

EFFICACY OF FLU VACCINE AMONG HAJJ PILGRIMS

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ABSTRACT

Millions of people travel every year to Makkah to perform hajj, the pilgrimage of Muslims across the world. Overcrowding and congested living conditions make most of the pilgrims vulnerable to infectious diseases, especially airborne infection like influenza. During 2013 hajj more than 100,000 pilgrims performed hajj from Pakistan, and it was mandatory for all travelers that, they should be vaccinated for Influenza, apart from Meningitis and Polio. Objective of this cross sectional study was to assess the effectiveness of flu vaccine among Pakistani pilgrims. One hundred and seventy six pilgrims (127 male and 47 female) were selected by using convenient sampling technique. All of them were interviewed by a team of doctors and volunteers. Out of 170, 94.9% were vaccinated against influenza while 5.1% were not vaccinated or not aware about vaccination. All those vaccinated received monovalent H,N, rather than recommended trivalent (TIV) vaccine for high risk groups. Within 4-6 week, after receiving vaccine, 27.87% had developed influenza as diagnosed by preset clinical criteria. We strongly recommend a large scale study for efficacy of influenza vaccine with availability of PCR for influenza virus and long term follow up.

Key Words: Efficacy; Vaccine; Influenza; Pilgrims; Hajj; Pakistan

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INTRODUCTION

“Our Lord! And make us submissive unto You and of our offspring a nation submissive unto You, and show us our Manasik (all the ceremonies of pilgrimage - Hajj and Umrah, etc.), and accept our repentance. Truly, You are the One Who accepts repentance, the Most Merciful.¹

The annual Hajj pilgrimage to Mecca, Saudi Arabia, is one of the largest mass gatherings in the world. In 2013, Hajj took place from 13th to 18th October. Approximately two million people visited Makkah to perform Hajj from all over the world including Pakistan. From Pakistan more than 140,000 people visited this year². Because of the overcrowding, mass gatherings such as Hajj and Umrah are associated with unique health risks, including various infectious diseases like influenza, pneumonia, meningitis and gastroenteritis³. Influenza continues to be a major cause of mortality and morbidity among high risk group especially elderly people.⁴

Influenza caused by RNA virus of orthomyxovirus family, is a highly contagious airborne viral disease that occurs in seasonal epidemics. These deadly strains produced 3 global pandemics in the last century, the worst of which occurred in 1918, called the Spanish flu, this pandemic killed an estimated 20-50 million persons, with 549,000 deaths in the United States alone.⁵ Influenza results from infection with 1 of 3 basic types of influenza virus: A, B, or C; A generally more pathogenic than B. Epidemics of influenza C have also been reported.⁶ Influenza A is further sub typed on the basis of the surface hemagglutinin(H) and neuraminidase(N) antigens. Influenza A has 16 distinct H subtypes and 9 distinct N sub types, of which only H1, H2, H3, N1 and N2 have been associated with epidemic of disease in humans. Influenza B and C virus similarly designated.⁷

Influenza outbreaks occur almost every year and pandemic with variable intervals.⁸ The most effective strategy for preventing influenza is annual vaccination. Strategies that focus on providing routine

vaccination to persons at higher risk for influenza complications have long been recommended. The efficacy (i.e., prevention of illness among vaccinated persons in controlled trials) and effectiveness (i.e., prevention of illness in vaccinated populations) of influenza vaccines depend in part on the age and immunocompetence of the vaccine recipient, the degree of similarity between the viruses in the vaccine and those in circulation.

Purpose of this study was to assess the efficacy of flu vaccine among Pakistani pilgrimage who visited Makkah to perform hajj during October-November 2013.

MATERIAL AND METHOD

This pilot study was conducted from October, 20, 2013 to November, 18, 2013 in Makkah among Pakistani pilgrims who visited for performing hajj in October 2013. The design of study was cross sectional and sample size was 176 pilgrims calculated using 5% level of significance and 95% confidence interval. Prevalence as calculated by pilot study was 12%. Sample size calculated was 162. We took 14 more to consider the non response of some of the respondents. During this period a team of doctors and volunteers visited various temporary residential suits for Pakistani pilgrims in various districts of Makkah. In their visit they conducted survey about vaccination status, demography, confirmation of flu infection according to preset clinical criteria. For the purpose of the diagnosis of flu a clinical criterion standardized performa was designed. Criteria for the suspected case of influenza were presence of fever, throat pain, cough and rhinitis. Pilgrims were selected using convenient sampling technique. All data was entered and analyzed using the SPSS software program version 20.

LIMITATION

We diagnosed the patient of flu on the basis of clinical criteria, as culture facilities are not available. Vaccination status should have been confirmed through serological test but it was not possible during hajj period due to non availability of resources. According to recommended standards the pilgrims

should have been followed from the date of vaccination till completion of whole year, but it was not possible as pilgrims went back to Pakistan after performing their hajj.

RESULTS

We selected 176 Pakistani pilgrims, 127 (72 %) males and 49 (27.8%) females. One hundred sixty seven (94.9%) pilgrims were vaccinated with Influenza vaccine, remaining were either not vaccinated or unaware about their vaccination status. Thirty three percent of them were government employees and rest were privately employed, retired or unemployed including house wives. Among all pilgrims, who had been vaccinated only 19 (10.8%) had knowledge about the name of vaccination, Sixty eight percent had vaccination card issued by hajj authority or travel agents. After review of these cards we got the information that only 33% of card holders were vaccinated by three vaccines i.e. H1NI, meningitis and polio, while remaining cards either did not mention the name of vaccine or their card were in possession of their sponsor. Almost all of the pilgrims had taken their vaccination 10-15 days before their arrival in Makkah. Out of 167 pilgrims who received vaccination, 34 (20.3%) developed flu, (based on our clinical criteria above) and 25 of them were males.

DISCUSSION

Makkah, popularly called Makkah-al-Mukarramah, is the historic heart and spiritual center of Islam, pilgrimage of which is obligatory once in lifetime for every Muslim who can afford it and in reasonably good health. Makkah features desert climate. Unlike other cities, it retains its warm to hot temperature in winter, which can range from 18 °C at night to 30 °C in the day. Summer temperatures are extremely hot often being over 40 °C during the day dropping to 30 °C at night. Extreme weather conditions, compounded by overcrowding, close contact and congested living conditions make pilgrimage to Makkah more vulnerable for various infectious illnesses among pilgrims. Influenza is one of the most common illnesses during hajj. Although most pilgrims received influenza vaccine since last few years but significant number of

TABLE 1

	Total pilgrims interviewed	Male (72%)	Female (27.8%)	Total Vaccinated (94.9%)	Awareness about vaccination (10.9%)	No information about vaccine (88.4%)	Developed flu like symptom (20.3%)
Numbers	176	127	49	167	19	148	34

pilgrims seek medical consultation for flu like symptoms during their stay in Makkah-al-Mukarramah. In this study we did survey among Pakistani pilgrim to assess the efficacy of influenza vaccination.

Influenza is considered a preventable disease by effective use of vaccination; in developed world it is recommended for all persons above the age of more than six months.¹⁰⁻¹¹ There are many types of vaccines available for use which are active against various strain of influenza vaccine, most of these are trivalent; there is a recently approved quadrivalent vaccine, while monovalent like H₁N₁ vaccine is also available. The 2010-2011 trivalent vaccine contains A/California/7/2009(H₁N₁)-like antigen, A Perth/16/2009(H₃N₂)-like antigen, and B/Brisbane/60/2008 like antigen. The A/California/7/2009(H₁N₁)-like antigen is derived from a pandemic 2009 influenza (H₁N₁) virus and is the same vaccine antigen used in the influenza A (H₁N₁)2009 monovalent vaccine.¹²

In our survey most of the pilgrims (95%) were vaccinated against influenza. All of them had taken vaccine against H₁N₁, which is monovalent, recommended after the 2009 pandemic, more than 15 days before travelling to Makkah-Al-Mukarramah. We did not get any information regarding use of trivalent or quadrivalent vaccines. Most recent recommendation for influenza is trivalent (TIV), but some authorities recommend quadrivalent vaccine as well.^{13, 14} Remaining 72.2% have no evidence of flu at the time of interview within 45 days of vaccination. Although those who have flue like symptom need laboratory confirmation of influenza vaccination by throat swab culture or PCR to be certain of influenza, typical symptoms in mass gatherings give a reasonably certain clue of the occurrence.

Although the efficacy of influenza vaccines assessed in healthy adults is often estimated to be between 70 and 90 percent, a 2012 comprehensive review suggested that efficacy may be considerably lower.¹⁵ The influenza vaccine was only 56 percent effective overall and 9 percent effective for the type A H3N2 strain in adults aged 65 years or older during the 2012-13 flu season.¹⁶ In another study Osterholm and colleague found the effectiveness of flu vaccine in their study to be 62%.¹⁷

There is marked difference between effectiveness of live attenuated and inactive vaccine.¹⁸ On June 11, 2009, WHO declared a world-wide pandemic of novel influenza A(H1N1) in multiple areas of the world.¹⁹ Vaccines against novel influenza A (H1N1) virus infection are being produced using methods similar to those used for seasonal influenza vaccines. In our

study almost all of the pilgrims have been vaccinated with H₁N₁ instead of recommended trivalent or quadrivalent influenza vaccine and this might be cause of failure of vaccine in our cases.

The Food and Drug Administration (FDA) and WHO have selected A/California/07/2009 (H1N1) for use as the strain for the vaccines currently being manufactured.²⁰ Clinical studies of the 2009 H1N1 monovalent vaccines indicate that this vaccine antigen is immunogenic and response rates are similar to those observed after immunization with influenza A antigens found in typical seasonal influenza vaccines.^{21, 22} But this data is available for children under the age of nine year while data for other clinical groups like co morbid illness or pregnant women is not available or insufficient. Limited data is available of those persons who received seasonal influenza vaccination and were not protected.²⁰

In various published data efficacy of flu vaccine was variable; in our study we found this as 62.8%; it is to be reminded that this survey was conducted within 4-6 weeks of vaccination, while all vaccinated people should be observed for longer period to assess efficacy of vaccine. We strongly recommend a large scale study for the assessment of efficacy of flu vaccine among pilgrims, the study should provide the facility of influenza virus culture and long term follow up in Pakistan. We also emphasize that all pilgrims should receive trivalent or quadrivalent vaccine rather than vaccine based on monovalent strains which are recommended by WHO and CDC.

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