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Influenza vaccination and risk of hospitalization among adults with laboratory confirmed influenza illness☆

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ABSTRACT

Background: Influenza vaccine is moderately effective for preventing influenza illness. It is not known if vaccination reduces the risk of subsequent hospital admission among patients with vaccine failure and laboratory confirmed influenza illness.
Methods: Patients in a community cohort presenting with acute respiratory illness were prospectively enrolled and tested for influenza during 8 seasons to estimate seasonal vaccine effectiveness. Hospital admissions within 14 days after illness onset were identified for all participants aged ≥20 years with laboratory confirmed influenza. The association between vaccination and hospital admission was examined in a propensity score adjusted logistic regression model. The model was validated by examining the association between vaccination and hospital admission in participants without influenza.
Results: Influenza was identified in 1393 (28%) of 4996 participants. Sixty-two (6%) of 1020 with influenza A and 17 (5%) of 369 with influenza B were hospitalized. Vaccination was not associated with a reduced risk of hospital admission among all participants with influenza [adjusted odds ratio (aOR) = 1.08; 95% CI: 0.62, 1.88]; or among those with influenza A (aOR = 1.35; 95% CI: 0.71, 2.57) or influenza B (aOR = 0.67; 95% CI: 0.21, 2.15). Influenza vaccination was not associated with hospitalization after non-influenza respiratory illness (aOR = 1.14; 95% CI: 0.84, 1.54).
Conclusions: Influenza vaccination did not reduce the risk of subsequent hospital admission among patients with vaccine failure. These findings do not support the hypothesis that vaccination mitigates influenza illness severity.

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1. Introduction

Influenza is an important cause of death and serious illness, particularly among adults aged ≥65 years and those with certain underlying chronic conditions. In the United States, approximately 226,000 hospital admissions are attributed to influenza each year [1]. As a result, annual influenza vaccination is recommended for all persons aged ≥6 months to prevent seasonal influenza infection and its complications [2]. However, influenza vaccine failure is common even during seasons with optimal antigenic match between circulating and vaccine viruses. Among adults, vaccine efficacy in preventing laboratory confirmed influenza illness is estimated to be approximately 60% [3]. Similar efficacy has been reported for preventing hospital admission with laboratory confirmed pandemic or seasonal influenza [4–10]. It is not clear if influenza vaccination prevents serious outcomes by primary prevention of influenza infection, by reducing severity of influenza illness, or both.

We conducted a population based study of laboratory confirmed influenza among adults aged ≥20 years over multiple seasons to determine if receipt of same-season influenza vaccine was associated with reduced risk of hospital admission within 14 days after onset of influenza illness.

2. Methods

2.1. Study population and design

This was a secondary analysis of data from population-based studies of influenza vaccine effectiveness during eight influenza seasons, 2004–05 through 2012–13, in Marshfield, Wisconsin [11–14]. In this community, residents receive nearly all outpatient and inpatient care from the Marshfield Clinic. A single acute care hospital (St. Joseph's) serves the study population, and both inpatient and outpatient diagnoses are accessible through a combined electronic medical record. The electronic medical record captures

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90% of outpatient visits, 95% of hospital discharges, and 99% of deaths for the residents in the area [15–18].

During each influenza season, eligible community dwelling residents were recruited by trained research coordinators during or after an inpatient or outpatient medical encounter for acute respiratory illness. Research coordinators used an electronic appointment system to identify and recruit eligible persons in all primary care clinics and in urgent care on weekdays, evenings, and weekends. Eligible persons were also recruited at the hospital that is contiguous with Marshfield Clinic. Most ill persons who were not approached during a clinical encounter were identified on the following day by use of electronic diagnosis codes entered by attending physicians (ICD-9-CM codes 382.0, 382.4, 382.9, 460–466, 480, 483–486, 487, 490, 780.6, and 786.2). These individuals were contacted by telephone, and a swab sample was obtained at home from those who were eligible and consented.

Participants completed a short interview to assess illness symptoms and onset date; nasopharyngeal swabs were obtained for influenza testing. Real-time reverse transcription polymerase chain reaction (RT-PCR) and viral cultures were performed at the Marshfield Clinic Research Foundation as previously described [11]. Culture alone was performed on samples collected in 2004–05 and RT-PCR was performed in subsequent years. Subtype results based on RT-PCR were not available for 11% of influenza A positive samples. For those samples, the subtype was assumed to be the predominant subtype identified among study participants during that season. This analysis excluded the 2009–10 season because monovalent vaccine was not available to the local population when the pandemic wave arrived in October–November 2009, and influenza was absent from the study population in the subsequent winter months.

2.2. Influenza vaccination status

Influenza vaccination status was determined by a real-time, internet-based vaccination registry used by all public and private vaccination providers serving the population (http://www.recin.org). A validation study of the registry during the 2006–07 and 2007–08 influenza seasons demonstrated that the registry captured 95% of all influenza vaccinations that were received by study participants [19]. A similar high level of capture was demonstrated in a validation study during the 2011–12 season (unpublished data). Adults were classified as vaccinated if they had received influenza vaccine $\geq$14 days before the onset of illness.

2.3. Ascertainment of hospital admissions and clinical history

Dates of hospital admission and discharge diagnoses were identified from the electronic medical record for a 14 day period after onset of influenza illness. To adjust for use of antiviral drugs, we extracted dates of antiviral prescriptions for all participants.

2.4. Outcome and covariates

The main outcome was an acute care hospital admission occurring within 14 days of influenza symptom onset. Although most hospital admissions occurred after an outpatient enrollment, some participants were initially enrolled and swabbed after admission to the hospital. Covariates included age, gender, antiviral prescription, specific high risk medical conditions, year, and influenza type/subtype [A/H3N2, A/H1N1, pandemic H1N1 (A/H1N1pdm09), B]. Study participants were classified as having a high risk medical condition if they had at least one visit during a recent 12 month period with an ICD-9 CM diagnosis code of interest. High risk conditions were classified into the following groups: cancer, cardiovascular disease, diabetes, pulmonary, and other.

Antiviral prescription was defined as a prescription of oseltamivir, zanamivir, amantadine, or rimantadine within 14 days of symptom onset for persons not hospitalized and between symptom onset and hospital admission for persons who were hospitalized.

2.5. Analyses

We restricted the analysis of hospital admissions to enrolled adults aged $\geq$20 years because influenza-related hospitalization was less common in children, and potential confounding factors are likely to be different for adults and children.

Studies of influenza vaccination and hospital admission are particularly susceptible to confounding, since persons who are vaccinated may be more likely to have pre-existing chronic medical conditions or other risk factors for hospital admission. To minimize confounding by indication for vaccination, we used a propensity score regression adjustment [20,21]. Propensity scores allow adjustment for multiple potential confounders when the data are too sparse to include a separate effect for each potential confounder in the regression model. The propensity scores were generated from a multivariable logistic regression model that assessed the probability of influenza vaccination as a function of the potential confounders. In the propensity model, the dependent variable was influenza vaccination status and the independent variables were potential confounders identified a priori. The propensity score covariates included age, gender, cancer, cardiovascular disease, diabetes, pulmonary disorders, other high risk conditions, and year. The propensity scores from the model were then included as a continuous variable in the final logistic regression model that assessed the association between influenza vaccination and hospital admission.

To determine the effect of influenza vaccination among persons with laboratory confirmed influenza, the final logistic regression model predicting hospital admission included the following covariates: propensity score, influenza vaccination, age group, influenza type/subtype, receipt of antiviral drug prescription. The primary analysis included all study participants with laboratory confirmed influenza. Secondary analyses included subgroups based on influenza type (A or B). We excluded the small number of participants with both A and B infection because the risk of hospitalization may be different for those co infected with both types and persons with unknown vaccination status.

Since the primary outcome included all hospital admissions during a 14 day period, we performed a secondary analysis restricted to hospital admissions that were directly related to influenza infection. These included individuals who received any discharge diagnosis (among the top three diagnosis codes) for influenza, pneumonia, bronchitis, exacerbation of chronic pulmonary disease, or acute respiratory infection. In addition, one individual with a discharge diagnosis of fever was included in this group because symptoms of influenza like illness were present at the time of admission. We also performed an analysis restricted to persons who were enrolled in the outpatient setting and subsequently admitted to the hospital.

Finally, we evaluated residual confounding by examining the association between influenza vaccination and hospital admission among study participants with a negative influenza test in a logistic regression model. The propensity scores for study participants with a negative influenza test (i.e., non-influenza respiratory illness) were generated using the same method as described above. If the propensity scores adequately adjusted for confounding, there should be no association between influenza vaccine receipt and hospital admission in that group. We assumed that confounders would be the same for influenza negative and influenza positive study participants.

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