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Prevalence of prediabetes in patients with idiopathic frozen shoulder: a prospective study

Vivek Pandey, MS*, Sashitejmen Aier, MS, Saksham Agarwal, MS, Avneet Singh Sandhu, MS, Sujayendra D. Murali, MS

Department of Orthopaedics, Kasturba Medical College, Manipal, Manipal Academy of Higher Education, Karnataka, India

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Background: The association between diabetes and frozen shoulder is well established. However, the data regarding prediabetes and primary frozen shoulder (PFS) are still lacking.

Methods: In a prospective study, 158 patients with PFS were included. The prediabetes status was ascertained by estimating serum hemoglobin A1c (HbA1c) levels in patients with PFS. According to the level of HbA1c, patients were classified into normoglycemic, prediabetic, and diabetic. In addition, random blood sugar (RBS) was also performed.

Results: Out of 158 participants, 84 (53.2%) were male and 74 (46.8%) were female. Nine patients had bilateral shoulder involvement, and all were diabetics; 47.5% (n = 75) of the patients were in the age group of 51-60 years, 16.5% (n = 26) of the participants were normoglycemic, 37.3% (n = 59) were prediabetics, and 46.2% (n = 73) were diabetics. The difference in mean HbA1c values between the 3 groups was statistically significant ($P < .001$). However, there was no statistical difference in various age groups ($P = .86$) or gender ($P = .68$) between normoglycemics, prediabetics, and diabetics. The difference in mean RBS values between diabetic-nondiabetic and diabetic-prediabetic groups were statistically significant ($P < .001$), whereas no significant difference was detected between nondiabetic and prediabetic ($P = .355$).

Conclusion: The prevalence of prediabetes is 37.5% in patients with PFS. Single-point HbA1c estimation is an acceptable tool to detect prediabetes, whereas RBS estimation should not be used to detect prediabetes.

Frozen shoulder is one of the common conditions affecting the shoulder typically in 4th to 6th decades, characterized by the insidious onset of pain and limited articular mobility.[26] The prevalence of frozen shoulder in the general population is estimated to be between 2%-5%.[7,22] Although frozen shoulder affects many patients and has been studied extensively, its etiology remains uncertain. Increasing evidence suggests the role of inflammatory mediators and disturbance in local collagen translation resulting in global fibroplasia.[2,4,13,15]

Despite the lack of a clear cause-and-effect relationship, it is well established that individuals with diabetes are predisposed to frozen shoulder.[28,33,36] The prevalence of frozen shoulder in people with diabetes is estimated to be around 13.4%.[36] Kim et al attributed a hyperglycemic state and frozen shoulder to an Intercellular adhesion molecule-1 (ICAM-1), which is higher in people with diabetes than controls and plays a critical role in the immune system-mediated inflammatory response.[25]

Though literature shows plenty of evidence that frozen shoulder has a strong association with diabetes,[36] the literature associating 'prediabetes' or 'prediabetic dysglycemia' with a frozen shoulder is still scarce. Prediabetes is a metabolic disorder in which blood glucose levels are elevated but not high enough to be classified as diabetes. Though few recent studies have shown a varying prevalence of prediabetes in frozen shoulders (8%-48%), more research is needed to establish it as an independent risk factor.[30,32] Furthermore, the development of a frozen shoulder is also linked to poorly controlled diabetes and higher hemoglobin A1c (HbA1c) levels.[10] Therefore, early detection of diabetes, especially in the prediabetic dysglycemic stage, may help prevent the complications of diabetes and perhaps the severity of a frozen shoulder.

Institutional Ethical Committee Kasturba Hospital, Manipal approved this study (Registration no- ECR/146/Inst/KA/2013/RR-13) study number - IEC/908/2020. Clinical trial registry (India) approval: CTRI/ 2021/04/032645.

*Corresponding author: Vivek Pandey, MS, Arthroscopy and Sports Injury Unit, Department of Orthopaedics, Kasturba Medical College, Manipal, Manipal Academy of Higher Education, Madhav Nagar, Manipal, Udupi, India 576104.

E-mail address: vivekortho@yahoo.co.in (V. Pandey).

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In our prospective study, we aim to assess the prevalence of prediabetes in patients diagnosed with frozen shoulder using HbA1c and compare the prevalence of prediabetics with normoglycemics and diabetics.

Materials and methods

The study was initiated only after the Institutional Ethics Committee (IEC/908/2020) and Clinical Trials Registry, India (CTRI/ 2021/ 04/032645) approvals were obtained. Prospectively, 158 consecutive patients with primary frozen shoulder (PFS) were recruited and presented to our outpatient department from April 2021 to December 2022. The definition of the PFS was adapted from International Society of Arthroscopy, Knee Surgery, and Orthopaedic Sports Medicine upper limb committee, suggesting that a frozen shoulder develops without any specific trauma or underlying disease process.[24]

Clinical evaluation

All cases were selected after a detailed case history and physical examination done by a single senior surgeon with experience of more than 15 years in managing shoulder pathologies. The baseline data comprising age at presentation, sex, duration of complaints, the side affected, and presence of diabetes (or not) were noted. A clinical examination of the shoulder was performed to assess the active and passive range of movement of the index and contralateral shoulder. The diagnosis of idiopathic frozen shoulder was considered if there were restrictions of movements in at least 2 planes of the shoulder movement. Special tests were done to rule out rotator cuff tear. Once a clinical diagnosis of a PFS was made, patients underwent laboratory and radiological assessment to confirm the diagnosis.

Laboratory evaluation for assessment of prediabetes

As per the American Diabetes Association's (ADA) recommendation, there are three methods to assess prediabetes; impaired glucose tolerance (IGT), impaired fasting glucose (IFG), and assessment of HbA1c.[3] The ADA defines prediabetes as a fasting plasma glucose of 100-125 mg/dL (IFG), a plasma glucose level 2 hours after a 75-g glucose challenge of 140-199 mg/dL (IGT), or a HbA1c level of 5.7%-6.4%.[3] Per our institutional ethical committee suggestions and convenience to the patient, we decided to assess prediabetes based on a 1-time assessment of serum HbA1c value, as many patients with shoulder pain arrive at the hospital after having food. HbA1c >6.5 was considered diabetic, while HbA1c <5.7 was considered normoglycemic. Furthermore, since most patients arrive at the hospital after having food, we decided to assess random blood sugar (RBS). The RBS values <140 mg% were considered normal, and value above 140 mg% was considered abnormal. Both known diabetics on treatment and new-onset diabetic patients were included in the study. For all patients whose HbA1c and RBS were within normal limit were categorized as 'normoglycemics.' All others who were prediabetic and new onset diabetics, an endocrinologist opinion was sought to clearly categorize them into 'prediabetic' and 'diabetic' category and initiate appropriate treatment. So, we had a total of 3 categories based on HbA1c assessment; normoglycemics, prediabetics, and diabetics. The HbA1c and RBS values were not repeated again, unless sought by the consulting endocrinologist.

Radiological evaluation

All patients underwent plain radiographs (anteroposterior view) and ultrasound (USG) of the shoulder. X-rays were done to rule out any underlying secondary cause of pain, such as calcification, arthritis, tumour, or infection. A fellowship-trained musculoskeletal radiologist performed USG to rule out a rotator cuff tear, partial, or complete. In addition, the thickness of the coracohumeral ligament was assessed, which is often thickened in the frozen shoulder.[14]

Inclusion and exclusion criteria

All patients above the age of 18 who presented with limitation of range of movement in at least 2 planes for a minimum duration of 6 weeks, with normal findings on x-rays and absence of rotator cuff tear were included in the study.

Patients with ipsilateral shoulder or upper extremity trauma, rotator cuff tears (partial or complete), associated arthritis, any other detectable shoulder pathology in the radiograph or USG, or any secondary cause of shoulder stiffness were excluded. Furthermore, any condition that would affect the shoulder's movement temporarily or permanently, such as cerebrovascular accidents, angioplasties, and thoracoabdominal or breast surgeries, were also excluded. Also, patients with gestational diabetes and those on diabetogenic medications, such as steroids, were excluded.

Sample size calculation

The prevalence of prediabetes varies from 4% to 48% in different populations due to ethnic differences.[5,23,32,34] Considering the highest reported prevalence of prediabetes in their study by Tighe et al as 48%, the minimum sample size required for the study was calculated to be 98. However, we continued to enroll patients till the end of the study completion to have a bigger sample size.

Statistical analysis

SPSS v23 (IBM Corp., Armonk, NY, USA) was used for data analysis. Descriptive statistics were presented as means, standard deviations (SDs), and medians for continuous variables, frequencies, and percentages for categorical variables. Chi-squared test was used for group comparisons of categorical data. Statistical significance was kept at $P < .05$.

Results

A total of 176 consecutive patients with idiopathic frozen shoulders were asked to participate in the study, of whom 158 agreed (89.7%). A total of 158 patients were included in the study, with 84 (53.2%) male and 74 (46.8%) female participants; 79 (50%) patients had right shoulder involvement, while 70 (44.3%) participants had left shoulder involvement. Nine patients (5.7%) reported having a bilateral frozen shoulder at the time of presentation. All patients with bilateral involvement had diabetes. The mean age of the patients (±SD) was 55 (±7.61) years (range, 39-72); 47.5% (n = 75) of the patients were in the age group of 51-60 years, whereas 27.8% (n = 44) and 22.8% (n = 36) were in the age group of 36-50 years and 61-75 years, respectively.

Based on HbA1c values and known history of diabetes, patients were distributed into three groups- normoglycemic, prediabetic, and diabetic; 16.5% (n = 26) of the participants were normoglycemic, 37.3% (n = 59) were prediabetics, and 46.2% (n = 73) were diabetics (Table I). The difference in mean HbA1c values between the three groups was statistically significant ($P < .001$) (Table I).

Age distribution of 3 groups

The mean age (±SD, range) in the nondiabetic, prediabetic, and diabetic groups was 54.54 (8.62, 39-70), 56.69 (7.41, 39-75), and 54.21 (7.29, 31-72), respectively. There was no statistical difference between the 3 groups ($P = .86$).

Sex distribution of 3 groups

The sex distribution of the 3 glycemic groups is mentioned in Table II. There was no significant difference between the various groups regarding gender (0.68).

Duration of symptoms in 3 groups

The mean duration of symptoms in months (±SD) in the nondiabetic, prediabetic, and diabetic groups was 4.04 (3.87), 3.54 (2.61), and 4.36 (4.21), respectively. There was no significant difference between the various groups regarding the duration of symptoms ($P = .192$) (Table III).

RBS distribution in 3 groups

The mean (±SD) of RBS (mg/dL) in the nondiabetic, prediabetic and diabetic groups was 101.58 (±18.58), 112.64 (±30.80), and 175.54 (±93.31), respectively (Table IV); 84.7% of prediabetic patients had average RBS values <140 mg%. The difference in mean RBS values between diabetic-nondiabetic and diabetic-prediabetic groups was statistically significant ($P < .001$), whereas no significant difference was detected between nondiabetic and prediabetic ($P = .355$) (Table V).

Discussion

The key finding of our study is that there is a high prevalence of prediabetes (37.3%) in patients diagnosed with PFS. Furthermore, mere RBS value alone is not an appropriate investigation to detect prediabetes as RBS values are often normal while HbA1c is abnormal.

Bridgman et al first recognized the association between frozen shoulder and diabetes and reported the prevalence of diabetes in patients having frozen shoulders at 10.8%.[6] After that, scores of studies have confirmed the association of diabetes with frozen shoulder.[6,32,33,36] However, any association between prediabetes and frozen shoulder was not explored till recently, when few authors concluded the association of prediabetes with a frozen shoulder.[30,32,34] According to these studies, the reported prevalence of prediabetes in frozen shoulder varies from 8% to 48% (Table VI), while it is 37.5% in our study. One of the reasons for such a variable prevalence of prediabetes could be ethnicity, as the latter is a known factor affecting abnormal glycemia in the population.[12,20,35]

In the last decade, much work has been done to assess the prevalence of prediabetes in various parts of the world. According to the Centers for Disease Control and Prevention, 37% of Americans over 18 years are prediabetic.[29] Furthermore, 18% of United States teenagers are prediabetic.[1] Ceriello et al suggested that an acute increase in plasma glucose produces oxidative stress, which induces cellular expression of ICAM-1.[9] They reported a significant increase in plasma levels of circulating ICAM-1 in both diabetic and nondiabetics when subjected to high glucose levels. Perhaps, this can explain the high prevalence of frozen shoulder in prediabetics, as increased levels of ICAM-1 are noted in transient hyperglycemic states of all individuals.

It is also noteworthy that in practice, many physicians prefer performing RBS assessments to screen for diabetes, as many patients do not arrive at the hospital on an empty stomach. RBS values below 140 mg/dl are considered normal, while above 200 mg/% are considered diabetic range. Although RBS is a good tool for detecting diabetes,[31] it is not recommended by ADA to assess prediabetes.[18] Notably, 84.7% of our prediabetic patients had average RBS values <140 mg%, which would be categorized as normoglycemic if HbA1c had not been performed. It is also evident from the results wherein there is a statistically significant difference between the RBS values of the normal and prediabetic groups, indicating that a simple RBS assessment without HbA1c may lead to the prediabetics being missed. This gives an important message to clinicians to test patients for both RBS and HbA1c and not depend on mere RBS for their diagnosis of prediabetes or diabetes.

Various other studies (Table VI) confirming an association between prediabetes and frozen shoulder have used IFG and IGT, whereas we have used HbA1c. However, our prevalence rate is

Table I
Mean HbA1c value in 3 groups.

Values	Glycemic diagnosis			*P* value
	Nondiabetic (n = 26)	Prediabetic (n = 59)	Diabetic (n = 73)	
Mean HbA1c (±SD)	5.39 (0.22)	5.97 (0.21)	7.98 (1.92)	<.001
Range (min-max)	4.9-5.6	5.7-6.4	5-13.3	

HbA1c, hemoglobin A1c; *SD*, standard deviation.

Table II
Gender distribution in 3 groups.

Gender	Glycemic diagnosis				*P* value
	Nondiabetic (%)	Prediabetic (%)	Diabetic (%)	Total (%)	
Male	13 (50.0)	34 (57.6)	37 (50.7)	84 (53.2)	.685
Female	13 (50.0)	25 (42.4)	36 (49.3)	74 (46.8)	
Total	26 (100.0)	59 (100.0)	73 (100.0)	158 (100.0)	

Table III
Duration of symptoms of frozen shoulder in 3 groups.

Duration (mo)	Glycemic diagnosis			*P* value
	Nondiabetic	Prediabetic	Diabetic	
Mean (±SD)	4.04 (3.87)	3.54 (2.61)	4.36 (4.21)	.192
Range, min-max	1-12	1-12	1-24	

SD, standard deviation.

Table IV
Mean RBS value in 3 groups.

RBS (mg/dL)	Glycemic diagnosis			*P* value
	Nondiabetic	Prediabetic	Diabetic	
Mean (±SD)	101.58 (18.58)	112.64 (30.80)	175.54 (93.31)	<.001
Min-max	79-152	71-251	87-489	

RBS, random blood sugar; *SD*, standard deviation.

Table V
Pairwise comparison of 3 groups regarding mean values of random blood sugar.

Pairwise comparison of subcategories of glycemic diagnosis using RBS	*P* value
Diabetic - nondiabetic	<.001
Diabetic - prediabetic	<.001
Nondiabetic - prediabetic	.355

RBS, random blood sugar.

Table VI
Summary of studies establishing the prevalence of prediabetes and diabetes in frozen shoulder.

Study	Number of patients	Age group (y)	Prediabetes detection method	Prevalence
Tighe et al 2008[34]	88	21-80	FBS, 2-h GTT	32.95%—Prediabetic 38.6%—Diabetic
Safran et al 2016[32]	50	35-60	FBS, 2-h GTT	8%—Prediabetic 0%—Diabetic
SK Rai et al 2018[30]	135	30-60	FBS, 2-h GTT	15.5%—Prediabetic 27.4%—Diabetic
Our study	158	18-no upper limit	HbA1c	37.3%—Prediabetic 46.2%—Diabetic

FBS, fasting blood sugar; *GTT*, glucose tolerance test.
Number in parenthesis/brackets indicate reference number from manuscript.

similar to Tighe et al (32.95%), who considered patients up to 80 year old.[34] In contrast, our prevalence rate was higher than the ones reported by Safran et al and Rai et al, as both had not considered patients older than 60 years.[30,32] We believe that since we are looking for an association between frozen shoulder and prediabetes, we must consider considering all ages because both prediabetics and diabetics need active treatment.

A study from the United States National Health and Nutrition Examination Survey found that the use of fasting glucose identified twice as many subjects as having prediabetes compared with HbA1c (28 vs. 13 %), while only 8 % satisfied both criteria.[27] Further, Guo et al recommended that HbA1c is noted to have low sensitivity but high specificity to diagnose prediabetes and diabetes when pitted against fasting and 2-hour blood glucose.[21] However, when most patients arrive in the orthopedic outpatient department regarding consultation for their shoulder pain, they are not fasting. Hence, the possibility of performing a fasting glucose assessment would require one more visit to the hospital. Therefore, HbA1c is a quick tool to detect prediabetes or diabetes. Nevertheless, due to the lesser sensitivity of HbA1c to detect prediabetes, it is prudent that the prediabetic status of the patient must be confirmed with fasting and 2-hour postprandial blood glucose on another follow-up.

Apart from linking the association of prediabetes with frozen shoulder, it is essential to rule out prediabetic dysglycemia, as the latter also increases the risk of adverse cardiovascular events and stroke.[17] Furthermore, type 2 diabetes accounts for 90%-95% of diagnosed diabetes across the globe; preventing or delaying the progression to type 2 diabetes in individuals with prediabetes will have significant clinical and public health benefits.[5]

It is also important to note that HbA1c is an indirect measurement of the glycemic index, affected by conditions such as anemia, gender, hemoglobinopathies, and chronic hepatic and renal failure, which could influence HbA1c values independent of the glycemic index of the individual.[8,11,16] Although we did not include any known anemic patients in our study, we did not routinely perform hemoglobin assessments in patients to assess anemia. Therefore, it is impossible to conclude the effect of Hemoglobin over HbA1c in our study. However, gender did not affect the glycemic index in our study.

While Safran et al and Rai et al kept the upper age limit as 60, no upper-end age limit was considered by Tighe et al, similar to our study. Safran et al excluded patients above 60 years as they assumed that most patients above 60 would have prediabetes and diabetes, which may result in skewed data. However, we included all patients of all age groups presenting with primary frozen as we feel that patients above 60 years with prediabetes or diabetes require more attention to prevent prediabetes or diabetes-related cardiovascular or neurological complications.

Limitation of the study

First, all patients were tested only once for HbA1c to determine prediabetes. Given the possibility of factors causing variation in HbA1c, it is conceivable that some patients with HbA1c values close to the cut-off value between normal and prediabetic (5.7%) could have been either normal or prediabetic, resulting in either under- or over-diagnosis of prediabetes. Second, we did not perform fasting glucose to confirm the impaired glucose response assessed with HbA1c. However, that needed one more mandatory visit from the patient and ethical approval, which we did not have. Third, we did not assess the severity of pain or disability in patients with prediabetes and diabetes and whether controlling prediabetes would help amelioration of symptoms faster than ones in frank diabetics. However, it is a known fact that the severity of frozen shoulder increases with higher values of HbA1c.[19] Fourth, apart from clinical history, we did not perform any laboratory investigation to rule out other underlying disorders which might affect HbA1c, such as anemia or hemoglobinopathies. However, it is not feasible in a clinical scenario to investigate all patients for rare disorders like hemoglobinopathies. Other conditions like anemia, renal, and liver disorders were ruled out based on history and clinical records. Fifth, we do not have any control group (with any other musculoskeletal disorder) with which levels of HbA1c in prediabetics could be compared. Therefore, it cannot be determined with certainty whether the prevalence of prediabetes in patients with frozen shoulder is higher than in the general population or patients with other musculoskeletal disorders.

Conclusion

Based upon assessment by HbA1c, our study concludes that the prevalence of prediabetes is high in patients with frozen shoulder. However, to validate the utility of HbA1c in establishing the diagnosis of prediabetes, more well-designed prospective studies, along with assessments of IFG and IGT, are required. Furthermore, as the prevalence of prediabetes and diabetes remains high in patients with frozen shoulder, all patients must be screened for dysglycemia.

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