

THE COMPARISON OF INFLUENZA VACCINE EFFICACY ON RESPIRATORY DISEASE AMONG IRANIAN PILGRIMS IN THE 2003 AND 2004 SEASONS

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Abstract- Prolonged cough occurs in a large proportion of the 2 million pilgrims who participate in the annual Hajj in Saudi Arabia. There is not any unique cause for pilgrims' respiratory involvement, but several studies suggest a high incidence of influenza as a cause of the disease. To determine influenza vaccine efficacy against respiratory disease in pilgrims, we conducted two similar cohort studies on 51100 Iranian pilgrims who had participated in the annual Hajj in the years 2003 and 2004. We calculated vaccine efficacy in these two years with the use of "1- odd's ratio" formula and compared the results. The vaccine efficacy for prevention of influenza like illness in the year 2003 was 51% but the vaccine was not efficient in the year 2004. It was concluded that etiologic agents other than influenza virus should be considered as the cause of respiratory disease in Hajj. Bacterial infections superimposed on chronic respiratory diseases, and allergic or toxic conditions are suggested courses for more investigation.

Acta Medica Iranica, 43(4): 279-281; 2005

Key words: Influenza like illness, Hajj, flu-vaccine efficacy, respiratory disease

INTRODUCTION

Prolonged cough occurs in a large proportion of the 2 million pilgrims who participate in the annual Hajj in Saudi Arabia (1). In Hajj pilgrimage season, people gather together to a small confined area in Mecca. Respiratory tract infection is the most common disease transmitted during this period.

One type of above mentioned respiratory tract infections is influenza like illness (ILI) that presents with sore throat, cough, fever of at least 38 degrees centigrade, symptoms of upper respiratory tract involvement and myalgia. In one study in Saudi Arabia, 500 Hajj pilgrims from different parts of the world presenting with upper respiratory tract

symptoms were screened by throat swab for viral culture, including influenza A and B, parainfluenza, respiratory syncytial virus (RSV), adenovirus, herpes simplex virus (HSV) and enteroviruses. In this study, 54 patients (10.8%) had positive viral throat cultures. Of these, 27 (50%) were influenza B and 3 (5.6%) were influenza A. The findings from this study suggest a high incidence of influenza as a cause of upper respiratory tract infection among pilgrims (2). So, vaccine against influenza should be considered for pilgrims before entry in to Saudi Arabia (3). Ministry of health, Kingdom of Saudi Arabia, also recommends all countries to use influenza vaccine, especially for high risk people like the elderly, diabetics and patients of renal failure, hepatic failure, cardiac failure and chronic respiratory diseases (4).

In this study we have determined influenza vaccine efficacy against clinically defined ILI among Iranian pilgrims attending the Hajj in the years 2003 and 2004, and we have compared the vaccine efficacy in these two years.

Received: 24 Nov. 2004, Revised: 29 Dec. 2004, Accepted: 9 Jan. 2005

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MATERIALS AND METHODS

This study was conducted on 32370 Iranian pilgrims who had participated in the annual Hajj in the year 2003 and 18730 pilgrims in the year 2004. It was implemented by a “nested case–control study” in the year 2003 and by a similar cohort in the year 2004 during Hajj ceremonies.

We compared cases vaccinated against influenza virus and unvaccinated ones in relation to respiratory involvement. Our operational definition for respiratory involvement was presence of sore throat, fevers over 38°C and acute and tormenting cough with or without coryzal symptoms and myalgia.

For determination of vaccine efficacy we used “1-odd's ratio” formula and for statistical analysis we have applied SPSS software version 10. There was no ethical limitation in our study.

RESULTS

The total number of Iranian pilgrims was 91883 in the year 2003 and 92192 in the year 2004. The understudied population in the year 2003 were 32370 (35.96%) who were selected from 180 large groups (caravans) and in the year 2004 were 18730 (20.3%) from 110 caravan. The total vaccinated cases against influenza virus in the year 2003 were 3465 (10.7%) and in the year 2004 were 14100 (75.2%). Table 1 shows the frequencies of vaccinated and unvaccinated pilgrims according to suffering or non-suffering to ILI, in the years 2003 and 2004. In the year 2003, odd's ratio was 0.49 and vaccine efficacy (1-OR) was 51% (*P* value < 0.001 and confidence interval 95%). According to above statistical

findings, the vaccine efficacy for ILI prevention in the year 2003 was 51%.

In the year 2004, odd's ratio was determined as 1.14 and vaccine efficacy for ILI prevention was -0.14 which means vaccine has not been efficient.

DISCUSSION

In this study we have determined Influenza vaccine efficacy against clinically defined ILI among Iranian pilgrims attending the Hajj in the years 2003 and 2004. Vaccine efficacy in the year 2003 was about 51%, but it was not efficient in the year 2004. There is not any unique cause for pilgrim's respiratory involvement in Hajj season. In one study, 500 Hajj pilgrims presenting with upper respiratory tract symptoms from different parts of the world were screened by way of a throat swab for viral culture, including 7 types of viruses, among them influenza virus type A and B. The findings from this study suggest a high incidence of influenza as a cause of upper respiratory tract infection among pilgrims (2). In addition to viruses, other probable causes of respiratory involvement are bacterial agents, allergens, toxins, chronic respiratory diseases and mycotic agents (7). Balkhy *et al.* showed that only 10.8% of the causes of common respiratory disease in Hajj are respiratory viruses (2). EL-Sheikh and co-workers showed that 19.5% of the causes of disease are viruses and bacterial pathogens can be detected in 29.9% of specimens (6). Wilder-Smith *et al.* suggest that pertussis has a high incidence among Hajj pilgrims (1). Till now, there is not any study in the literatures to explain allergens, toxins or fungi as the sources of the disease.

Table 1: Distribution of respiratory involvement according to influenza vaccination among Iranian pilgrims in Hajj ceremonies in the years 2003 and 2004*

Vaccination Status	Year 2003†			Year 2004		
	Diseased	Not diseased	Total	Diseased	Not diseased	Total
Vaccinated	1939 (55.95)	1526 (44.5)	3465 (10.7)	5150 (36.5)	8950 (63.5)	14100 (75.2)
Unvaccinated	20769 (71.85)	8136 (28.15)	28905 (89.3)	1552 (33.5)	3078 (66.5)	4630 (24.8)
Total	22708 (70.15)	9662 (29.85)	32370 (100)	6702 (35.8)	12028 (64.2)	18730 (100)

* Data are given as number (percent).

† P=0.001, confidence interval 95%.

Our study shows that in the year 2003, the cause of at least a part of the ILI among Iranian pilgrims has been influenza virus; therefore, the flu-vaccine was partially efficient. Since vaccine was not efficient in the year 2004, the major cause of the disease could not be influenza virus. Considering prevailing signs and symptoms in the patients, it can be suggested that other causes such as adenoviruses, allergens and toxins should be considered as etiologic agents. This study concluded that we should investigate etiologic agents other than influenza virus, especially bacterial infections superimposed on allergic or toxic conditions or on chronic respiratory diseases.

Acknowledgement

The authors wish to thank all of the physicians who cooperated in monitoring the pilgrims and dear collaborators, Dr. Ziaee, Dr. Nejat, Dr. Sadeghipoor, Dr. Taammoly and all of the health workers in Hajj pilgrimage medical team in I.R.O.I.

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