Post-Immunization Arthropathy: The DoD Experience

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Background

- Case reports of post-immunization arthropathy are described in the literature. The etiology is believed to be inadvertent penetration of the shoulder bursa and/or capsule by vaccine antigen, which produces inflammation and injury in structures outside the deltoid. Subdeltoid or subacromial bursitis are the most frequently described pathologies, but other affected structures and diseases have been observed.
- Our purpose was to enhance current clinical knowledge, guide patient care, and support future scientific inquiry of this adverse event.

Methods

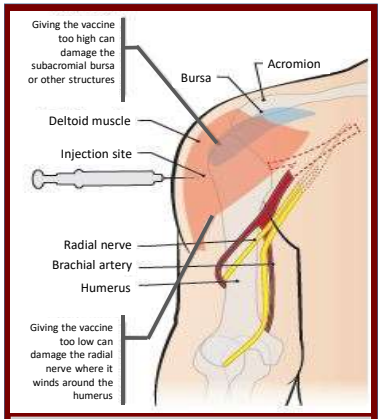
- We performed retrospective chart reviews of 52 cases from the DHA-IHD Vaccine Adverse Events Clinical System database.
- The cases were analyzed for trends in demographics, the immunization event, pain, functional impact, provider evaluation, injuries, treatment modalities and outcomes. MRIs in a subset of cases were reviewed by orthopedics. Appropriate non-parametric tests were applied by our statistician.
- The protocol was deemed exempt from IRB review by the Womack Army Medical Center Human Research Protections Office.

Results

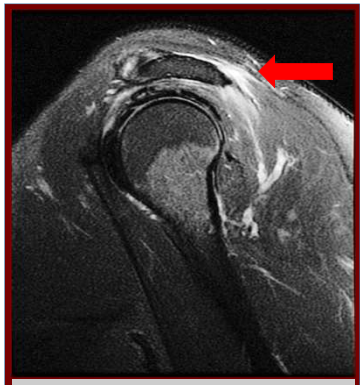
- The sample was nearly 70% Whites & women.
- Service Members accounted for 42%.
- Median BMI was 26.3; median age was 43 years.
- Ten IM vaccines were associated: 4 not previously reported.
- Vaccine administration error was present for 94% of cases.
- Pain was reported as severe by over 67% of patients; 23% were seen in emergency room or urgent care; 92% reported sleep disruption. Parasthesias symptoms were reported by 39%.
- MRIs in a subset of patients revealed 9 pathologies of 8 shoulder structures.
- The typical subdeltoid or subacromial bursitis was seen in 42% of cases but 92% had other pathologies as well.
- No injury was pattern associated with any particular vaccine.
- PT was provided for 64% but symptom duration was not decreased.
- Steroid injection was provided for 32%; 71% had pain relief, but symptom duration was not decreased; 41% had recurrences.
- The median time to functional resolution was 143 days.
- Surgical referral was provided for 7.6% of cases.

Table 1. Demographic Characteristics

Demographic	N	Statistic	p
Age (Median)	52	43.0 (QR:33.0, 55.5)	
BMI (Median)	50	26.3 (QR: 23.6, 28.9)	
Active Duty	22	42.3%	0.27
Non-Active Duty	30	57.7%	
Whites	36	69.2%	0.01
All Other Races	16	30.8%	
Women	35	67.3%	0.01
Men	17	32.7%	



Source: Australian Government Department of Health: Australian Immunization Handbook Avoiding shoulder injury related to vaccine administration. Used with permission.



Case series subject #12 : Sagittal T2 Fat Suppressed MRI of the shoulder showing posterior subdeltoid and subacromial bursitis (red arrow).

Image downloaded from IMPAX.

Conclusions

- **This is the largest DoD clinical case series to date describing this immunization related adverse event**
- **Active Duty Service Members were 42% of affected individuals**
- **Risk factors included Whites and women**
- **Low BMI was not a risk factor**
- **A spectrum of pathologies was observed**
- **The symptoms can be severe, prolonged and may impact medical readiness**
- **Neither PT nor steroid injection demonstrated a superior treatment pathway**
- **Vaccine administration error precipitated the majority of cases which can be mitigated through education**

ABBREVIATIONS: **Body Mass Index (BMI)** **Institutional Review Board (IRB)** **Magnetic Resonance Imaging (MRI)** **Intramuscular (IM)** **Defense Health Agency-Immunization Healthcare Division (DHA-IHD)**

Discussion

- Our cohort was 7-9 years younger than previously reported cases and lower BMI was not a risk factor. Whites and women demonstrated an increased risk. In women, we hypothesize this may be due to differences in muscle mass quantity, fat pad depth or increased sensitivity to antigen producing more inflammation.
- Ten vaccines were identified: 6 were previously reported (pneumococcal, influenza, tetanus, hepatitis A/B, IPV) & 4 newly seen (anthrax, typhoid, Japanese encephalitis & rabies). Influenza was the most commonly associated vaccine at 54%. It is unknown if this is related to frequency of use or an element specific to influenza vaccine. There are no common excipients or adjuvants to all 10 vaccines.
- Documentation of site placement or spatial vaccine administration error was identified in 94% of cases, supporting this vaccine associated adverse event is strongly associated with technique errors.
- The symptom severity was significant and supported by documentation of high pain scores, emergency room and urgent care use, functional loss, sleep disruption and prolonged symptom duration. These elements would all significantly affect readiness of the individual. Of note, only one Service Member received a profile.
- Parasthesias were a common confounding symptom complaint. We recommend electrodiagnostic studies for paresthesia symptoms, but orthopedic injuries should remain on the differential.
- Imaging identified a wide variety of affected structures and pathologies, with only 8% demonstrating solely the classic bursitis finding. We hypothesize there is a spectrum of possible injuries which may vary with the injury error mechanism, vaccine type or exacerbation of preexisting quiescent pathology.
- No best practice treatment pathway was identified. Neither physical therapy nor steroid injection decreased the time to functional resolution. Steroid injection provided symptom relief but 41% had recurrences.

Limitations

A number of significant limitations in this case series are worthy of note. Our sample sizes are small. We were limited to available documentation, which had no consistency. Cases were frequently not followed to resolution. Imaging cannot differentiate vaccine causality from other etiologies. We believe our convenience sample may overrepresent very severe cases and may underrepresent total cases.

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