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How to cite

GONZALEZ, Amanda et al. Influenza vaccination is not associated with increased number of visits for shoulder pain. In: Clinical orthopaedics and related research, 2020, vol. 478, n° 10, p. 2343–2348. doi: 10.1097/CORR.0000000000001215

This publication URL: https://archive-ouverte.unige.ch/unige:176960

Publication DOI: 10.1097/CORR.0000000000001215

Clin Orthop Relat Res (2020) 478:2343-2348
DOI 10.1097/CORR.0000000000001215

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

Clinical Research

Influenza Vaccination Is Not Associated with Increased Number of Visits for Shoulder Pain

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Received: 28 October 2019 / Accepted: 21 February 2020 / Published online: 2 March 2020

Abstract

Background Shoulder injury from vaccination was approved for automatic compensation from the Vaccine Injury Compensation Program (VICP)—a federal government program started in 1988 to shield the manufacturers of childhood vaccines from liability. The approval was made on the basis of case reports rather than experimental evidence. This, combined with the addition of influenza vaccination to the VICP in 2005 (which broadened coverage to include adults) and other social factors, was associated with a rapid rise in the number of claims of shoulder injury from vaccination over the last decade, which now account for more than half of all claims to the VICP. Given the high prevalence of newly symptomatic sources of shoulder pain such as rotator cuff tendinopathy, combined with the high prevalence of annual influenza vaccinations, there is a substantial risk of overlap leading to the post hoc ergo propter hoc fallacy ("after this, therefore because of this") contributing to misdiagnosis and inappropriate management of patients that perceive injury from vaccination. Records of medical care after a large number of vaccinations have a good chance of detecting serious shoulder pathology, even it is uncommon, which would result in an increased prevalence of visits for shoulder problems and specific types of shoulder pathology.

Questions/purposes Is there a difference in the proportion of visits for shoulder pain within 3 months before and after vaccination among students and faculty receiving an influenza vaccination in the shoulder?

Methods We studied people who were vaccinated for influenza between 2009 and 2018 at a university health service. During the study period, a comprehensive billing database identified 24,206 influenza vaccinations administered to 12,870 people (median age 20 years, range 16-77; 57% women). We had 80% power to detect a 0.1% increase in the proportion of shoulder problems after vaccination compared with before vaccination. Visits with coded ICD-9 shoulder diagnoses were identified from the electronic medical record. We compared the proportion of shoulder evaluations within 3 months before and 3 months after vaccination.

Results With the numbers available, the proportion of visits for shoulder problems were not different before (1.1% [52 of 4801]) and after vaccination (1% [40 of 3977],

One of the authors certifies that he (DR) has received or may receive payments or benefits during the study period in an amount of between USD 10,000 and 100,000 for expert witness services for the Health Resources and Service Administration (Washington, DC, USA). Each of the remaining authors (AG, MM, JK) certify that neither he or she, nor any member of his or her immediate family, have funding or commercial associations (consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.
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risk ratio 1.1 [95% CI 0.8 to 1.5]; p = 0.72). Among all vaccinations, 49% (11,834 of 24,206) were preceded or followed by an appointment within 3 months before (20% [4801 of 24,206]), after (16% [3977]), or both before and after (13% [3056]) vaccine administration, and 1.4% (170) of these visits were related to a shoulder issue. The most common reason for shoulder-related appointments was atraumatic shoulder pain (79% [134 of 170]).

Conclusions Shoulder symptoms sufficient to seek care are notably common, even among relatively young adults, and are not more common after vaccination. Although this does not rule out an important rare pathology specific to vaccination, it seems important to consider the potential harms of assuming, based largely on chronology, that persistent shoulder pain after vaccination—something expected to be common based merely on the anticipated frequency of overlap of vaccination and common shoulder problems—represents harm from vaccine.

Level of Evidence Level III, therapeutic study.

Introduction

The U.S. federal government instituted the Vaccine Injury Compensation Program (VICP) in 1988 to shield vaccine manufacturers from liability when concerns related to febrile seizures associated with diphtheria vaccination were motivating manufacturers to stop making vaccine [15]. VICP is a no-fault alternative to the traditional legal system for resolving petitions about vaccine injuries and is administered by the Health Resources and Services Administration of the United States Department of Health and Human Services, Department of Justice, and Court of Federal Claims. It covers all vaccinations recommended by the CDC for routine use in children and pregnant women [9].

Seventy-five cents from the payment for every vaccination contributes to a fund to cover liability claims [15]. Since the 2010 to 2011 influenza season, the CDC has recommended an annual influenza vaccination for every individual 6 months or older, thereby making seasonal influenza vaccines eligible for compensation by the VICP and allowing adults to file claims [8]. Adult claims of shoulder injury after vaccination were made shortly thereafter. Clinician-reviewers at the Health Resources and Services Administration noted this and described 13 adults with common shoulder conditions, such as rotator cuff tendinopathy and adhesive capsulitis, that they felt were related to vaccination [2]. These observations seemed to legitimize such claims beyond what the scientific evidence supports, as did introduction of the acronym SIRVA (shoulder injury after vaccine administration) [17]. The National Academy of Medicine reviewed vaccine safety in 2011 and, despite reassuring data from postmarket surveillance of hepatitis A vaccinations [6], it interpreted a few case reports and case series as establishing a connection between vaccination and deltoid bursitis [13], a diagnosis that musculoskeletal experts do not use. In another well-intended maneuver—although insufficiently grounded in evidence and insufficiently attentive to the degree to which concepts can cause illness [3]—persistent shoulder pain after vaccination was added to the Vaccine Injury Table, a list of illnesses that are pre-approved for compensation in 2017 [10]. There is a rising prevalence of injury claims because of shoulder vaccination at the VICP [4], with 54% (671 of 1238) of the claims filed in 2018 addressing shoulder pain.

We believe that most orthopaedic surgeons are not aware of these developments. Awareness is growing as orthopaedic surgeons are increasingly asked to provide expert review of claims to the VICP. The Patient Safety Committee of the American Academy of Orthopaedic Surgeons reviewed the issue and raised a concern about potential harm to individuals and society based on the scientifically unsupported concept that vaccinations may harm the shoulder [1]. A study in which vaccine was intentionally injected into human joints documented no harm [18]. Another study documented no difference in the rate of visits for bone and joint problems before and after hepatitis A vaccination at the shoulder [6]. There are case reports describing persistent pain after vaccination, and most people described have common shoulder pathologies such as rotator cuff tendinopathy or adhesive capsulitis [2] for which the probability of overlap without causal association is high. Most VICP claims related to the shoulder are for these common shoulder conditions [11]. No issues are seen in children, even though their small size theoretically puts them at greater risk. In addition, injury claims are not prevalent in other countries where there is no compensation.

It is difficult to rule out an uncommon serious event at the shoulder after vaccination. The most evocative case documented chondral pathology and synovitis, but the patient had a prior shoulder dislocation and subsequent surgery that might account for the observed pathophysiology [16]. A better understanding of suspected shoulder injury from vaccination will help: Either by clearly defining the problem and its solutions (such as when it was discovered that peptic ulcer disease was due to infection by *Helicobacter pylori* and antibiotics proved beneficial) or by identifying that all or most of these claims are better explained by coincidence. Plausibility alone is insufficient to establish a link and indeed is often the basis for a false link [5].

A study of the postmarket surveillance of hepatitis A vaccinations found no differences in visits for bone and joint pain before and after vaccination among a cohort of 49,932 vaccinations [6]. At our state university, which has one of the largest student populations in the United States, a large number of vaccinations are performed; this provided an opportunity to repeat this experiment looking

specifically at visits related to shoulder problems and addressing influenza vaccine in particular.

With these data, we asked: Is there a difference in the proportion of visits for shoulder pain within 3 months between before and after vaccination among students and faculty receiving an influenza vaccination in the shoulder?

Patients and Methods

Study Design

After institutional review board approval of this study, we performed a retrospective study of all students and faculty receiving influenza vaccinations at University Health Services at the University of Texas at Austin between October 1, 2009 and December 31, 2018.

Outcome Measures

For each vaccination, using the electronic medical record, we identified people receiving an influenza vaccination. We also recorded demographic variables including the patient's gender and age at the time of vaccination, visits within 3 months before and 3 months after vaccination. We identified shoulder problems during these visit using ICD-9 codes. We did not distinguish care for the immunized compared with the nonimmunized shoulder.

To confirm that no shoulder problems were overlooked and to identify more details about the shoulder problem than are available in the ICD-9 coding system, we retrieved information from the diagnosis and reason-for-appointment fields of the electronic medical record, and searched for the following keywords: shoulder, scapula, rotator cuff, and impingement, and we classified the problem as fracture or dislocation; other shoulder injury, including fall, contusion, and abrasion; and other shoulder issues, including rotator cuff tendinopathy, shoulder instability, shoulder pain, and nonspecific shoulder problems.

Because the influenza vaccination is a seasonal vaccination administered annually, vaccinations might have been administered more than once to the same patient during the study period. To account for this, we calculated the total number of vaccinations administered during the study period for each patient.

Patients Characteristics

During the study period, 24,206 influenza vaccinations were administered to 12,870 people. The mean (range) age of patients in the cohort was 20 years (interquartile range 19 to 23), and 57% were women (Table 1). Among the 12,870 participants, 4641 received more than one vaccination during the study period.

Statistical Analysis

Continuous variables are reported as the mean and SD or as the median and interquartile range when non-normally distributed, and discrete variables are reported as proportions.

The risk of any appointment within 3 months before or after the vaccination date was calculated. To assess the association between having a shoulder-related appointment and an influenza vaccination, we calculated the proportion of shoulder-related appointments in the group with visits before vaccination only and compared this with the proportion in the group with visits after vaccination only; then, we generated a risk ratio. We had 80% power to detect a 0.1% increase in the proportion of shoulder problems after vaccination compared with before vaccination.

Results

The proportions of visits for shoulder problems were no different before (1.1% [52 of 4801 visits]) and after vaccination (1% [40 of 3977 visits], risk ratio 1.1 [95% CI 0.8 to 1.5]; $p = 0.72$) with the number of vaccination events available (Table 2). Among all vaccinations, 49% (11,834 of 24,206) were preceded or followed by an appointment within 3 months before (20% [4801 of 24,206]), after (16% [3977 of 24,206]), or both before and after (13% [3056 of 24,206]) vaccine administration, and 1.4% (170 of 11,834) of these visits were related to a shoulder issue (Table 2). The most prevalent reason for shoulder-related appointments was atraumatic shoulder pain (79% [134 of 170 visits]), and fracture or dislocation and other shoulder injuries accounted for 12% (21 of 170) and 9% (15 of 170), respectively (Table 3). When only patients with one vaccination during the study period were included (see Appendix Table 1, Supplemental Digital Content 1, http://links.lww.com/CORR/A319), the results remained unchanged (see Appendix Table 2, Supplemental Digital Content 2, http://links.lww.com/CORR/A320).

Discussion

Claims of a causal association between vaccination and injury should be supported by scientific experimental evidence to avoid creating or reinforcing ideas that lead to or worsen illness. Nonexperimental reports of a perceived association between vaccination and injury may have

Table 1. People who received influenza vaccine in the shoulder

Variable	Number, % (total vaccinations = 24,206)
Age (years)	Median 20 (IQR 19-23)
Women	57 (13,807)
Appointment within 3 months of vaccination	
No	51 (12,372)
Yes	49 (11,834)
Before vaccination only	20 (4801)
After vaccination only	16 (3977)
Before and after vaccination	13 (3056)

IQR = interquartile range.

created the idea that vaccination may harm the shoulder [2, 7]. The experimental evidence on this topic, including a study in which a vaccine was intentionally injected into joints [18] and a postmarket surveillance of hepatitis A vaccination [6], is limited but reassuring. More evidence is needed, which is what prompted this analysis of shoulder symptoms before and after influenza vaccinations in which we looked for an increase in the proportion of shoulder problems after vaccination. In this analysis of 24,206 vaccinations into the shoulder, visits for shoulder problems were no more common after vaccination than before, and no potential harm to the shoulder was identified.

This study has some limitations. One of the authors became aware of the idea of shoulder injury from vaccination when contacted by a reviewer for the VICP. The authors reviewed 16 claims for VICP on behalf of the Health Resources and Services Administration and the Department of Justice as this was the only way to learn about the nature of such claims in detail. To review these claims, the author had to become a government contractor and be paid for his services. This study cannot identify all potential rare, serious events. It does, however, set the probability of such an event as much lower than the probability of coincident, newly symptomatic common shoulder pathologies such as rotator cuff tendinopathy. Some of the shoulder-related visits may have been for the opposite shoulder. That, if anything, would decrease the already low rate of shoulder symptoms in the vaccinated shoulder. Although the number of total vaccinations is high, the percentage of the total number of students, staff, and faculty receiving vaccinations at the university health service is relatively low. We are likely studying the subset of patients who regularly use the university health service for other aspects of their care, which increases the likelihood that they would seek care for subsequent problems at the place they received the injection. We studied young people, with a median age of 20, which limits the generalizability of our findings. However, this may be an advantage when looking for harm from vaccination because if a vaccine injures the shoulder, it will do so at any age. On the contrary, the more likely scenario—that common, often age-related conditions become symptomatic after vaccination—would be less prevalent, making it easier to detect a relative increase in shoulder problems. Nevertheless, the findings of this study are best applied to relatively young adults.

Table 2. Proportion of shoulder-related appointments

Events	Before vaccination (n = 4801)	After vaccination (n = 3977)	Risk ratio (95% CI)
Percent of shoulder-related appointments (n)	1.1 (52)	1.0 (40)	1.1 (0.8 to 1.5)

The observation that visits to a university health service are just as common after influenza vaccination as before, and relatively common overall (1% of all visits) supports the concept that the probability of shoulder symptoms being mistakenly ascribed to shoulder damage from vaccination is greater than the probability of a rare serious problem related to vaccination. These findings are consistent with those of the large postmarket surveillance of hepatitis A vaccination [6] described above, and consistent with the results of a study of intentional intra-articular vaccine administration that documented no harm in the brief evaluation period [18]. The human mind is designed to form patterns and rationalize, and resulting cognitive biases and cognitive errors must be considered [19]. Given the prevalence of shoulder symptoms and shoulder pathology, it will be difficult to distinguish a rare, serious, specific vaccine-related pathophysiology from the expected high chance frequency of overlap of new symptoms from established problems and vaccination. A recent review of uncontested claims to the VICP identified common age-appropriate shoulder pathology with most claimants in the age-range for expected pathologies [11]. Another recent review of reports to the CDC's voluntary reporting site had similar findings [12]. And a recent case report and review of published cases documented pathology indistinguishable from what would be commonly expected in most people presenting to a specialist with shoulder pain [14]. It may be best to consider only distinct, vaccine-specific pathophysiology as potentially related.

We found that shoulder health is similar before and after influenza vaccination and that shoulder symptoms are relatively common with or without vaccination. Among 24,206 vaccinations, no serious injuries related to vaccination were documented. People with new shoulder pain were likely to

Table 3. Visits for shoulder pain before and after vaccination

Variable	All patients (n = 170)	Shoulder problem (n = 170)		
		Fracture or dislocation (n = 21)	Other shoulder injury (n = 15)	Atraumatic shoulder pain (n = 134)
Age (years)	21 (20-26)	20 (18-23)	21 (19-27)	22 (20-27)
Women, % (n)	39 (66)	33 (7)	40 (6)	40 (53)
Appointment within 3 months before or after vaccination				
Before vaccination only, % (n)	31 (52)	14 (3)	33 (5)	33 (44)
After vaccination only, % (n)	24 (40)	38 (8)	20 (3)	22 (29)
Before and after vaccination, % (n)	46 (78)	48 (10)	47 (7)	46 (61)
Diagnosis				
Abrasion	3		3	
Acromioclavicular separation	4	4		
Clavicle fracture	3	3		
Contusion	1		1	
Shoulder dislocation or subluxation	14	14		
Fall or unspecified shoulder injury	13		13	
Shoulder instability	5			5
Shoulder pain	51			51
Rotator cuff tendinopathy	42			42
Scapula issue	20			20
Unspecified shoulder problem	16			16

Continuous variables are presented as the median (interquartile range); discrete variables are presented as the number (percentage).

wonder if they were injured and were likely to make connections with recent painful shoulder events such as vaccination. Clinicians can validate these concerns without agreeing that the shoulder is injured. If the pain is nonspecific or due to common shoulder pathologies such as rotator cuff tendinopathy or adhesive capsulitis, the most likely scenario is that these are related chronologically. It is not clear that vaccination leads to a serious and vaccine-specific pathophysiology, and if does so, it seems rare. Some unanswered questions remain, including how often does a vaccine get into the subacromial space through the subdeltoid space because of an unintentionally deep injection? Can a vaccine cause specific pathophysiology in this space that is distinct from common shoulder pathologies? If so, does that pathophysiology cause permanent damage to shoulder structures? And if so, can such pathology be reliably and accurately distinguished from common shoulder pathologies? If glenohumeral pathology is identified and the rotator cuff is intact, does that eliminate the vaccine as the cause of the problem? If inadvertent injection into the potential space between the deltoid and the humerus (the so-called deltoid bursa) occurs, does it always cause a vaccine-specific pathology or only in combination with other factors (such as genetic variations in the immune system)? Future studies could test the reliability of blinded observers distinguishing vaccine-specific pathology from common shoulder pathologies. Studies of even larger numbers of vaccinations may look at the amount of shoulder pain before and after injection, the types of pathologies identified, and whether or not there is a rare, vaccine-specific pathology that causes lasting harm to the shoulder. In the meantime, clinicians should understand that reinforcing unhealthy misconceptions such as pain represents damage or is something that needs to be repaired can cause psychological, financial, and iatrogenic harm [3]. There does not appear to be sufficient evidence to make persistent shoulder pain after vaccination automatically compensable at the VICP and that decision bears reconsideration.

Acknowledgments None.

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