THE INCIDENCE OF INFLUENZA LIKE ILLNESS AND DETERMINATION OF THE EFFICACY OF FLU VACCINE IN IRANIAN PILGRIMS DURING HAJJ PILGRIMAGE

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Abstract- Every year, millions of Moslems depart to Saudi Arabia from more than one hundred countries around the world for paying to Hajj precept. High percentages of these pilgrims suffer from an influenza-like illness (ILI). This study was designed and conducted on 32370 Iranian pilgrims (36% of total number of Iranian pilgrims) to evaluate the incidence of the illness and determination of influenza vaccine's efficacy to prevent it. A total of 3465 individuals, 10.7% of under studied population, had vaccinated themselves voluntarily against the influenza and the rest were not vaccinated. As a whole, 70% of the studied population suffered from ILI. In this study, the incidence of illness among those vaccinated was about 56% and among those not vaccinated about 72%; the difference was significant ($P < 0.001$), with odds ratio (OD) = 0.50 and (1 - OD) = 0.50; thus the efficacy of the vaccine in this study was estimated to be 50% and it was efficient in reducing the cases of ILI. We recommend administration of the influenza vaccine to Iranian pilgrims one month before departure to Saudi Arabia for Hajj pilgrimage.

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Key words: Influenza-like illness, Influenza vaccines , Hajj

INTRODUCTION

Every year, millions of Moslems from more than one hundred countries around the world depart to Saudi Arabia for paying to Hajj precept. A high percentage of these pilgrims suffer from an influenza-like illness (ILI). In the majority of cases, the signs and symptoms of this disease are fever, respiratory findings such as tormenting cough that takes time, coryza and sometimes difficulty in breathing, headache, sore throat and myalgia.

No unique etiologic cause for this illness has been found till now. The probable etiologic agents include 1) respiratory viruses like influenza virus, respiratory syncytial virus and coronaviruses, 2) bacterial agents like Pneumococci, *Haemophilus influenza* and Mycoplasma, 3) allergic reactions like allergies due to disinfectants and villosities of Ihram towels, 4) fungi and 5) physical factors like hot and dry weather.

Among the above mentioned causes, viruses are more important than other causes and among the viruses, influenza virus is the most important virus.

Influenza is an acute and highly contagious respiratory disease which manifest with sudden headache, dry cough, high fever, myalgia, coryza, malaise and loss of appetite (1). Influenza is responsible for at least 3000-4000 deaths per year in the UK, and during epidemics, death rates from pneumonia and Influenza are much higher in elderly than younger people (2). In the United States, approximately 10%-20% of the population will contact the flu each year. Overall attack rate is 10%-20% and this rate reach 40%-50% in closed

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populations (3). The main approach for controlling the flu has been and remains prophylaxis by means of vaccination (3).

The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians now recommend that all adults above age 50 be routinely offered the vaccine, in addition to younger people with chronic medical conditions including those with heart disease (2). ACIP have proposed that the age of vaccination should be decreased from 65 years to 50 years because 24% to 32% of individuals older than 50 years suffer from chronic illnesses and influenza infection increases the rate of hospitalization in these patients or even causes death (4).

Influenza vaccinations may significantly reduce mortality and morbidity in patients who suffer from chronic conditions like congestive heart failure (CHF), diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), chronic renal failure (CRF), immunosuppressive conditions like malignancies (5), alcoholism, asthma (6), emphysema, rheumatic diseases and ischemic heart diseases and therefore the vaccine is recommended in these conditions. Influenza vaccination is recommended annually in the fall (optimally between October and mid-November); it is a three valent vaccine against 3 strains of virus.

In the year 2003, 91883 Iranian pilgrims departed to Saudi Arabia as 467 groups. Approximately 47.5% of them were older than 50 (7). Since a high percentage of the pilgrims are older than 50 years and many have chronic diseases not controlled before departure to Saudi Arabia (8), vaccination against influenza have been recommended by Saudi Arabia health ministry (9). Vaccination has also been recommended by Iranian authorities for individuals older than 50 years and high risk Iranian pilgrims but it is not obligatory (10, 11).

The main purposes of this study were to determine the incidence of ILI among Iranian pilgrims and to compare two vaccinated and not vaccinated groups of pilgrims and ultimately to reply to the question “whether recommendation for vaccination against influenza for pilgrims is justified or not”.

MATERIALS AND METHODS

This study was conducted on Iranian pilgrims during Hajj precept in the year 2003. It is a nested case control study. In the year 2003, 91883 Iranian pilgrims departed to Saudi Arabia as 467 groups (caravans). Recommendation had been made to the pilgrims via media and also by their physicians to vaccinate themselves against the influenza, voluntarily. The vaccine was 3 valent and confirmed by World Health Organization.

The pilgrims were dispatched to Saudi Arabia on the first day of Feb. 2003. The number of pilgrims in every group (caravan) ranged from 100-300, whose health problems were managed by one physician. During the journey, whenever they were feeling ill they were examined and their data were recorded by their physicians. The physicians were educated about the subject, objectives, methods and the manners of data collection on their arrival in Saudi Arabia when referred to Hajj and Pilgrimage Medical Team of Islamic Republic of Iran to take over their drugs and medical equipments. At the end of the journey, they submitted the collected data. The data collection was done by a short questionnaire consisting of 6 questions and a long questionnaire with 20 variables and the results were compiled in two separated researches.

The operational definition of the cases was cough and fever more than 38° C with or without the coryzal symptoms and myalgia. On the basis of an error type I of 5%, the power of study was 90% (1-3).

Data analysis was accomplished with SPSS software version 10, X^2 test (Pearson Chi square test) and calculation of odds ratio (OR). Vaccine efficacy was calculated with the use of the equation of 1 - OR.

RESULTS

The total number of pilgrims in Hajj in the year 2003 was 91883, traveling in 467 caravans, and each caravan was accompanied by a general practitioner or a specialist to Saudi Arabia. Every physician was in charge of monitoring 100 to 300 pilgrims.

The mean age of the pilgrims was 51 years and about 10% of them were aged over 65 years; about 25% of the pilgrims had coexisting risks factors such as COPD, DM, hypertension and cardiovascular diseases. The number of the studied population (compiled from physicians on the end of journey) was 32370 individuals (about 36% of total number of Iranian pilgrims); 18363 (56.73%) of them were male and 14007 (43.31%) were female and the mean age of them was 51. A total of 3465 individuals (10.7%) were vaccinated against influenza and 28905 individuals (89.3%) were not. These two groups were examined by their responsible physicians during the journey and compared with each other.

As a whole, 22708 (70.15%) of the studied population suffered from ILI. The ratio of ILI among pilgrims that were vaccinated was 55.97% (1939) and in those not vaccinated was 71.85% (20769).

The results are shown in table 1. Odds ratio (OR) was 0.05. Vaccine efficacy (1- OR) was 50% (95% confidence interval, 0.54-0.46; $P<0.001$) for preventing respiratory illness signs.

DISCUSSION

This study was carried out on 32370 Iranian pilgrims in Hajj 2003, and the main goal was determination of influenza vaccine efficacy in reducing ILI.

In a typical epidemic of influenza, 5-15% of the general population can become infected (12). The very high incidence of ILI (70%) in our study indicates some etiologic agents other than influenza virus involve in this epidemic process in Hajj.

Table 1. Distribution of influenza-like illness in Iranian pilgrims*

Vaccination	ILI positive	ILI negative	Total
Vaccinated	1939	1526	3465
	(55.97)	(44.05)	(10.7)
Not vaccinated	20769	8136	28905
	(71.85)	(28.15)	(89.3)
Total	22708	9662	32370
	(70.15%)	(29.85)	(100)

Abbrivation: ILI, influenza-like illness.
*Data are given as number (percent).

At least 20% of Iranian pilgrims in Hajj 2003, were at high risk because of conditions such as age above 65 years, DM, COPD, cardiovascular diseases and asthma (13). Influenza can cause a more serious illness and greater mortality in groups such as very young individuals or elderly, the immunocompromised patients and those with chronic diseases including COPD, asthma, cardiovascular diseases and DM. These groups are considered to be at high risk because influenza may exacerbate their underlying disease or predispose them to secondary complications such as pneumonia or bacterial infections (12). During influenza epidemics, 80-90% of excess deaths occur among those over 65 years (12). This indicates the necessity of the influenza vaccine in the elderly. Historical data show that when the vaccine and circulating strains are similar, influenza vaccines are 70-90% effective in preventing ILI in healthy adults aged <65 years, but it is only 30 - 40% effective in those aged >65 years (12). Ikomatsu *et al.* have investigated the efficacy of influenza vaccine in the elderly. They studied serologically diagnosed 166 vaccinated and 104 unvaccinated cases. The rate of influenza infection in unvaccinated people was 25% and in vaccinated cases was 3.6% (14). In our study there were 3456 (10.7%) vaccinated pilgrims and 28905 (89.3%) unvaccinated cases, and the rate of ILI in vaccinated individuals was 55.97% and in unvaccinated cases was 71.85%. These results are compatible with above mentioned study. In our study, the vaccine efficacy was 50% ($P<0.001$) and the results indicate that vaccination against influenza reduced the ILI among Iranian pilgrims significantly. This is in agreement with other studies, for example to determine influenza vaccine effectiveness against clinically defined ILI among Malaysian pilgrims attending the Hajj in Saudi Arabia, a case-control study was conducted during February and March 2000. The results of this study indicated that influenza vaccine was effective in preventing clinical visits for ILI and antibiotic use (15).

During the Hajj 1999, Qureshi *et al.* studied the incidence of vaccine preventable ILI and the medication used among Pakistani pilgrims to the Hajj

in Saudi Arabia (16). They have suggested that pilgrims traveling to the Hajj in Saudi Arabia should consider influenza vaccination (16). Grotto *et al.* in a study on healthy adults showed that vaccine efficacy for preventing fever and upper respiratory signs was 41.6% (17). In a meta-analysis of 20 cohort studies, the pooled estimates of vaccine efficacy (l-OD) were 56% for preventing respiratory illness (18). Couch *et al.* indicated that vaccine efficacy in adults aging 30-40 years varied from 37% to 72% and in elderly people <60 years was 50% (19). And finally, the cost-benefit and cost-effectiveness of influenza vaccination are well established for elderly people (20).

In conclusion, influenza is a major cause of morbidity and mortality in worldwide population, especially for people over 65 years of age and those with high-risk medical conditions. Since the mean age in Iranian pilgrims is about 50 and the number of people with high-risk medical conditions such as CHF, renal failure, hypertension and COPD is high, it is strongly recommended that each pilgrim and health worker, at least one month before traveling to Saudi Arabia is vaccinated against influenza.

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