Ethics

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Review Committee of the Central Institute of Family Medicine (No. CIFM/ERC-25/0028). Written informed consent was obtained from every participant before data collection: literate participants signed the consent form, and participants who could not read or write gave a thumb impression after the form had been read and explained to them.

2.3. Sampling and participants

A door-to-door approach was used within Ichhra. A trained data-collection team visited households along successive residential streets and, within multioccupancy buildings, approached the individual flats and rented rooms in turn so that both long-term resident families and tenants who had settled in the area from various parts of Pakistan for work were represented. One eligible adult was interviewed per household or occupied unit; where more than one adult was present, the person available and willing at the time of the visit was enrolled. Sampling was therefore consecutive and convenience-based within the visited streets, and nonsmokers continued to be enrolled alongside smokers to preserve a workable comparison group.

Eligible participants were adults older than 18 years, whose age was confirmed against the date of birth on their Computerized National Identity Card (CNIC), who were residents of Ichhra at the time of the survey (as long-term residents or as tenants relocated for work), were able to provide informed consent and complete the interview in a single sitting and reported no chronic illness recognizable to a layperson as attributable to smoking, such as a known diagnosis of lung cancer or chronic obstructive pulmonary disease, so that personal illness experience would not inflate risk knowledge. People who could not understand and communicate in English or a local language (Urdu, Punjabi or Saraiki) and those who did not complete the core questionnaire were excluded.

Participants were classified by self-reported status as current cigarette smokers or nonsmokers, which is consistent with the smoking status classification used in the source study [8]; a current smoker was a person who reported smoking cigarettes at the time of the survey, whether daily or occasionally, and a nonsmoker was a person who reported not currently smoking.

2.4. Sample size

The required sample size was estimated for the primary comparison, the difference in the proportion with good knowledge between smokers and nonsmokers, using the standard formula for two independent proportions (Equation 1) [14]:

$$n = [z_{1-\alpha/2} \sqrt{(2\bar{p}(1-\bar{p}))} + z_{1-\beta} \sqrt{(p_1(1-p_1) + p_2(1-p_2))}]^2 / (p_1-p_2)^2 \quad (1)$$

The anticipated proportion of smokers with good knowledge (p_1) was set at 0.54 on the basis of the 54.4% reported among smokers in the source study [8], and a difference of 20 percentage points ($p_2 = 0.74$ in nonsmokers) was taken as the smallest difference of practical importance. With a two-sided alpha of 0.05 ($z = 1.96$) and 80% power ($z = 0.84$), the calculation yielded 90 participants per group or 100 per group after allowing for 10% incomplete responses. The achieved sample of 260 smokers and 146 nonsmokers exceeds this requirement and provides adequate power for the primary comparison.

2.5. Instrument

Data were collected with a structured questionnaire adapted with minor modifications from a previously published instrument used in Pakistan [8], for which permission to adapt and use was obtained from the original authors. Because the participants ranged from highly educated to those with little or no formal schooling, the questionnaire was interviewer-administered: trained members of the data-collection team read each item aloud in the participant's preferred language and recorded the responses rather than leaving the respondents to complete it unaided. Before the main survey, the instrument was pilot tested on a small convenience sample of adults from the same setting to check the clarity and comprehensibility of the items, the appropriateness of the local-language wording, the average time to complete the interview, and the internal consistency of the scales; only minor wording adjustments followed, and the pilot responses were not included in the analysis. The questionnaire recorded sociodemographic characteristics (age group, sex, marital status, education, personal and family income band, source of income, district of origin and family system) and, for smokers, the number of cigarettes smoked per day, the duration of smoking in years, feelings about smoking and any previous quit attempt. Health-risk knowledge was assessed with 14 items covering ischemia and myocardial infarction, chronic obstructive lung disease, respiratory disorders, six cancers (esophagus, larynx, lung, oral cavity, pharynx and stomach), male impotence, pregnancy-related complications, the presence of toxic chemical constituents, and awareness of second-hand smoke and its dangers. Each correct answer was given one point, for a total of 0 to 14 points. Warning-label attitudes were captured by ten yes/no endorsement items, and for smokers who had attempted to quit, perceived barriers to quitting were rated on six five-point items covering fear of failure, irritability, difficulty concentrating, craving, loss of pleasure and weight gain.

2.6. Derived measures

Overall knowledge was classified by the modified Bloom cutoff as good (80% or more, that is, 12 to 14 correct), moderate (50 to 79%, that is, 7 to 11 correct) or poor (below 50%, that is, fewer than 7 correct) [8,15]. Age, personal income and family income were collected as ordered bands and were retained as categorical variables for description; in regression, they were entered as ordinal scores corresponding to the rank of the band. Education was dichotomized as graduate or higher versus up to intermediate. Because the sample combined long-term Lahore residents with tenants who had moved in from elsewhere, participants were classified by background as city-based when their district of origin was a metropolitan city and as having a rural background when their district of origin was a predominantly rural area. Body weight was recorded in whole kilograms and analyzed as a continuous variable, whereas height was recorded only in whole feet, which is too coarse for a valid body mass index; thus, body mass index was not computed.

A warning-label support score (0 to 10) and a quit-barrier score (6 to 30) were derived by summation.

2.7. Statistical analysis

Analyses were performed using IBM SPSS Statistics version 27 (IBM Corp., Armonk, NY, USA). Categorical variables, including age and income bands, are summarized as counts and percentages within each smoking group and were compared using the Pearson chi-square test or Fisher's exact test when a 2 × 2 table had an expected cell count below 5, with the Cramer V effect size. Weight, the only continuous characteristic, is summarized as the mean and standard deviation (SD) and was compared using the independent-samples t test with the Cohen d effect size. The overall knowledge score (0 to 14) is summarized as the median and interquartile range and compared using the Mann–Whitney U test, with the effect size r calculated as Z/√N from the standardized test statistic. Across the 14 knowledge items, raw *p* values were multiplied by 14 (Bonferroni correction) because testing 14 items each at the 0.05 level carries an approximately 51% probability of at least one false-positive result; an item difference was considered significant only when its Bonferroni-adjusted *p* value was 0.05 or less. Internal consistency was quantified using the Kuder–Richardson 20 (KR-20) coefficient for dichotomous scales and the Cronbach's alpha coefficient for the Likert quit-barrier scale [16]. Dimensionality was examined by exploratory factor analysis with principal axis factoring and varimax rotation after confirming sampling adequacy with the Kaiser–Meyer–Olkin (KMO) measure and Bartlett's test of sphericity. Associations between the knowledge score and other ordinal or continuous variables were assessed with Spearman's rank correlation. Independent predictors of good knowledge were estimated with binary logistic regression, and the ordered three-level knowledge outcome was estimated with proportional odds ordinal logistic regression; correlates of smoking status and, among smokers, of quit attempts were modeled with binary logistic regression, and model fit is reported as the Nagelkerke R^2. The results are reported as adjusted odds ratios (aORs) with 95% confidence intervals. Sex was excluded from the knowledge models because only nine participants were women. A two-sided *p* value of 0.05 or less was considered significant.

3. Results

3.1. Sample characteristics

Among the 406 participants, 260 (64.0%) were smokers, 146 (36.0%) were nonsmokers, and 397 (97.8%) were men. The smokers consumed a mean of 7.6 (SD 3.9) cigarettes per day and had smoked for 6.2 (SD 4.8) years; 148 described themselves as contented with their smoking and 112 as concerned, and 137 of 260 (52.7%) had made at least one quitting attempt. Smoking status was associated with education, marital status, source of income, personal income, family income and weight but not with age, sex, background or family system (Table 1). Compared with nonsmokers, smokers were more often graduates and unmarried and less often held a private-sector job. Nonsmokers reported higher personal and family incomes and a higher mean body weight (73.3 kg versus 69.5 kg; $p = 0.001$).

Table 1. Sociodemographic and smoking characteristics by cigarette smoking status (N = 406).

Characteristic		Smokers (n = 260) n (%)	Nonsmokers (n = 146) n (%)	*p* Value	Effect Size
Sex	Male	254 (97.7)	143 (97.9)	> 0.99	V = 0.008
	Female	6 (2.3)	3 (2.1)		
Background	City-based	164 (63.1)	91 (62.3)	0.881	V = 0.007
	Rural background	96 (36.9)	55 (37.7)		
Family system	Joint	176 (67.7)	104 (71.2)	0.459	V = 0.037
	Nuclear	84 (32.3)	42 (28.8)		
Education	Graduate or higher	142 (54.6)	54 (37.0)	0.001	V = 0.169
	Up to intermediate	118 (45.4)	92 (63.0)		
Marital status	Married	165 (63.5)	113 (77.4)	0.004	V = 0.144
	Unmarried	95 (36.5)	33 (22.6)		
Source of income	Business	35 (14.7)	5 (3.8)	< 0.001	V = 0.211
	Government job	64 (26.9)	25 (18.8)		
	Private job	139 (58.4)	103 (77.4)		
Age group, years	Below 20	3 (1.2)	3 (2.1)	0.142	V = 0.130
	21 to 30	134 (51.5)	61 (41.8)		
	31 to 40	46 (17.7)	38 (26.0)		
	41 to 50	63 (24.2)	32 (21.9)		
	51 and above	14 (5.4)	12 (8.2)		
Personal income, PKR	Below 10 000	45 (18.9)	9 (6.8)	0.002	V = 0.226
	10 001 to 20 000	66 (27.7)	38 (28.6)		
	20 001 to 30 000	87 (36.6)	46 (34.6)		
	30 001 to 40 000	22 (9.2)	24 (18.0)		
	40 001 to 50 000	13 (5.5)	15 (11.3)		
	Above 50 000	5 (2.1)	1 (0.8)		
Family income, PKR	10 001 to 20 000	23 (8.8)	0 (0.0)	< 0.001	V = 0.234
	20 001 to 30 000	42 (16.2)	18 (12.3)		
	30 001 to 40 000	55 (21.2)	21 (14.4)		
	40 001 to 50 000	37 (14.2)	25 (17.1)		
	Above 50 000	103 (39.6)	82 (56.2)		
Weight, kg, mean (SD)		69.5 (10.2)	73.3 (11.3)	0.001	d = 0.351

Categorical variables were compared using the Pearson chi-square test or Fisher's exact test for sex because one expected cell count was less than 5 (effect size Cramer V), and weight was compared using the independent-samples t test (effect size Cohen d). $p \leq 0.05$ was considered to indicate statistical significance. Abbreviations: PKR, Pakistani rupees; SD, standard deviation; V, Cramer V. Sources of income and personal income were missing for 35 participants (22 smokers and 13 nonsmokers); percentages for these two variables are based on the 238 smokers and 133 nonsmokers with data.

3.2. Scale reliability

The 14-item knowledge scale and the 10-item warning-label support scale each showed acceptable internal consistency (KR-20 = 0.71 and 0.72, respectively). The six-item quit-barrier scale showed good internal consistency (Cronbach's alpha = 0.84, 95% confidence interval 0.79 to 0.88), supporting its use as a summary measure.

3.3. Item-level and overall knowledge

Nonsmokers answered most items correctly more often than smokers did. After the Bonferroni correction, six items remained significant, all of which favored nonsmokers: larynx, pharynx and stomach cancer; awareness of toxic chemical constituents; having

heard of second-hand smoke; and recognizing second-hand smoke as dangerous (Table 2). Four further items (chronic obstructive lung disease, esophageal cancer, lung cancer and pregnancy-related complications) differed at the unadjusted 0.05 level but not after correction. The two sex-specific items, male impotence and pregnancy-related complications, were among the least well known in both groups and did not differ significantly after correction. The median knowledge score was 12 of 14 in both groups, but the distribution shifted toward higher scores among nonsmokers (Mann–Whitney U test, $p = 0.001$; r = 0.17). Good knowledge was more common among nonsmokers than smokers, and poor knowledge was less common (Table 3; chi-square = 14.87, $p = 0.001$, V = 0.191).

Table 2. Correct responses to the 14 health-risk knowledge items by smoking status (N = 406).

Knowledge Item	Smokers n/N (%)	Nonsmokers n/N (%)	*p* Value	Bonferroni *p*	V
Ischemia and myocardial infarction	216/260 (83.1)	117/146 (80.1)	0.459	1.000	0.037
Chronic obstructive lung disease	213/260 (81.9)	131/146 (89.7)	0.036	0.503	0.104
Respiratory disorders	232/260 (89.2)	121/146 (82.9)	0.068	0.955	0.091
Esophageal cancer	204/260 (78.5)	127/146 (87.0)	0.034	0.471	0.105
Larynx cancer	197/260 (75.8)	137/146 (93.8)	< 0.001	< 0.001	0.227
Lung cancer	230/260 (88.5)	138/146 (94.5)	0.044	0.620	0.100
Oral cavity cancer	217/260 (83.5)	129/146 (88.4)	0.182	1.000	0.066
Pharynx cancer	212/260 (81.5)	142/146 (97.3)	< 0.001	< 0.001	0.226
Stomach cancer	193/260 (74.2)	130/146 (89.0)	< 0.001	0.005	0.176
Male impotence	174/260 (66.9)	90/146 (61.6)	0.284	1.000	0.053
Pregnancy-related complications	193/260 (74.2)	94/146 (64.4)	0.036	0.510	0.104
Contains toxic chemicals	192/260 (73.8)	132/146 (90.4)	< 0.001	0.001	0.198
Heard of second-hand smoke	200/260 (76.9)	138/146 (94.5)	< 0.001	< 0.001	0.226
Second-hand smoke as dangerous	187/260 (71.9)	130/146 (89.0)	< 0.001	0.001	0.199

Items were compared using the Pearson chi-square test (effect size Cramer V). n, number of correct answers; N, number of responses in that group. Bonferroni *p*, raw *p* value multiplied by the number of items (14) and capped at 1.000; an item difference was considered significant when the Bonferroni *p* was ≤ 0.05. V, Cramer V.

Table 3. Overall knowledge level (modified Bloom classification) by smoking status (N = 406).

Knowledge Level	Smokers, n (%)	Nonsmokers, n (%)	*p* Value
Good (12 to 14)	138 (53.1)	106 (72.6)	0.001
Moderate (7 to 11)	107 (41.2)	35 (24.0)	
Poor (below 7)	15 (5.8)	5 (3.4)	

Comparisons were performed using the Pearson chi-square test (chi-square = 14.87, Cramer V = 0.191). $p \leq 0.05$ was considered to indicate statistical significance.

3.4. Independent predictors of good knowledge

In the multivariable binary logistic model, three variables independently predicted good knowledge after mutual adjustment (Table 4). Compared with nonsmokers, smokers had less than half the odds of having good knowledge (aOR 0.42, 95% confidence interval 0.26 to 0.68), and compared with city-based participants, participants with a rural background had similarly reduced odds (0.45, 0.28 to 0.71). Higher personal income was associated with modestly greater odds of good knowledge (1.24 per income band, 1.01 to 1.54, $p = 0.041$). Age, education, family system and marital status were not independently associated with knowledge. The proportional-odds ordinal model reproduced the same pattern for the two principal predictors, with aORs of 0.45 (0.28 to 0.73) for smoking and 0.45 (0.29 to 0.70) for a rural background, confirming that the associations were robust to model specification.

Table 4. Multivariable binary logistic regression for good knowledge (N = 371).

Predictor	aOR	95% CI	*p* Value
Smoker (versus nonsmoker)	0.42	0.26 to 0.68	< 0.001
Rural background (versus city-based)	0.45	0.28 to 0.71	0.001
Personal income (per band)	1.24	1.01 to 1.54	0.041
Age (per band)	1.04	0.81 to 1.34	0.738
Graduate or higher (versus lower)	0.97	0.59 to 1.59	0.892
Joint family (versus nuclear)	1.27	0.79 to 2.04	0.321
Married (versus unmarried)	1.36	0.80 to 2.31	0.264

Abbreviations: aOR, adjusted odds ratio; CI, confidence interval. Age and personal income were entered as ordinal band scores (per band increase). $p \leq 0.05$ was considered to indicate statistical significance. Nagelkerke $R^2 = 0.13$.

3.5. Correlates of smoking status and quitting attempts

Modeling smoking status itself revealed a socioeconomic gradient (Table 5). Compared with less-educated participants, graduates had approximately three and a half times greater odds of being smokers (3.48, 2.13 to 5.68), whereas married participants (0.50, 0.28 to 0.86) and those with higher family income (0.58 per income band, 0.47 to 0.71) had lower odds. Age, sex, background and family system were not independently associated with smoking. Among smokers, feeling concerned rather than contented about smoking was the strongest predictor of having attempted to quit (aOR 2.13, 1.26 to 3.60; $p = 0.005$), whereas a longer smoking duration was associated with slightly lower odds of a quit attempt (0.92 per year; 0.85 to 1.00; $p = 0.046$) and a higher knowledge score with modestly lower odds (0.87 per point; 0.79 to 0.97; $p = 0.011$). The Nagelkerke R^2 for this model was 0.12.

Table 5. Multivariable binary logistic regression for being a smoker (N = 406).

Predictor	aOR	95% CI	*p* Value
Graduate or higher (versus lower)	3.48	2.13 to 5.68	< 0.001
Married (versus unmarried)	0.50	0.28 to 0.86	0.013
Family income (per band)	0.58	0.47 to 0.71	< 0.001
Age (per band)	1.08	0.84 to 1.39	0.537
Female (versus male)	0.78	0.17 to 3.55	0.752
Rural background (versus city-based)	0.68	0.42 to 1.09	0.107
Joint family (versus nuclear)	1.01	0.62 to 1.66	0.968

Abbreviations: aOR, adjusted odds ratio; CI, confidence interval. Age and family income were entered as ordinal band scores (per band increase). $p \leq 0.05$ was considered to indicate statistical significance. Nagelkerke $R^2 = 0.17$.

3.6. Scale dimensionality and correlations

The quit-barrier scale was suitable for factor analysis (KMO = 0.76, Bartlett test $p < 0.001$) and resolved into two factors that together explained 61.1% of the variance, broadly separating affective and physical withdrawal from craving and irritability. For the 14 knowledge items (KMO = 0.69), the two sex-specific items, male impotence and pregnancy-related complications, loaded together on a distinct factor, indicating that knowledge of sex-specific risks behaves as a separate and systematically weaker dimension. The knowledge score correlated positively with warning-label support (Spearman rho = 0.33, $p < 0.001$) and with the personal income band (rho = 0.18, $p < 0.001$) but not with age, education or weight, indicating that more knowledgeable participants were also more supportive of stronger pack warnings.

4. Discussion

In this community sample of adults in Punjab, nonsmokers knew more about the health harms of cigarette smoking than smokers did, and this difference persisted after adjustment for age, education, background, family system, marital status and income. Current smoking status, a rural background and lower personal income independently predicted poor knowledge. These findings differ in an important way from those of the earlier Pakistani student study that used the same knowledge battery, which reported no difference in knowledge between smokers and nonsmokers and identified rural residence as a correlate of smoking rather than of knowledge [8]. This difference is unlikely to be an artifact of measurement because the present analysis confirmed the acceptable reliability of the instrument and used a Bonferroni correction and effect sizes rather than unadjusted tests alone. A more plausible explanation is that the community sample, which was older, more occupationally diverse and almost entirely male, captures a population in which the informational advantage of not smoking is more pronounced than among relatively homogeneous, health-aware university students.

The observation that current smokers know less than nonsmokers do is consistent with international work using knowledge indices, in which former smokers and nonsmokers tend to score higher than current smokers do, and greater knowledge is linked to greater concern about personal risk [11]. It also echoes an Iraqi study in which awareness of specific health harms was lower among smokers than among nonsmokers [12], and it aligns with evidence that disadvantaged groups often carry both a higher smoking burden and lower risk awareness [13]. The relocation of the rural signal from behavior to knowledge is noteworthy. In this sample, a rural background was not an independent correlate of smoking, but it strongly predicted poor knowledge, which points to the unequal reach of health information rather than a simple rural excess of smoking and suggests that communication channels serving people of rural origin deserve specific attention [3].

The socioeconomic pattern of smoking status was counterintuitive. Graduate education was associated with approximately three and a half times higher odds of being a smoker, while higher family income and being married were protective. That graduate education was associated with higher odds of smoking but not with better knowledge cautions against the assumption that formal schooling alone will curb tobacco use in this setting, and this pattern is compatible with reports that the direction of the socioeconomic gradient in smoking varies with a country's stage in the tobacco epidemic [4,6]. These relationships were most clearly seen after multivariable adjustment, underscoring the value of regression modeling alongside unadjusted comparisons in observational tobacco research.

Two applied findings stand out for messaging. First, the sex-specific harms of smoking (male impotence and pregnancy-related complications) were the least well-known items in both groups and formed their own factor in the knowledge structure, replicating a gap reported both in earlier student studies and in other populations and highlighting a concrete, targetable deficit for warning content [8,17]. Second, knowledge covaried with support for stronger pack warnings, and among smokers, those who felt concerned about their smoking were approximately twice as likely to have attempted to quit. These findings are consistent with evidence that stronger and more affective warnings increase perceived harm and quit intentions and attempts [9,10] and that complementary mass-media campaigns can further raise awareness and support cessation [18]. These findings suggest that messages that involve concern, rather than information alone, may be particularly effective, since risk perception and personal relevance shape how young adults respond to smoking information [19]. The modest inverse association between

knowledge score and having attempted to quit should be interpreted cautiously because in a cross-sectional design, it may reflect reverse causation, with smokers who struggle to quit becoming more informed over time.

This study has several limitations. The design is cross-sectional, so associations cannot be interpreted causally. The sample was recruited by convenience and was almost entirely male, which precludes analysis of sex differences and limits generalizability to women and to the wider community. Age and income were recorded as bands rather than exact values, background was classified operationally from the participant's district of origin, and height was too coarse to permit a valid body mass index. Finally, knowledge and attitudes were self-reported and may be subject to social desirability bias. Strengths include the community-based rather than student sampling frame, the explicit reliability and dimensionality assessment of the scales, the correction for multiple comparisons across the knowledge battery, and the use of both binary and ordinal multivariable models, which together provide a more rigorous basis for inference than descriptive comparison alone does.

5. Conclusions

Among adults in Punjab, current smokers, participants with a rural background and those with lower personal income had poorer knowledge of the health harms of cigarette smoking, sex-specific harms were poorly understood across the board, and knowledge was linked to support for stronger pack warnings. Graduate education was paradoxically associated with smoking, and concern about smoking predicted attempts to quit. Tobacco-control messaging in this setting should prioritize smokers and people with a rural background, for whom the reach of health information and the social determinants of smoking differ from those of long-term city residents [20], strengthen content on sex-specific harms, and engage the affective concern that appears to drive quitting attempts. Sustained implementation of pack warnings and broader tobacco-control measures remains essential, as national tobacco prevalence declines only slowly [21]. Longitudinal and more representative studies that include women are needed to confirm these associations and to guide the design of warning labels.

Abbreviations: aOR, Adjusted odds ratio; CI, Confidence interval; CNIC, Computerized National Identity Card; KMO, Kaiser–Meyer–Olkin; KR-20, Kuder–Richardson 20; MPOWER, Monitor, protect, offer, warn, enforce and raise; PKR, Pakistani rupees; SD, Standard deviation.

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Original Article

Effects of muscle energy technique and core stability exercises on pain and disability in adults with sacroiliac joint dysfunction attending a private hospital in Lahore, Pakistan

Atabiq Javed [a,*], Rida Fatima [b], Adina Arif Lone [b], Hafiz Mudassir Riaz [c], Gull Mahnoor Hashmi [c]

[a] Applied Neurosciences in Sports & Exercise, Universität Paderborn, Germany
[b] Hussain College of Health Sciences, Lahore, Pakistan
[c] Physiotherapy Department, University of Health Sciences, Pakistan

* Correspondence: daratabiq@gmail.com

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Abstract

Sacroiliac joint (SIJ) dysfunction is a common but frequently overlooked source of low back and pelvic pain, and the comparative value of the available conservative treatments remains uncertain. This study examined whether the muscle energy technique (MET) and core stability exercises reduce pain and disability in adults with SIJ dysfunction and whether the two differ. A quasiexperimental, nonrandomized, two-group design with assessments before and after treatment was used. Seventy-two adults with clinically diagnosed SIJ dysfunction were recruited from a private hospital in Lahore, Pakistan, by purposive sampling and allocated by an odd/even identifier system to the MET (n = 36) or core stability exercise (n = 36) group; both groups additionally received a baseline program of hot pack and transcutaneous electrical nerve stimulation over three weeks. Pain was measured with a visual analog scale (VAS, 0 to 10), and disability was measured with the modified Oswestry Disability Index (ODI, 0 to 100). Within-group changes were tested with paired t tests, corroborated by the Wilcoxon signed-rank test, and posttreatment scores were compared by analysis of covariance (ANCOVA) with adjustment for baseline. Both groups improved significantly: the modified ODI decreased from 70.67 to 17.00 in the MET group and from 56.00 to 17.67 in the core stability group, and the VAS score decreased from 6.54 to 3.38 and from 5.88 to 3.83, respectively (all $p < 0.001$). After adjustment for baseline, the groups did not differ in terms of disability ($p = 0.607$), whereas the MET group experienced significantly less pain than the core stability group did (adjusted VAS score 3.31 vs 3.89, $p < 0.001$). Both techniques reduced pain and disability in SIJ dysfunction; MET was superior for pain but equivalent for disability. Because allocation was nonrandom and the groups differed at baseline, adequately powered randomized trials with longer follow-up periods are needed.

Keywords

Core stability exercises; Low back pain; Muscle energy technique; Oswestry Disability Index; Physiotherapy; Sacroiliac joint dysfunction; Visual analog scale

1. Introduction

The sacroiliac joint (SIJ) transmits load between the spine and the lower limbs and is stabilized by a dense arrangement of ligaments and by the muscular and fascial connections linking the sacrum, pelvis, and trunk [1]. It is a true diarthrodial joint whose ridged articular surfaces and strong posterior ligaments favor stability over mobility, and disturbance of this finely balanced system can become a source of persistent pain [1]. Historically, the SIJ was regarded as a principal cause of low back pain until interverte-

bral disc pathology dominated clinical thought in the mid-twentieth century, but it is now recognized again as an important contributor to pain in the lower back and pelvic region [2,3]. Contemporary estimates suggest that it accounts for approximately 15 to 30% of cases of chronic, nonradicular low back pain [2].

SIJ dysfunction describes pain arising from the joint, which is typically attributed to either excessive or restricted movement and is often accompanied by muscular imbalance around the pelvis [2,4]. The pain is usually felt at the base of the spine and over the buttock and may be provoked by sitting, rising from a seat, climbing stairs, single-leg loading, or traveling in a vehicle [2]. Because its presentation overlaps with that of lumbar disc herniation, facet joint syndrome, and spinal stenosis, SIJ dysfunction is easily misattributed, and diagnosis relies on a combination of history, palpation, and a battery of provocation tests [2]. Recognized risk factors include leg-length discrepancy, altered gait, prior lumbar fusion [5], and pregnancy, the last of which alters pelvic biomechanics and commonly produces sacroiliac and pubic pain [6,7].

Among the conservative options, the muscle energy technique (MET) is a manual approach in which the patient performs a controlled voluntary muscle contraction against a precisely applied counterforce, after which the tissue is taken to a new length [8]. It is used to restore range of motion, reduce local pain, and normalize muscle function, and its benefits are thought to be mediated through neurological effects, such as reflex muscle relaxation and hypoalgesia, rather than through purely biomechanical change [9]; systematic reviews and trial evidence support its usefulness across a range of musculoskeletal complaints, including neck, shoulder, and low back pain [10,11,12]. Core stability exercise takes a different route to achieve the same goal, training the deep trunk and pelvic muscles that provide segmental control of the spine and pelvis; the rationale is that improved neuromuscular control restores support to the lumbopelvic complex and interrupts the cycle of recurrent mechanical pain [13,14,15].

Low back pain is among the leading causes of disability worldwide [16], and exercise-based rehabilitation is among the most widely recommended conservative approaches [17]; when the SIJ is the source, however, the problem is frequently overlooked, and misdiagnosis can lead to ineffective or unnecessary treatment [2]. For everyday physiotherapy practice, it therefore matters which conservative techniques are effective and whether any one of them is preferable, particularly in settings where access to advanced imaging and interventional options is limited. Despite the popularity of both approaches, evidence on their effectiveness specifically in SIJ dysfunction remains limited, and there is little guidance on how the two compare in routine practice, particularly in private-sector settings in low- and middle-income countries [4,18]. This study was therefore conducted to determine whether MET and core stability exercises reduce pain and disability in adults with SIJ dysfunction and to compare the two techniques directly.

2. Methods

This manuscript is reported in accordance with the TREND statement for nonrandomized evaluations of behavioral and public health interventions [19].

2.1. Study design

A quasiexperimental, nonrandomized, two-group study was conducted, with participants assessed at baseline and again at the end of the third week of intervention.

2.2. Setting and duration

Data were collected from a private-sector hospital in Lahore, Pakistan (Hussain Memorial Hospital), between April and August 2023.

2.3. Participants and eligibility

Adults who presented to the orthopedic, physical therapy, and outpatient departments with a clinical diagnosis of SIJ dysfunction were screened. Eligible participants were men and women aged 20 years or older with pain around the pelvic girdle. Patients were excluded if they had degenerative joint disease, a history of pelvic surgery, or trauma to the pelvic region. Written informed consent was obtained from all participants.

2.4. Sample size

The required sample size was estimated by comparing the primary pain outcome (VAS, 0 to 10) between the two independent treatment groups, using the standard formula for the difference between two independent means [20]: n (per group) = $2\sigma^2(Z\alpha/2 + Z\beta)^2 \div d^2$, where $Z\alpha/2 = 1.96$ (two-tailed $\alpha = 0.05$), $Z\beta = 0.84$ (80% power), $\sigma = 1.5$ is the anticipated common standard deviation of the VAS pain score, and $d = 1.0$ is the minimum between-group difference in mean VAS considered clinically meaningful for SIJ dysfunction [21]; this threshold was set conservatively, below the minimal important change of approximately 2 points proposed by international consensus for pain in low back pain, so that the calculation would not underestimate the required sample. The assumed standard deviation was based on the VAS pain scores reported for manual therapy and exercise-based interventions in comparable SIJ dysfunction trials [22,23], and it closely matched the baseline VAS variability later observed in this sample. Substituting these values, $n = 2 \times (1.5)^2 \times (1.96 + 0.84)^2 \div (1.0)^2 = 2 \times 2.25 \times 7.84 \div 1 = 35.3$, rounded up to 36 participants per group. This estimate was cross-checked using G*Power (version 3.1.9.7) for an independent-samples t test with the same parameters [24]. No further allowance for attrition was added, as the short, closely supervised three-week protocol was expected to retain all the enrolled participants. The target enrollment was therefore 72 participants: 36 allocated to the MET group and 36 to the core stability exercise group.

2.5. Sampling and group allocation

Participants were enrolled by purposive (nonprobability) sampling. Seventy-two patients were allocated to two equal groups by a systematic, nonrandom method: each patient received an alphanumeric identifier; those with odd-numbered identifiers were assigned to Group A (MET); and those with even-numbered identifiers were assigned to Group B (core stability exercises). Because this is a systematic allocation rather than true randomization, the baseline comparability of the groups was examined explicitly and is reported below.

2.6. Interventions

Both groups received the same baseline conventional program at each visit: hot pack and transcutaneous electrical nerve stimulation (TENS) for approximately 10 minutes. Each intervention was delivered at low intensity for approximately 30 minutes per session, four sessions per week for three weeks (12 sessions in total). This dosage is consistent with the 12-session protocols commonly reported for manual therapy and stabilization exercise in patients with SIJ dysfunction [18].

2.6.1. Group A (MET)

With the patient supine and the therapist on the affected side, postisometric relaxation MET was applied to the quadratus lumborum, erector spinae, iliopsoas, and hamstrings. For each muscle, the patient produced a submaximal isometric contraction (approximately 20 to 30% of maximum) against the therapist's counterforce for 7 to 10 seconds; after relaxation, the tissue was taken gently to the new restriction barrier and held, with the sequence repeated across the session [8].

2.6.2. Group B (core stability exercises)

Patients performed a graded program of bridging, wall squats, knee-to-chest, and prone contralateral arm-and-leg raise, progressing in hold time and repetitions across the three weeks (for example, bridging progressed from a 5-second hold for 5 repetitions in week one to a 10-second hold for 10 repetitions by week three) [13].

2.7. Outcome measures

Two patient-reported outcomes were recorded at baseline and at the end of week three. Pain was assessed with a visual analog scale (VAS), a 0 to 10 scale anchored at "no pain" and "worst imaginable pain"; four dimensions were recorded (current pain, pain during activity, average pain over the preceding week, and change in pain since the start of treatment) and averaged for analysis. Disability was assessed with the modified Oswestry Disability Index (ODI), a ten-item questionnaire in which each item is scored from 0 to 5; the summed score was expressed as a percentage from 0 (no disability) to 100 (maximum disability), with higher scores indicating greater limitations [25].

2.8. Statistical analysis

The data were analyzed in SPSS version 26. Descriptive statistics were used to summarize the sample, and baseline comparability between groups was tested with independent-samples t tests for continuous variables and the chi-square test for categorical variables. The distribution of change scores was assessed with the Shapiro–Wilk test. Within-group changes from baseline to week three were tested with a paired t test for each group, with the Wilcoxon signed-rank test as a nonparametric confirmation. The two techniques were compared by analysis of covariance (ANCOVA) on posttreatment scores, with the corresponding baseline score entered as a covariate to account for baseline differences [26]; the homogeneity-of-regression-slopes assumption was checked. Statistical significance was set at $p \leq 0.05$.

2.9. Ethics

Ethical approval was obtained from the Ethics Review Committee of Hussain College of Health Sciences, Lahore, Pakistan (No. HCHS/2023/ERC/34). The study was conducted in accordance with the Declaration of Helsinki, and confidentiality was maintained throughout.

3. Results

3.1. Participant characteristics and baseline comparability

Seventy-two patients (36 in each group) were enrolled and analyzed. The mean age was 40.7 years, and 66.7% were women. Because allocation was nonrandom, baseline characteristics were compared between groups (Table 1). The groups were similar in terms of age, sex, and pain duration but differed significantly in years of education,

monthly household income, locality, baseline pain severity, and baseline disability, with the MET group being more disabled at baseline (modified ODI 70.7 vs 56.0). These imbalances were addressed in the between-group analysis by adjusting for baseline scores.

Table 1. Baseline characteristics of participants by group.

Characteristics	MET (n = 36)	Core (n = 36)	Baseline Comparison	
	Mean ± SD	Mean ± SD	t/χ^2	*p* Value
Age (years)	39.5 ± 12.0	41.9 ± 14.8	-0.77	0.445
Education (years)	7.7 ± 6.6	11.5 ± 4.0	-2.97	0.004 **
Monthly household income (PKR)	58,333.3 ± 18,439.1	142,777.8 ± 154,385.6	-3.26	0.002 **
Duration of pain (weeks)	8.0 ± 4.7	6.7 ± 5.8	1.07	0.286
Female, n (%)	24 (66.7%)	24 (66.7%)	0.00	1.000
Married, n (%)	30 (83.3%)	24 (66.7%)	1.85	0.174
Urban, n (%)	12 (33.3%)	30 (83.3%)	16.51	< 0.001 **
Severity (mild/moderate/severe)	0/24/12	6/18/12	—	0.029 **
Baseline modified ODI (0 to 100)	70.7 ± 18.9	56.0 ± 28.8	2.55	0.013 **
Baseline VAS (0 to 10)	6.5 ± 1.5	5.9 ± 1.7	1.76	0.082

* Between-group comparisons were performed by independent-samples t tests (continuous) or chi-square (χ^2) tests (categorical), except for severity, for which Fisher's exact test was used because two expected cell counts were below 5; values are the mean ± SD or n (%) within each group. ** Statistically significant ($p \leq 0.05$). *** Abbreviations: MET, muscle energy technique; ODI, Oswestry Disability Index; SD, standard deviation; VAS, visual analog scale.

All participants reported SIJ pain, and attendance was complete across the 12 supervised sessions. The clinical and pain characteristics of the whole sample are summarized in Table 2. Pain was most often localized to the lower back and gluteal region and was commonly provoked by mechanical loading, such as stair climbing and prolonged sitting, and most participants reported difficulty with activities of daily living.

Table 2. Clinical and pain characteristics of the whole sample (N = 72).

Characteristics		n (%)
Pain localized to low back		60 (83.3%)
Pain in gluteal region		60 (83.3%)
Pain in thigh		24 (33.3%)
Pain worse climbing stairs		66 (91.7%)
Avoids prolonged sitting		60 (83.3%)
Onset in pregnancy/postpartum		24 (33.3%)
Aggravated by vehicle travel		60 (83.3%)
Painful single-leg standing		48 (66.7%)
Morning pain		42 (58.3%)
Radiation to lower leg		24 (33.3%)
Tingling/numbness in leg		24 (33.3%)
Absence from work		18 (25.0%)
Difficulty with activities of daily living (ADLs)		66 (91.7%)
Diagnosed systemic disease		24 (33.3%)
Psychological stress		54 (75.0%)
X-ray report available		66 (91.7%)
MRI report available		18 (25.0%)
Severity	Mild	6 (8.3%)
	Moderate	42 (58.3%)
	Severe	24 (33.3%)
Temporal pattern of pain	Intermittent	54 (75.0%)

Characteristics		n (%)
	Consistent	18 (25.0%)
Nature of pain	Aching	30 (41.7%)
	Burning	18 (25.0%)
	Cramping	18 (25.0%)
	Other	6 (8.3%)
Activity associated with pain	Sitting	6 (8.3%)
	Standing	30 (41.7%)
	Repetitive bending	36 (50.0%)
Main method of pain relief	Rest	42 (58.3%)
	Medication	24 (33.3%)
	Changing positions	6 (8.3%)

3.2. Within-group change

Both interventions were associated with large, statistically significant within-group improvements in pain and disability from baseline to week three (Table 3). Shapiro–Wilk tests indicated that the change scores were not normally distributed, so the Wilcoxon signed-rank test was used to corroborate the paired t tests; all comparisons remained highly significant. Effect sizes were large in both groups (Cohen's dz ≥ 1.3).

Table 3. Within-group comparisons of pre- and postintervention scores.

Group	Outcome	Preintervention (A)	Postintervention (B)	Change (A-B)	*p* (Paired t)	*p* (Wilcoxon)	Cohen's dz
		Mean ± SD	Mean ± SD				
MET	Modified ODI	70.67 ± 18.91	17.00 ± 13.39	53.67	< 0.001 ***	< 0.001 ***	2.44
MET	VAS	6.54 ± 1.47	3.38 ± 0.54	3.17	< 0.001 ***	< 0.001 ***	2.52
Core	Modified ODI	56.00 ± 28.80	17.67 ± 12.36	38.33	< 0.001 ***	< 0.001 ***	1.29
Core	VAS	5.88 ± 1.73	3.83 ± 0.38	2.04	< 0.001 ***	< 0.001 ***	1.39

* Within-group change from baseline to week 3. ** *p* (paired t test), paired-samples t test; *p* (Wilcoxon test), Wilcoxon signed-rank test (nonparametric confirmation); dz, Cohen's d for paired samples. *** All improvements were statistically significant ($p \leq 0.05$). **** Abbreviations: ODI, Oswestry Disability Index (0 to 100); VAS, visual analog scale (0 to 10); MET, muscle energy technique; SD, standard deviation.

3.3. Between-group comparisons

When the two techniques were compared by ANCOVA, adjusting the posttreatment scores for baseline, the homogeneity-of-regression-slopes assumption was satisfied for both outcomes (Table 4). With respect to disability, the adjusted posttreatment modified ODI did not differ between groups ($p = 0.607$), indicating that the greater improvement in the raw score in the MET group was largely explained by its higher baseline score. With respect to pain, however, compared with core stability exercise, MET resulted in a significantly lower adjusted posttreatment VAS score (3.31 vs 3.89, $p < 0.001$), a difference that persisted after baseline adjustment. In absolute terms, this difference in pain was modest (approximately half a point on the 0 to 10 scale), with both groups ending in the mild range.

Table 4. Between-group comparisons by ANCOVA (posttreatment score adjusted for baseline).

Outcome	Adjusted MET	Adjusted Core	Adjusted Difference (MET − Core)	95% CI (Lower–Upper)	F (1,69)	*p* Value	Partial η^2
Modified ODI	16.51	18.15	-1.64	-7.97, 4.69	0.27	0.607	0.004
VAS	3.31	3.89	-0.58	-0.76, -0.40	42.00	< 0.001 **	0.378

* Between-group comparisons were performed by analysis of covariance (ANCOVA) on posttreatment scores adjusted for the corresponding baseline score; adjusted means were estimated at the pooled baseline mean. ** Statistically significant ($p \leq 0.05$): the groups differed in pain (VAS) but not disability (modified ODI). *** Abbreviations: CI, confidence interval; MET, muscle energy technique; ODI, Oswestry Disability Index; VAS, visual analog scale; η^2, partial eta squared.

4. Discussion

In this quasiexperimental study, both MET and core stability exercises, each delivered alongside a baseline program of hot pack and TENS, were associated with significant reductions in pain and disability in adults with SIJ dysfunction over three weeks. When the two were compared directly with adjustment for baseline, they were equivalent for disability, but MET was significantly better for pain. This more precise picture supersedes any simple claim that one technique is uniformly superior: the advantage of MET was specific to pain and modest in absolute size, while disability improved comparably with either approach.

These findings are broadly consistent with the existing, if limited, literature. MET has previously been shown to reduce pain and disability in patients with SIJ dysfunction [18], and this is supported by systematic review evidence that MET is a safe adjunct for musculoskeletal and low back pain [10]. The improvement seen with core stability exercise likewise echoes earlier work in which strengthening of the stabilizing musculature reduced sacroiliac and nonspecific low back pain [13,27,28]. That both approaches produced clinically meaningful gains supports the broader observation that more than one exercise-based or manual strategy can help this population and that the choice may reasonably be guided by clinician skill, available equipment, and patient preference [4,18].

Direct comparisons with individual trials are complicated by differences in comparators, dosages, and outcome measures. A recent randomized trial reported additional benefits when a quadratus lumborum MET was combined with gluteus medius strengthening in SIJ dysfunction [18], whereas other recent studies, one comparing manipulation with stabilization exercise and another combining motor control training with balance training, reported comparable improvements in the same population [23,28]. The present finding of broad equivalence for disability, with a modest pain advantage for MET, sits within this emerging picture rather than contradicting it and adds a head-to-head comparison of the two techniques that the earlier single-arm or placebo-controlled studies did not provide.

Notably, these results reveal a dissociation between pain and disability outcomes. Although MET produced a statistically greater reduction in pain, the two techniques were indistinguishable for disability once the baseline difference was taken into account, and the absolute pain advantage amounted to only approximately half a point on the 0 to 10 scale. Clinically, these findings suggest that either technique can be offered with a reasonable expectation of meaningful functional recovery and that MET may be preferred when rapid pain relief is the main treatment goal. The basis of the pain advantage cannot be established from these data, but it is consistent with the proposed neurological and hypoalgesic effects of MET acting relatively quickly, whereas the functional gains from either approach may depend more on the gradual restoration of neuromuscular control that accrues similarly over the treatment period [9,10,13]. The modest absolute size of the

difference is also in keeping with broader evidence that exercise-based and conservative treatments for low back pain tend to produce real but limited average effects [17].

The sample was predominantly female (66.7%), and a substantial proportion reported the onset of symptoms during pregnancy or the postpartum period, which is consistent with the recognized link between altered pelvic biomechanics during pregnancy and sacroiliac pain [6,7]. The heavy reliance on plain radiography, the near-absence of advanced imaging, and the high burden of activity limitation and psychological stress reflect the realities of managing a largely clinical diagnosis in a resource-constrained private-sector setting and reinforce the value of low-cost conservative interventions of the kind evaluated here.

Several limitations should be borne in mind when these findings are interpreted. Allocation was systematic rather than truly random, and the groups consequently differed at baseline in terms of education, income, locality, pain severity, and disability. ANCOVA adjusts only for the baseline outcome score and cannot eliminate confounding from these other imbalances, so residual confounding cannot be excluded; the marked imbalance in locality is of particular concern because urban and rural participants were unevenly distributed between the two techniques. There was no untreated or sham comparison group, so improvement could not be fully separated from natural recovery, the coadministered conventional program, or the nonspecific effects of attention and supervised adherence. The change scores were not normally distributed, although nonparametric testing confirmed the within-group results. The follow-up period ended at three weeks, so the durability of the improvements is unknown; the outcomes were self-reported; and the participants were drawn from a single hospital in one city, limiting generalizability. Complete session attendance, while encouraging, is unusual and may reflect the close supervision of a study protocol rather than routine care. The study also has strengths: outcomes were analyzed on the full sample of 72 patients with complete data, the analysis explicitly modeled the baseline imbalance rather than ignoring it, and the within-group findings were confirmed with nonparametric testing, which lends robustness to the conclusions despite the nonrandomized design.

5. Conclusions

MET and core stability exercises, each combined with a baseline conventional program, produced statistically significant improvements in pain and disability in patients with SIJ dysfunction over three weeks. After adjustment for baseline, the two techniques were equivalent for disability, whereas MET was superior for pain, albeit with a modest absolute margin. Because allocation was nonrandom and the groups differed at baseline, these findings should be regarded as preliminary. Adequately powered randomized controlled trials with a true between-group comparison, an untreated or sham comparator, and longer-term follow-up are needed to confirm these findings and to define the optimal technique and dosage.

6. Recommendations

Future studies should use randomized allocation with concealment and a direct, baseline-adjusted comparison between techniques; add supplementary neuromuscular training to enhance muscle activation and rebalancing; extend follow-up to capture longer-term outcomes; and account for potential confounders such as sleep, stress, and physical activity. An investigation of other sacroiliac dysfunction patterns, such as upslip, downslip, and rotational dysfunctions, would broaden the applicability of the results.

Abbreviations: ADLs, Activities of daily living; ANCOVA, Analysis of covariance; CI, Confidence interval; MET, Muscle energy technique; MRI, Magnetic resonance imaging; ODI, Oswestry Disability Index; PKR, Pakistani rupees; SD, Standard deviation; SIJ, Sacroiliac joint; SPSS, Statistical Package for the Social Sciences; TENS, Transcutaneous electrical nerve stimulation; TREND, Transparent Reporting of Evaluations with Nonrandomized Designs; VAS, Visual analog scale.

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Viewpoint

Algorithmic blind spots: bias, opacity and the clinical translation gap in artificial intelligence-driven personalized medicine

Atif Adnan

Institute of Life Sciences, Shenyang Medical College, Shenyang, P.R. China; Liaoning Province Key Laboratory for Phenomics of Human Ethnic Specificity and Critical Illness, Shenyang Medical College, Shenyang, P.R. China; Liaoning Provincial Belt and Road Joint Laboratory for China-Pakistan Human Phenomics Research, Shenyang Medical College, Shenyang, P.R. China

Correspondence: mirzaatifadnan@gmail.com

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Extract

The use of machine learning has changed how molecular and clinical data are used to detect disease, forecast prognosis and select treatment, yet a gap remains between reported performance and clinical use. Few published models have been tested prospectively, and several that have reached practice perform far worse than expected. From this perspective, I argue that clinical translation should be seen as a continuum from data to decision. Three weaknesses explain much of the gap: models whose outputs cannot be checked against biology, data that are unrepresentative or inconsistently recorded, and the absence of shared standards for evaluation and oversight. I propose a five-stage framework that links representative, high-quality data; clinically interpretable models; external and prospective validation; workflow integration; and postdeployment monitoring and governance. Low- and middle-income countries need locally governed data and regional validation networks rather than imported tools. The goal is safer, more equitable clinical decisions, not better prediction alone.

Keywords

Artificial intelligence; Machine learning; Precision medicine; Molecular diagnostic techniques; Healthcare disparities; Validation studies as topic; Bias

Integrating machine learning and artificial intelligence (AI) into molecular diagnostics has changed how disease detection, prognostic forecasting and treatment selection are approached [1]. Models that draw on genomic, transcriptomic, imaging and electronic health record (EHR) data promise care tailored to the individual patient. I refer to this goal as personalized medicine and use the term "precision medicine" synonymously. Published reports of predictive performance are often impressive, but the record in clinical practice is far weaker. A systematic review of deep learning studies in medical imaging revealed that of 81 nonrandomized studies comparing algorithms with clinicians, only nine were prospective, and only six were tested in a real clinical setting; nevertheless, the performance of 61 was at least comparable to that of clinicians [2]. A later review revealed only 41 randomized trials of machine learning interventions in health care; none adhered fully to the Consolidated Standards of Reporting Trials–Artificial Intelligence (CONSORT-AI) reporting guidelines, and approximately half were conducted at a single site [3]. A 2024 scoping review of 86 randomized trials likewise revealed a predominance of single-center studies with little demographic reporting [4]. The evidence that these tools help patients lags well behind the enthusiasm for them [5].

I argue that clinical translation is best understood as a continuum running from data to decision rather than as a single validation step. Even a model with strong reported performance can fail if its input data arrives late or are incomplete, if it fits poorly into the clinical workflow, or if its predictions are not linked to a clear clinical action [5]. Weaknesses at three points along this continuum explain much of the gap: models whose outputs cannot be checked against biology, data that are neither representative nor consistently recorded, and the lack of shared standards for evaluation and oversight. In response, I propose that clinical AI should pass through five linked stages: representative, high-quality data; a clinically interpretable model; external and prospective validation; integration into clinical workflow and decisions; and postdeployment monitoring and governance, with findings from monitoring feeding back into each earlier stage.

The first weakness is the distance between what an algorithm concludes and what is biologically plausible. Many deep learning systems are opaque, mapping inputs to clinical outcomes through statistical association with no account of the biology underneath. When a model latches onto a surrogate variable or an artifact of how the data were collected, rather than a true driver of disease, its performance tends to collapse in external testing. Zech and colleagues showed this with a pneumonia model trained on chest radiographs. Because the prevalence of pneumonia differed sharply across hospitals, the model performed worse on data from other hospital systems than on internal data [6]. During the coronavirus disease 2019 (COVID-19) pandemic, a living systematic review of 232 prediction models revealed that every one had a high or unclear risk of bias [7]. An external validation of a proprietary sepsis model used in hundreds of hospitals in the United States revealed an area under the receiver operating characteristic curve (AUROC) of 0.63; the model missed 67% of patients who developed sepsis while generating alerts for 18% of all hospitalized patients [8].

It helps to separate three properties that are often conflated. Predictive validity means that a model forecasts outcomes reliably in the population where it will be used. Clinical interpretability means that the intended user can understand enough about how an output was produced to judge whether to act on it. Mechanistic or causal validity means that the features driving a prediction reflect real disease processes. A model can predict well without identifying any causal mechanism, and a biologically plausible explanation does not by itself prove causation; thus, each property needs its own evidence. Post hoc explanation methods, such as heatmaps laid over an image, can look reassuring while describing the model only loosely, and they may create false confidence at the level of the individual patient [9]. I agree with Rudin that, for high-stakes decisions, models should be interpretable from the outset rather than explained after the fact [10]. When an inherently interpretable model performs as well as a black box, it should be preferred. Where explanations are offered, they should be meaningful to the intended clinical user and decision, not only to data scientists, and should point to recognizable features such as a known pathway, a validated biomarker or a plausible radiological sign. Such plausibility guards against shortcut learning but is not proof of mechanism.

The second weakness concerns the data. The value of personalized medicine depends on the breadth of the population behind it. In 2016, approximately 81% of participants in genome-wide association studies were of European ancestry [11]; by 2021, this share had risen to 86%, whereas South Asian participants accounted for only 0.8% [12]. Polygenic risk scores built on these data are several times more accurate in people of European descent than in other groups [13]. It is worth distinguishing the bias already present in the health system that generates the data from the bias introduced by modeling choices. One widely used commercial algorithm in the United States relies on health care costs as a proxy for illness. Because unequal access meant that less money was spent

on black patients, they had to be considerably sicker than white patients were to receive the same risk score. This inequity originated in the health system, but the choice of label carried it into the algorithm; correcting it would have increased the percentage of black patients flagged for additional care from 17.7% to 46.5% [14]. Chest radiograph classifiers have similarly been shown to underdiagnose female, black, Hispanic and low-income patients, with compounded underdiagnosis in some intersectional subgroups, such as Hispanic female patients [15].

Representativeness is only part of the problem. Real-world performance also depends on the quality and consistency of the wider data ecosystem: whether records are complete and timely, whether diagnoses and laboratory tests are coded consistently, whether duplicate records and mismatched patient identifiers are resolved, and whether EHRs, laboratory information systems and diagnostic platforms can exchange data reliably. In practice, a model built on curated research data may encounter missing values, new assay platforms or local coding habits. Changes of this kind, known as dataset shifts, can degrade performance silently, without any change to the model itself [16]. Generalizability is therefore a property of the model together with the data system that feeds it.

These issues are sharper in low- and middle-income countries (LMICs), such as Pakistan. Their populations are poorly represented in the genomic and imaging datasets on which most commercial tools are trained [12], and a model validated in North America or Europe cannot be assumed to perform equally well in a South Asian hospital. Underrepresentation is compounded by fragmented digital systems, variable laboratory capacity, inconsistent data standards and few local datasets suitable for validation [17]. A scoping review revealed only 10 studies evaluating real-world applications of AI in health care in LMICs and reported problems with reliability, workflow fit and adaptation to the local context [18]. Rather than simply importing externally trained tools, these settings need locally governed data, regional validation networks and, where necessary, models developed or recalibrated for their own populations and health systems.

The third weakness is the absence of shared standards for evaluation. Clinical assessment should look beyond discrimination measures such as the AUROC. Calibration, the agreement between predicted and observed risk, is often unreported, yet a poorly calibrated model can mislead clinical decisions even when its discrimination is good [19]. Sensitivity, specificity and predictive values at the intended decision threshold, performance in relevant subgroups, and clinical utility (for example, net benefit estimated through decision curve analysis [20]) are equally important. The choice of metric should follow from the intended decision and from the relative harms of false-positive and false-negative results. The sepsis model described above illustrates this point: its low sensitivity and heavy alert burden are more important in practice than any single summary statistic is [8].

Validation should also be treated as continuing rather than as a single event. Prospective, multisite evaluation within real clinical workflows, ideally through randomized trials, remains essential, but it should include geographic, temporal and subgroup validation. Once deployed, models need continuous monitoring for drift in their inputs and performance. Clinical AI should follow a cycle of validation, deployment, monitoring, recalibration and revalidation rather than being regarded as permanently validated after one study [16,19]. Regulatory authorization is not a substitute for such evidence: of 521 AI-enabled medical devices authorized by the U.S. Food and Drug Administration, 226 (43%) lacked publicly reported clinical validation data [21]. The guidance largely exists. The Transparent Reporting of a Multivariate Prediction Model for Individual Prognosis Or Diagnosis + Artificial Intelligence (TRIPOD+AI) statement sets out how prediction models that use machine learning should be reported [22], the TRIPOD extension for

large language models (TRIPOD-LLM) applies the same principles to studies using these models [23], the Developmental and Exploratory Clinical Investigations of Decision support systems driven by Artificial Intelligence (DECIDE-AI) guideline covers the early clinical evaluation of decision support systems [24], and CONSORT-AI covers randomized trials [25]. What is missing is consistent enforcement. Journals can require adherence to these guidelines at submission, and regulators and hospital procurement committees can ask for external validation data, calibration and subgroup performance, and a post-deployment monitoring plan before a tool is adopted.

None of these steps are technically out of reach, but they require the research community to value careful evaluation as highly as it values headline performance. The ultimate aim of clinical AI is not better prediction but safer, more equitable and demonstrably better clinical decisions and patient outcomes. Tools that meet that standard will earn the trust of clinicians because they have been shown to work for all of their patients.

Abbreviations: AI, Artificial intelligence; AUROC, Area under the receiver operating characteristic curve; CONSORT-AI, Consolidated Standards of Reporting Trials–Artificial Intelligence; COVID-19, Coronavirus disease 2019; DECIDE-AI, Developmental and Exploratory Clinical Investigations of Decision support systems driven by Artificial Intelligence; EHR, Electronic health record; Low- and middle-income countries; TRIPOD+AI, Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis + Artificial Intelligence; TRIPOD-LLM, Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis–Large Language Models.

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