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Incidence of Shoulder Pain After Covid Vaccination- an Observational Study

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Abstract

Background: COVID-19 vaccines are key to restoring normalcy after the global pandemic. However, improper injection techniques due to lack of clear instructions and inexperienced personnel can lead to issues like shoulder injury related to vaccine administration (SIRVA), causing shoulder pain and limited mobility. Ensuring correct administration is crucial for vaccine efficacy and patient well-being. The aim of this study was to determine the incidence of shoulder pain following COVID-19 vaccination on public health. **Material & Methods:** This was an observational study and was conducted in the Department of - Anaesthesia, Analgesia and Intensive care medicine of Bangabandhu Sheikh Mujib Medical University (BSSMU, Dhaka, Bangladesh during the period from February 2023 to January 2024. The study included 120 patients, male and female, focusing on Shoulder Injury Related to Vaccine Administration (SIRVA) after COVID-19 vaccination. Physician-evaluated cases were analyzed to minimize diagnostic errors, using a checklist for data extraction. **Results:** Patients (29.2% aged 63-72 years) predominantly received Pfizer and Moderna vaccines (80%). Common symptoms were bursitis (36%) and adhesive capsulitis (44%). Onset varied, with 35.2% reporting immediate symptoms, 40.8% within 24 hours. Pain was predominant (92%). X-ray (63.2%) and MRI (36.8%) used for diagnosis. Treatment included oral steroids (56%), physical therapy (16%), and NSAIDs (24%). **Conclusions:** The significance of accurate vaccine administration to avoid complications like SIRVA. Clear guidelines and trained personnel are essential for the success of the COVID-19 vaccination campaign, ensuring both efficacy and the well-being of individuals.

Keywords:- COVID-19, Vaccine, Shoulder Pain, SIRVA.

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INTRODUCTION

The COVID-19 epidemic has significantly impacted daily life around the globe. The COVID-19 vaccinations, which have been widely used for immunization from the beginning of 2021, have been one of the primary contributors in assisting the return to regular living activities.[1] COVID-19 vaccinations and boosters across the globe at a speed and scale which has never been seen before This massive effort to immunize almost everyone on the globe has resulted in short-lived vaccination clinics as well as mass recruitment of staff, many of whom are unable to vaccinate the deltoid immunizations (IM). Few instructions on proper injection technique are provided by such bulk vaccination clinic methods. As an illustration, the BNT162b2 (Pfizer) vaccine guidelines specify that "the vaccine should be injected into the deltoid muscle, preferably in the non-dominant arm, by a suitably qualified individual with training in Good Clinical Practice (GCP) and experience in administering vaccines (such as physicians, nurses, physician assistants, nurse practitioners, pharmacists, or medical assistants)."[2] Similarly, the m-RNA-1273 SARS-CoV-2 vaccine from Moderna specifies that both doses should not be administered in the same arm. On the other hand, the Ad26.COV2.S (Janssen) vaccine simply indicates that the vaccine should be delivered through an intramuscular injection.[3,4] The Lack of clear instructions, inadequate training, and the exponential rise in the number of unskilled staff giving the vaccination all have the potential to significantly raise the risk of improper IM injection. Proper (IM) injection technique plays a crucial role in ensuring the vaccine is correctly administered into the well-supplied muscle, rather than the less vascularized subcutaneous tissue or neighboring structures like bursae, tendons, and nerves. The issue here is twofold: depositing the vaccine in a poorly vascularized area can lead to diminished immunogenicity, thus reducing the vaccine's efficacy, and it can also result in pain and potential complications such as Shoulder Injury Related to Vaccine Administration (SIRVA).[5]

SIRVA is characterized by shoulder pain and a reduction in the range of motion following the administration of a vaccine meant to be delivered intramuscularly in the upper arm. This condition is increasingly acknowledged as a possible adverse reaction linked to vaccines and is most frequently linked with the administration of influenza vaccines.[6,7] One potential explanation for SIRVA is the inadvertent injection into the subdeltoid bursa, resulting in conditions like bursitis, tendinitis, and/or capsulitis.[6]

Shoulder Injury Related to Vaccine Administration (SIRVA) is a complication that emerges within 48 hours after vaccination, characterized by primary symptoms of shoulder pain and restricted range of motion. While the precise origin of SIRVA remains unclear, a widely held hypothesis suggests that injecting the vaccine into the subdeltoid bursa triggers an extended inflammatory reaction.[8,9,10] This complication significantly impacts everyday activities like eating, bathing, and dressing. The primary cause of this complication is often an improper vaccine administration technique, involving factors like incorrect needle positioning or the use of an inaccurate injection landmark.[11]

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Objectives

The objective of the study was to determine the incidence of shoulder pain following COVID-19 vaccination on public health.

MATERIAL AND METHODS

This was an observational study and was conducted in the Department of - Anaesthesia, Analgesia and Intensive care medicine of Bangabandhu Sheikh Mujib Medical University (BSSMU, Dhaka, Bangladesh during the period from February 2023 to January 2024.

A total of 120 patients who were male and female were included in the study. SIRVA was characterized in this study as bursitis, unilateral shoulder discomfort, stiffness of the joint, or weakening on the injection side that appeared following ipsilateral deltoid IM COVID-19 immunization and did not improve within 48 hours after the onset of pain . Due to the huge increase in information regarding SIRVA during the COVID-19 pandemic and the exponentially greater number of self-entered cases on the VAERS database compared to prior years. Only cases that had been examined by a physician were included in an attempt to reduce diagnostic mistake. Data were reduced down by symptom search for the phrases "bursitis," "adhesive capsulitis, and "SIRVA." Data were manually examined and discarded if symptoms healed within 2 days, the injury or dysfunction was systemic or in a joint other than the shoulder, there was bilateral shoulder involvement, or there was a history of trauma or dysfunction before immunization. Separately, a subset of data having verified testing using a diagnostic procedure was evaluated. The terms "nerve," and "weakness" were initially included in an attempt to capture data regarding nerve injuries related to SIRVA, but were later removed because these search terms yielded thousands of reports irrelevant to this study and which could not be verified by a physician, testing, or imaging. A checklist was also created to capture important information from the history sheet and related medical records. Following the interview and study of the necessary investigation reports, data were evaluated immediately. The study only included COVID-19 vaccines and patients with confirmed diagnoses of shoulder pain. Vaccines given at the same time were excluded.

Statistical Analysis: All data were recorded systematically in preformed data collection form and quantitative data was expressed as mean and standard deviation and qualitative data was expressed as frequency distribution and percentage. Statistical analysis was carried out by using Statistical analysis was done by using SPSS (Statistical Package for Social Science) Version 26 for windows 10. P value <0.05 was considered as statistically significant. Ethical clearance was obtained from Institutional Review Board (IRB) of BSMMU to undertake the current study.

RESULTS

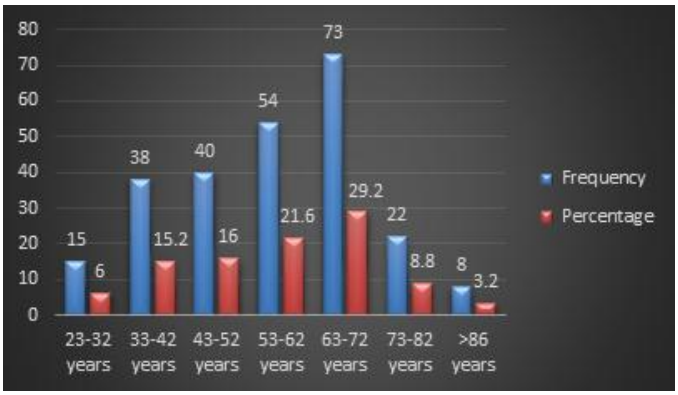

Figure 1: Distribution of respondents according to age

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[Figure 1] shows that majority (29.2%) of our patients were aged 63-72 years old, followed by 21.6% aged 53-62 years old. Among all participants 16%, 8.8%, 8% , 6% & 3.2% were aged between 43-52 years, 33-42 years, 73-82 years, 23-32 years & >86 above years old respectively. The mean age was 48 ± 12 years. We found the Mean ± SD of age was 53.4±21.77.

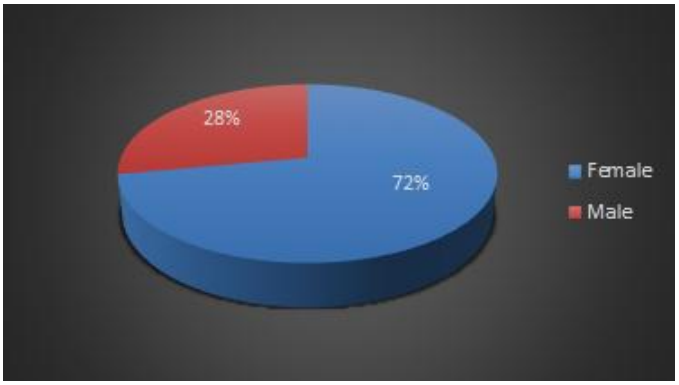

Figure 2: Distribution of our respondents by gender

[Figure 2] shows that the respondents according to gender, out of 250 respondents 72% were female and 28% were male.

[Table 1] shows that the type of vaccination and symptoms of the respondents. We found that the majority of individuals received Pfizer & Moderna vaccines, constituting 80% of the respondents, followed by AstraZeneca at 18%, and Sinovac at 2%. In terms of symptoms, 36% of individuals reported experiencing bursitis, while adhesive capsulitis was noted by 44% of the population. Additionally, 20% of individuals reported SIRVA (Shoulder Injury Related to Vaccine Administration).

[Table 2] shows that the onset of pain of the respondents. The onset of their symptoms in relation to vaccine administration, with 35.2% patients reporting immediate onset, 40.8% patients reporting onset within 24 h, 4% patients reporting onset between 24 and 72 h, and 20% patients reporting onset over days to weeks.

[Table 3] clinical data shows the prevalence of signs and symptoms, diagnostic tests, and treatment modalities within a studied population. Pain emerges as a predominant symptom, reported by a substantial 92% of individuals, indicating its widespread occurrence. Stiffness is noted in 20% of cases, while weakness is a less common manifestation at 4%. Diagnostic procedures reveal a prevalent use of X-ray, conducted in 63.2% of cases, while MRI is employed in 36.8% of cases, suggesting a balanced utilization of imaging modalities. In terms of treatment, oral Steroids is a predominant intervention, being administered to 56% of individuals, underlining its significance in managing the condition. Physical Therapy and NSAIDs are utilized in 16% and 24% of cases, respectively, providing insights into the pharmacological approaches adopted.

Table 1: Type of Vaccination and symptoms of the respondents

Variables		**Frequency**	**Percentage**
Type of Vaccine	Pfizer & Moderna	200	80
	AstraZeneca	45	18
	Sinovac	5	2
	Bursitis	90	36
Symptoms	Adhesive capsulitis	110	44
	SIRVA	50	20

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Table 2: Diagnosis of Onset of pain of the respondents

Onset of pain	Frequency	Percentage
Immediate	88	35.2
<24hr	102	40.8
24-72hr	10	4
>72	50	20

Table 3: Clinical data of the respondents

Variables		Number	Percentage
Signs and Symptoms	Pain	230	92
	Stiffness	50	20
	Weakness	10	4
Diagnostic Tests	X-ray	158	63.2
	MRI	92	36.8
Treatment	Oral Steroids	140	56
	Physical Therapy	40	16
	NSAIDs	60	24

DISCUSSION

The majority of SIRVA patients seek therapy from musculoskeletal specialists and orthopedic surgeons.[12] As a result, a clinical description of shoulder damage and prolonged discomfort following the COVID-19 immunization is critical for the physician's awareness. In the context of COVID-19 vaccination, Shoulder Injury Related to Vaccine Administration (SIRVA) exhibited a similar female predominance, constituting approximately 76% of cases being female and 24% male, with a median age of 51.5. This distribution was comparable to a prior study which reported 73% female, 24% male, with a median age of 51.[13] In this case, the patient had a mild cough and cold before receiving the vaccination. Following vaccination, severe symptoms of fever and cough persisted for a week. Subsequently, the patient presented with a complete loss of all shoulder movements for 2 days. The observed pathology is hypothesized to be an example of antibody-dependent enhancement. Pre-existing antibodies resulting from a prior infection or exposure to another strain of coronavirus (manifested as pre-existing cold and cough symptoms) might have cross-reacted with the inadvertently injected antigen in the bursa. This cross-reaction could have heightened the viral reproduction potential, leading to enhanced symptoms through the antigen-antibody reaction.[14] Radiographs showed pre-existing supraspinatus calcification, possibly predating the vaccination. The overlying bursae could have reacted inflammatorily to the vaccine antigen. It's advised to adhere to precise landmarking techniques during deltoid muscle vaccination, directing the needle at the triangle center formed by the acromion and deltoid muscle insertion for accurate administration.[15] Administering injections at a higher site carries the risk of injuring the underlying bursa, bone, or nerve. If the injection is too posterior, it may harm the axillary nerve. Using a needle that is too short may lead to antigen injection in the

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subcutaneous tissue, while an excessively long needle may cause injury to the underlying bursa. For patients weighing less than 60 kilograms (132 lbs.), a 16-mm (5/8-inch) needle is recommended, while those weighing 60-70 kg (132-154 lbs.) may use a 25-mm (1-inch) needle. Individuals weighing more than 70 kg (154 lbs.) can opt for a 25-mm (1-inch) or 38-mm (1.5-inch) needle. Reports indicate that Shoulder Injury Related to Vaccine Administration (SIRVA) can result from improper vaccination techniques.[16,17,18,19] Hence, it is suggested that patients may develop Shoulder Injury Related to Vaccine Administration (SIRVA) due to improper immunization techniques rather than inherent properties of the vaccine. In this case, the patient had been diagnosed with bursitis based on MRI findings.

(SIRVA) is characterized by shoulder pain commencing within 48 hours after vaccine administration and lasting for more than 7 days. It is most commonly reported following influenza and tetanus vaccinations.[18] Complaints related to SIRVA under the National Vaccine Injury Compensation Program (VICP) have shown a consistent increase over the last decade.[16] This rise in cases began after the publication of the first series involving 13 patients by Atanasoff et al. in 2010.18 In a 2020 report, the authors observed that symptoms persisted in the majority of patients even at their last clinic visit. However, many patients were seeking compensation and may have been disincentivized to fully disclose the true nature and severity of their pain.[16] Case reports of subacromial bursitis following COVID-19 vaccines have been documented. In earlier reports, bursitis developed after 8 weeks,[20] (Oxford-AstraZeneca COVID-19 injection - Serum Institute of India, India) and after 3 days (Sinovac vaccination - Sinovac Biotech, China) of COVID vaccine administration in separate publications.[17] Another case report,[19] noted pain developing 3 hours after the Oxford-AstraZeneca vaccine (Serum Institute of India, India). Honarmand et al. reported two cases of subacromial-subdeltoid bursitis after Moderna's mRNA 1273 and Pfizer-BioNTech's BNT162b2 vaccines.[21] Symptoms observed in the study were consistent with prior research, with pain and limited range of motion being the most prevalent. Previous studies on other vaccinations indicate that onset typically occurs within the first 48 hours.[18,22,23,24] In this study, over 75% of patients experienced symptom onset within the initial 24 hours. Notably, a significantly larger group of patients reported an insidious onset of shoulder pain between 72 hours and 2 weeks in comparison.

Previous research has revealed that the most prevalent signs of SIRVA are rotator cuff tendinopathy and bursa damage. However, in our analysis, the most prevalent finding was adhesive capsulitis, followed by bursitis, tendinopathy, nerve damage, and infection.[23,24] The relative delay in symptom onset and rise in adhesive capsulitis may be seen more clearly in. [Table 1] Only one participant commented on their COVID-19 status in this data collection, saying that they had COVID-19. A 52-year-old female received the Moderna vaccination and was diagnosed with shoulder bursitis as a result of an intra-bursal injection. While the dispersed anecdotes are far from scientific, they do highlight an essential gap in our scientific understanding because nothing is known about the immunogenicity of mRNA vaccines in the context of insufficient IM penetration. Proper

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IM vaccination delivery allows adequate vaccine antigen exposure to a blood-rich location while preventing damage. Overpenetration has been identified as the most critical component in the development of SIRVA, however proper technique is also crucial.[22] The subdeltoid bursa is located between 0.8 and 1.6 cm below the skin's surface, which is easily accessible with a typical 1-inch (25 mm) needle.[25] It is clearly recognized in the literature that a one-size-fits-all strategy for adult deltoid IM vaccines should not be used routinely.[26,27,28] Sex, age, and weight are important factors to consider when choosing needle length because females have less muscle mass and more delta fat pad thickness than men, increasing the chance of injury.[27] Some authors have recommended using steroid injections in the subacromial region following SIRVA due to the influenza vaccination,[29] while others have expressed doubts about its efficacy.[18] However, if subacromial bursitis is discovered on an MRI, subacromial steroids may be useful in alleviating pain complaints. MRI has not helped detect the pathology in SIRVA,[29] but it may be a fair next step if the patient's symptoms linger beyond a few weeks, even after NSAID therapy. The goal of this study is to discuss SIRVA in the context of COVID-19 immunization, raise physician knowledge, and propose preventative methods.

Limitations of the study

Our study was a single centre study. We could only study a few adverse effects within a short study period. Given the nature of this study, which depends on active and passive monitoring systems, SIRVA instances are likely to be under-reported. Increased knowledge of SIRVA, as mentioned above, may aid in increasing reporting rates. In other situations, the surveillance systems also restricted the information supplied by users, resulting in numerous cases being removed from study owing to inadequate information. Furthermore, due to the retroactive nature of data collection as part of safety surveillance, no data on needle length were obtained, therefore no research on whether this contributes to the mechanism of SIRVA can be done. In this investigation, it was not possible to compare various treatment techniques and related results.

CONCLUSIONS

In conclusion, vaccine administration errors can result in local inflammatory reactions and subacromial bursitis. Utilizing proper techniques, particularly in individuals with pre-existing cold and cough symptoms, is crucial to prevent such issues. Patients experiencing a sudden increase in pain and loss of shoulder movements after vaccination can be managed conservatively with rest and NSAID medications. Recognition and early treatment of shoulder pain and dysfunction attributed to local inflammatory pathology in the bursa are essential, involving the use of oral steroids and NSAID medications.

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