ANALYSIS OF ADVERSE EVENTS REPORTED FOLLOWING SINGLE DOSE MONOVALENT H1N1 (SWINE FLU) VACCINE

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ABSTRACT

Objective: *To identify the adverse events reported following monovalent single dose intramuscular Swine Flu Vaccine within a period of 6 weeks after vaccination.*

Methodology: *This descriptive study was conducted from November 2010 to January 2011 in Lady Reading Hospital Peshawar, a 1400 bedded, tertiary care hospital, where single dose monovalent swine flu vaccine was available free of cost. Recipients were all healthy hospital employees, above 18 years of age. A printed proforma was designed, in which adverse events were recorded (either by telephone or personal appearance) after 24 hours, 1 week and then after 6 weeks. Informed consent was taken before vaccine administration. The study was approved by the ethical review committee of the institution.*

Results: *Seven hundred and ninety two individuals were included in the study with mean age of 27.67 (SD=10.7). Males were 52.3% while the rest were female. Two hundred and fifty (31.6%) were students, 214 (27%) were paramedical staff, 153 (19.3%) were doctors, 139 (17.6%) were nursing staff, while 19 (2.4%) were senior teaching staff. After 24 hours of vaccination, redness at injection site was found in 36 (4.5%), soreness in 29 (3.7%), and itching in 23 (2.9%), headache in 66 (8.3%), nausea in 35 (4.4%), fever in 21 (2.7%), dizziness in 6 (0.8%), and muscle aches in 1 (0.1%). After 7 days, only 3 (0.4%) individuals had soreness and tenderness at injection site, 2 (0.3%) had fatigue, 4 (0.5%) had fever and 2 (0.3%) had dizziness. After 6 weeks, no local or systemic adverse events were noted.*

Conclusion: *swine flu vaccine causes minor local or systemic side-effects in the form of pain, headache, fever, and fatigue in the first 24 hours of administration, and is free of short term and serious adverse events.*

Key Words: *Swine flu, Vaccine, Adverse events*

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INTRODUCTION

According to World Health Organization statistics, from April 2009 to August 2010, more than 214 countries reported confirmed cases of pandemic influenza 2009 H1N1, with over 18,449 deaths[1]. Although the pandemic officially ended in August 2010, the virus was detected in 13.4% of the specimens tested in the United States during season 2010-11. It is likely that the same virus will cause epidemics and pandemics in future years[2]. Vaccination typically represents the major tool to reduce morbidity and mortality of influenza pandemics. Extraordinary efforts were devoted to the development of H1N1 vaccine worldwide.

Influenza A (H1N1) 2009 Monovalent Vaccine is an inactivated influenza virus vaccine indicated for active immunization of persons 4 years of age and older against influenza disease caused by pandemic (H1N1) 2009 virus[3]. Influenza A (H1N1) 2009 Monovalent Vaccine, a sterile suspension for intramuscular injection, is supplied in prefilled single dose syringe, 0.5-mL. The most frequently reported adverse reactions which have been reported in international literature are mild hypersensitivity reactions (such as rash), local reactions at the injection site, and influenza-like

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symptoms[4]. This vaccine has been reported to be free of serious adverse events including Guillain Barre` syndrome[5]. It does not produce swine flu, because the virus in the vaccine is killed.

The aim of this study was to find out the types and frequency of different adverse events after the use of Influenza A (H1N1) 2009 Monovalent Vaccine in the population of Khyber Pukhtunkhwa.

METHODOLOGY

This is a descriptive study which was started in Lady Reading hospital Peshawar in November 2010 and was stopped in January 2011. This vaccine was recently provided by World Health Organization to the Health department of our Province, who provided about 1000 doses to Lady Reading Hospital in September 2010, and the vaccination program was started in October 2010.The purpose of administration of this vaccine was to provide protection to the hospital employees due to the fear of spread of swine flu (where a recent global outbreak was observed). Only hospital employees were included in the study, because they were easily followed up for up to 6 months. People with co-morbidities like Diabetes and other chronic illnesses were excluded. All the employees who had received the vaccine were followed for 6 weeks for adverse events. The adverse events were documented on a Proforma (via telephonic contacts and direct face to face meetings) mentioning the events within 24 hours of administration of vaccine, after 1 week, and then after 6 weeks. The study population was followed for further 6 months. The data was analyzed on SPSS version 10.

RESULTS

Seven hundred and ninety two individuals were included in the study, with mean age of 29 years, (age range=16-60 years, SD=10.7, Median=26, Mode=21.6, Standard Error=1.5, and Variance=114.7). The results show that the 52.3 % of the study population were males, while 47.7% were females. Details of professional status of individuals are shown in Table 1. All the hospital employees were represented in the study. Most of the adverse events were observed within 24 hours. No adverse events were reported by 6 weeks of follow up. The nature and frequency of adverse events reported after 24 hours, one week, and then after 6 weeks are shown in Table 2. It is important to mention that no adverse events were reported after 6 weeks.

Table 1: Professional status of study population

S. No	Profession	Number of participants	Percentage
1	Students	250	31.6
2	Paramedical staff	214	27
3	Doctors	153	19.4
4	Nurses	156	19.7
5	Senior Teaching staff	19	2.4
Total		792	100

Table 2: Frequencies of adverse events

Adverse events	Local redness	Soreness and tenderness	Itching	Headache	Nausea	fever	dizziness	Muscle aches	fatigue
Within 24 hours	4.5%	3.7%	2.9%	8.3%	4.4%	2.7%	0.8%	0.1%	None
One week	None	0.4%	None	None	None	0.3%	None	None	0.5%
Six weeks	None	None	None	None	None	None	None	None	None

DISCUSSION

Influenza vaccination is recommended as the primary prevention measure against Swine flu infection, and health care workers are often one of the groups targeted to receive vaccine not only for their direct protection but also to indirectly protect vulnerable patients against nosocomial infection[6]. Influenza-associated morbidity and mortality increases with age, especially for an individual with high-risk conditions and it has been shown that influenza vaccination is associated with a reduced risk of morbidity and mortality[7].

We have summarized the adverse events of 792 hospital employees who received H1N1 vaccine in this study. The adverse events reported were seen in about 8% of individuals in the first 24 hours, and 1% in the first week. These were very mild and non-serious. Recently, a multicenter study conducted in china on the above mentioned vaccine revealed similar results as ours[8]. Most vaccine reactions occurred within 1 day after vaccination; few cases occurred more than 5 days after vaccination.

The influenza A (H1N1) vaccine recipients included students, nurses, doctors and other health care providers. These groups tend to be healthier and have greater access to health care. Also, since the vaccine studied was new, the recipients may have been more likely to report adverse events, especially soon after vaccination. Concern about vaccine safety tends to diminish over the period of vaccine use, as reflected by the decline in the rate of non-serious adverse events reported over the study period. The overall rate of reported adverse events in this study is similar to the rate reported in the United States after 82.4 million doses of the influenza A (H1N1) vaccine were administered[9]. A meta-analysis of 18 randomized controlled trials was conducted and presented in the online journal, Public Library of Science in 2011[10]. The finding of our study regarding the safety are comparable to the findings of this meta-analysis, where most of the adverse effects occurred in the first week and consisted of fever, myalgias and soreness at injection site.

There has been a concern regarding the development of Guillain Barre Syndrome after the use of H1N1 vaccination, but a study conducted in 5 countries in Europe revealed no evidence of increased risk for this condition[11]. A similar study conducted in Denmark reported no major and serious adverse event in 0.3 million population vaccinated[12]. Our study is not as large as the other studies mentioned, but we did not observe a single such case in our study. This is a small but first study of this kind in our country on H1N1 vaccine. Most of the studies conducted around the world revealed no evidence of a link to major and serious adverse events due to H1N1 vaccine.

CONCLUSION

It is a small study of this kind to find out the safety and adverse events related to this vaccine in a tertiary care hospital setting. These findings suggest that the monovalent single dose H1N1 vaccine has a reasonable safety profile, and there is no evidence that the vaccine is associated with an increased risk of serious adverse events like Guillain–Barré syndrome. More studies are needed for the immunogenicity and long-term adverse effects related to this single dose intramuscular H1N1 vaccine in our country.

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CONTRIBUTORS

FA designed the main theme, actively conducted research and wrote the manuscript. AR did the data collection & compilation of results. FM & NM helped in the data collection & vaccine administration. All the authors contributed significantly to the research that resulted in the submitted manuscript.