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# **Original Research Article**

# An observational study on pneumococcal and influenza vaccination status of patients with type 2 diabetes mellitus

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#### **ABSTRACT**

**Background:** India has more than sixty million subjects with diabetes. Diabetes confers an increased risk of developing and dying from infectious diseases with an enhanced susceptibility to morbidity, mortality and hospitalizations due to influenza and pneumococcal disease. The Advisory Committee on Immunization Practices (ACIP) recommends influenza and pneumococcal vaccines for all individuals with diabetes.

**Methods:** Around 249 patients with type 2 diabetes mellitus were enrolled in the study. All patients were asked a detailed history about diabetes, its duration, type of diabetes and the vaccinations for influenza and pneumococcus, who suggested vaccination and the reasons for declining the vaccination if it had been medically advised. Any other co-morbid condition such as hypertension, diabetes mellitus, heart disease, COPD, hypothyroidism and CKD were noted.

**Results:** Vaccination rates for influenza in patients aged 50 or more were higher (7.6% of 172 patients) as compared to those aged <50 years (0% of 77); (p=0.013) whereas pneumococcal vaccination rates were 8.1% as against 1.3% (p=0.036) respectively. In males the vaccination rates for influenza were 4.7% compared to females (5.8%); (p=0.675), whereas for pneumococcus the respective vaccination rates were 6.2% for male and 5.8% for female (p=0.903). Vaccination uptake among male and female were almost same. Patients having chronic kidney disease on dialysis were having highest vaccination rate.

**Conclusions:** The poor vaccination uptake for influenza and pneumococcus in patients with diabetes, calls for intensive efforts aimed at increasing coverage.

Keywords: Influenza vaccination, Pneumococcal vaccination, Type 2 diabetes mellitus

#### INTRODUCTION

In India there are already more than sixty million subjects with diabetes and the number is predicted to reach above hundred million by the year 2030. Diabetes confers an increased risk of developing and dying from infectious diseases with an enhanced susceptibility to morbidity, mortality and hospitalizations due to influenza and pneumococcal disease. <sup>2-4</sup> The Advisory Committee on

Immunization Practices (ACIP) recommends influenza and pneumococcal vaccines for all individuals with diabetes. <sup>5,6</sup> Influenza vaccination has been reported to facilitate a drop of up to 80% in influenza and pneumonia related hospitalizations in patients with diabetes and up to 50% in influenza-related mortality. <sup>7,8</sup> Influenza vaccination has shown itself to be capable of producing an adequate immunologic response in subjects with diabetes, proving effective in reducing mortality and

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morbidity in patients with underlying chronic diseases, including diabetes, and reducing hospital admissions among diabetic patients during influenza epidemics. <sup>9,10</sup> The rationale for the use of influenza and pneumococcal vaccine in patients with diabetes can be considered based on the facts that patients with diabetes may have abnormalities in immune function and presumed increased morbidity and mortality from infection.

#### **METHODS**

This study was conducted on 249 patients admitted in internal medicine ward and seen in diabetology clinic at Max Super Specialty Hospital, Saket, New Delhi. This was the prospective observational study conducted during period of June 2016 to December 2017.

#### Inclusion criteria

Adult more than 18 years of age with type 2 diabetes mellitus fulfilling ADA criteria or already on treatment for diabetes mellitus in form of oral hypoglycaemic drugs or injection insulin.

- American Diabetes Association (ADA) criteria
- Symptoms of diabetes plus random blood glucose concentration ≥11.1mmol/L (200mg/dL) or
- Fasting plasma glucose ≥7.0mmol/L (126mg/dL) or
- Hemoglobin  $A_{1c} \ge 6.5\%$  or
- 2-h plasma glucose ≥11.1mmol/L (200mg/dL) during an oral glucose tolerance test.

#### Exclusion criteria

- Patients who have gestational diabetes.
- Patients not willing to participate in the study.

Patients fulfilling the inclusion criteria were examined thoroughly and investigations including hemogram, renal function test, ECG, blood glucose (fasting and 2hours postprandial), HbA1c were sent. Patients were asked a detailed history about diabetes, its duration, type of diabetes, whether on oral hypoglycaemic agents or on injection insulin, complications related to diabetes.

History of vaccination for influenza (inactivated or live attenuated influenza vaccine, dose and route of administration) and pneumococcus (PPV23 or PCV 13) was taken. Patients were also asked questions like who suggested vaccination and whether they had any other comorbid condition such as hypertension, heart disease, COPD, hypothyroidism and CKD.

The questionnaire was provided to the patients and responses were noted in data collection sheet. If patient had received any vaccinations in the past 5 years, whether they had been advised vaccinations, who advised and the reasons for declining the vaccination (unaware, contraindication, cost, harmful, socio-cultural issues), if it had been medically advised were noted.

#### Statistical analysis

Categorical data is presented as proportion and analyzed by using chi-square or Fisher's exact test (to find the association) where applicable. Continuous data was analyzed by t-test. Unless specified otherwise, all statistical testing is two-sided and is performed using a significance (alpha) level of 0.05. All data is analyzed with the help of SPSS 2.0.0. A p-value of <0.05 was considered statistically significant.

#### RESULTS

A total of 249 patients were enrolled in the study, of which 120 were females and 129 were males, with age ranging from 28 years to 92 years (median 50 years) with 77 (30.9%) participants aged 50 years or more and 172(69.1%) aged less than 50 years. The duration of diabetes ranged from 1 year to 21 years (median 6 years) and all had type 2 diabetes (Table 1).

Table 1: Demographic parameters.

Group	Total no. n (%)	Vaccinated for influenza n (%)	Vaccinated for pneumococcus n (%)		
Total	249(100%)	13(5.2%)	15(6%)		
Age					
<50years	77(30.9)	0(0)	1(1.3)		
>50years	172(69.1)	13(7.6)	14(8.1)		
Sex					
Male	129(51.8)	6(4.7)	8(6.2)		
Female	120(48.2)	7(5.8)	7(5.8)		
Have a doctor told you about requirement of vaccination?					
Yes	16(6.4)	15(6)	16(6.4)		
No	233(93.6)	1(0.4)	0(0)		
Do you know dia	betes is an ad	lditional risk	for accruing		
infections					
Yes	16(6.4)	15(6)	16(6.4)		
No	233(93.6)	1(0.4)	0(0)		
Co-morbidities					
Hypertension	155(62.25)	12(7.7)	13(8.3)		
Ischemic heart disease	63(25.30)	7(11)	7(4.5)		
COPD	21(8.4)	4(19)	4(19)		
Hypothyroidism	17(6.8)	1(5.8)	1(5.8)		
CKD	39(15.6)	13(33)	13(33)		
Stroke	1(0.4)	0(0)	0(0)		

In males the vaccination rates for influenza were 4.7% compared to females (5.8%); (p=0.675), whereas for pneumococcus the respective vaccination rates were 6.2% for male and 5.8% for female (p=0.903) (Table 2).

Vaccination rates for influenza in patients aged 50 or more were higher (7.6% of 172 patients) as compared to those aged <50 years (0% of 77); (p=0.013) whereas

pneumococcal vaccination rates were 8.1% as against 1.3% (p=0.036) respectively (Table 3).

Patients having chronic kidney disease on dialysis were having highest vaccination rate. Amongst total patients in study, 39 were CKD patients and 13 have received both vaccines, so vaccination rate for both the vaccines was same 33%. 21 had COPD and amongst them 4 have received both vaccines, so rate of vaccination for both vaccines was same 19.04%. Rest presence of other comorbidity did not have significant effect on vaccination uptake.

Table 2: Gender wise status of vaccination.

Pneumococcus vaccine				Influenza vaccine		
Sex	Vaccinated n (%)	Not vaccinated n (%)	P value	Vaccinated n (%)	Not vaccinated n (%)	P value
Male	8 (6.2)	121 (93.8)	0.903	6 (4.7)	123 (96.3)	0.675
Female	7 (5.8)	113 (94.2)	0.903	7 (5.8)	113 (94.2)	0.073

Table 3: Age wise vaccination status.

Age wise vaccination status for pneumococcus					
Age	Total	Vaccinated n (%)	Not vaccinated n (%)	P value	
< 50 years	77	1 (1.3)	75 (98.7)	0.026	
> 50 years	172	14 (8.1)	158 (91.9)	0.036	
Age wise vaccination status for influenza					
Age	Total	Vaccinated n (%)	Not vaccinated n (%)	P value	
< 50 years	77	0 (0)	77 (100)	0.012	
> 50 years	172	13 (7.6)	159 (92.4)	0.013	

Table 4: Awareness of vaccination.

Awareness of vaccination for pneumococcus					
	n (%)	Vaccinated n (%)	Not vaccinated n (%)	P value	
Awareness	16 (1)	15 (93.8)	1 (6.2)	_	
No awareness	233 (100)	0 (0)	233 (100)	0.000	
Total	249	15 (6)	234 (94)		
Awareness of vaccination for influenza					
	n (%)	Vaccinated n (%)	Not vaccinated n (%)	P value	
Awareness	14 (100)	14 (100)	0 (0)		
No awareness	235 (100)	0 (0)	235 (100)	0.000	
Total	249	14 (5.8)	235 (94.2)		

Vaccination uptake among male and female were almost same. 233(93.6%) participants were unaware that diabetes posed any additional risk for influenza or pneumonia (Table 4) and only 16 (6.4%) had been recommended vaccination by their treating physicians.

## **DISCUSSION**

Consistent with the recommendations of the ACIP, the influenza vaccine should be recommended for patients with diabetes, age ≥6months, beginning each September.<sup>5</sup> Each year, a trivalent vaccine is constituted with strains of influenza A and B, which are most likely to circulate during the winter. Because the vaccine consists of egggrown viruses, it should not be administered to

individuals known to have anaphylactic hypersensitivity to chicken eggs or additional components of the influenza vaccine. Because immunity from influenza vaccination declines in the year after vaccination, yearly vaccination is recommended. Although antibody responses to repeat immunization have been reported to be greater in some people with diabetes, repeated immunization within the same season is not recommended.11 The influenza vaccine contains only noninfectious viruses and cannot cause influenza or other respiratory disease. The side effect most frequently experienced from vaccination is mild soreness at the vaccination site. In individuals with chicken egg allergy, immediate allergic reactions have been reported. In these patients, chemoprophylaxis with amantadine/rimantadine or immunization using a protocol as reported by Murphy and Strunk should be

considered. 12 A recent study reported a slight increased risk of Guillain-Barré syndrome in the 6weeks after influenza vaccination during the 1992-1993 and 1993-1994 flu seasons. 13 For this reason, it is recommended not to administer the influenza vaccine to individuals known to have developed Guillain-Barré syndrome within 6 weeks of a previous influenza vaccination. The current pneumococcal vaccine includes 23 purified capsular polysaccharide antigens representing 85-90% of the serotypes of Streptococcus pneumonia that cause invasive pneumococcal infections among children and adults in the U.S.<sup>5</sup> People with diabetes are susceptible to pneumococcal infection and are at increased risk for the morbidity and mortality of bacteremia from this organism.3 Additional risk is associated with being age ≥65 years and having chronic cardiovascular, pulmonary, and renal disease. A one-time revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the vaccine was administered more than 5 years ago. Other indications for repeat vaccination potentially relevant to patients with diabetes include nephrotic syndrome, chronic renal disease, and other immunocompromised states, such as post-organ transplantation.<sup>5</sup>

### **CONCLUSION**

The poor vaccination uptake for influenza and pneumococcus in patients with diabetes calls for intensive efforts aimed at increasing coverage by targeting patients, health care professionals as well as the vaccination delivery systems for an equitable and uniform vaccination.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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