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Investigating the Association Between Shingrix®, Skin adverse effects and Shoulder Injury Related to Vaccine Administration (SIRVA): A Review

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Abstract

Herpes zoster, commonly known as shingles, is caused by the reactivation of varicella zoster virus (VZV), the same virus responsible for chickenpox. It is estimated that one in three individuals will develop shingles during their lifetime, with the risk increasing to one in two among adults over 85 years old. *Shingrix*® (GlaxoSmithKline) is a recombinant zoster vaccine that has demonstrated high efficacy in preventing herpes zoster, especially in older and immunocompromised populations. However, concerns about shoulder injury related to vaccine administration (SIRVA), a rare adverse event also observed following COVID-19 vaccination, have prompted investigations into its potential association with other vaccines, including *Shingrix*. This scoping review explores the incidence of skin manifestations and SIRVA in the context of *Shingrix* vaccination by analyzing available evidence from MEDLINE, Embase, PsycINFO, the Cochrane Library, and Google Scholar databases. All forms of original research, including prospective and retrospective studies, cross-sectional analyses, and randomized controlled trials, were considered. For what concern cutaneous adverse effect the cases of VZV reactivation were lower with respect the general population. Other cases of non-HZ vesicular and bullous cutaneous eruptions were attributed to the vaccine's reactogenicity. Our findings reveal no significant evidence indicating a higher incidence of SIRVA following *Shingrix* administration compared to other vaccines. Nonetheless, isolated cases highlight the importance of proper vaccine administration techniques, including anatomical precision during injection, to minimize potential risks.

While current data do not establish a strong causal link, further studies are warranted to explore subtle associations. This review underscores the necessity of rigorous vaccination protocols to ensure safety and maintain public confidence in immunization programs.

Keywords: *Shingrix*; recombinant zoster vaccine; rotator cuff desease; SIRVA; Shoulder desease

Introduction

The Varicella-zoster virus (VZV), or human herpes virus 3, is the causative agent for both varicella and shingles/Herpes zoster (HZ) [1]. HZ represents a reactivation of Varicella-zoster virus (VZV) in the host and has gained interest due to the variable clinical presentation, which is important in the differential diagnosis of diseases. HZ remains dormant in the sensory ganglia of the cranial nerve or the dorsal root ganglia after a previous varicella infection.

After reactivation, the virus can replicate within neurons. Its survival and spread depends on its ability to evade the immune system by acting on pathways such as IFN signaling and MHC class II antigen presentation, thus contributing to the persistence of the infection in neuronal tissues. Viral particles travel along nerve axons to the associated dermatome, where the virus causes a painful, erythematous, vesicular rash that can affect any dermatome. HZ occurs worldwide without seasonal variations of incidence. The incidence of HZ is age-dependent and. [2] according to systematic reviews of studies conducted in the first two decades of the 2000s, the cumulative incidence was estimated at between 2.9 and 19.5 cases per 1000 inhabitants, with a predominance of women [3].

Risk factors for HZ include age over 50 years, immunodeficiency, acute infections, states of psychological stress, and female sex. But it has been shown that the risk also increases when patients are affected by diabetes, chronic respiratory diseases, such as asthma and chronic obstructive pulmonary disease, cardiovascular diseases, and in many other chronic diseases, including depression, rheumatoid arthritis, renal disorders, psoriasis, endocrine and metabolic disorders, inflammatory bowel disease, musculoskeletal disorders, post-stroke and other neurological condition [4].

In particular the elderly population is more frequently prone to infections also because of the gradual weakening of the immune system, as a consequence of advancing age. Therefore, a higher number of infectious diseases associated with greater clinical severity are observed. We must consider that in addition to the immediate effects related to the acuteness of the infectious episode, many elderly people do not show a complete recovery, and indeed may experience the worsening of pre-existing chronic pathologies, or a worsening of their health conditions with difficulties in daily activities up to the point of loss of independence [5].

It has to be taken into account that population ageing is a significant global demographic trend, driven by increased life expectancy. The World Health Organization (WHO) report projects the number of adults aged 60 and over will increase by 34% from 1 billion in 2019 to 1.4 billion by 2030 [6]. By 2050, this number is expected to exceed 2.1 billion, more than doubling the 2019 figure. Moreover it has been observed that life expectancy in the European Union rose from 75 in 1990 to 81 in 2018 and is projected to increase further by 2060 [7]. The number of worldwide herpes zoster (HZ) cases in people aged ≥50 was estimated at 14.million in 2020 and it is thought that it will increase to 17.0 million in 2025 and 19.1million by 2030 [8] Of the approximately one million cases of shingles that occur in the United States, an estimated 1-4% of patients may be hospitalized for complications, associated with prolonged morbidity, and most of these patients tend to be immunosuppressed.(HIV, cancer, or due to immunosuppressive drugs) [9].

Shingles is a condition characterized by the eruption of painful, fluid-filled blisters, primarily affects a single dermatome. The rash typically subsides within a period of seven to ten days (although it often requires antiviral therapy), with the complete healing process taking between two to four weeks. Prior to the manifestation of the rash, patients may experience symptoms such as pain, itching, numbness or tingling in the affected area. The distribution of pain is determined by the course of the dermatome, with discomfort experienced in the area innervated by the corresponding nerve. The VZV exhibits tropism to T cells, neurons, and skin cells and is able

to disseminates throughout the body within T cells, leading to complications [2-3].

One of the most serious complications of shingles is post-herpetic neuralgia (PHN), which is characterized by the persistence of long-lasting pain in the areas where the herpes zoster appeared, even after the vesicle has disappeared [10, 11]. This symptomatology may resolve within a few weeks or may take years. Approximately 10%-50% of patients who develop herpes zoster manifest PHN [12].

It should be considered that post-herpetic neuralgia (PHN) creates, in advanced age, important long-term consequences to the point of determining a compromise of normal daily activities and accentuating the physiological functional decline.

Rare but possible complications of shingles include ocular complications such as blindness, when virus affect the temporal arteries causing giant cell arteritis, skin infections, pneumonia, facial nerve palsy, hearing problems, encephalitis, and death. HZ has been associated with a transient increased risk of developing stroke in the period immediately following a herpes episode, particularly in ophthalmic HZ [13]. An increased risk of myocardial infarction has also been documented due to a probable direct effect of the virus on the vessel walls [14].

It is important to note that shingles is not contagious; however, if someone comes into direct contact with the vesicle fluid, Varicella-zoster virus (VZV) can be transmitted if they are not immune. Patients who develop shingles should always keep the rash covered, avoid scratching, washing their hands regularly, and avoid contact with high-risk individuals during the blistering phase [9, 10].

After an initial episode, HZ may recur. Patients affected by hematological malignancies or who present immunodeficiency due to viral infections (HIV) present high recurrence rates with values ranging from 13 to 26% [15].

But recurrence is not limited to immunocompromised individuals and can occur more than once in the same individual [16].

Factors that increase the risk of shingles recurrence include reduced immunity, female gender, family history, and other chronic conditions. Pain that persists for a long time after the first episode of shingles and the presence of ophthalmic herpes zoster, can also increase the risk of recurrence. In addition a recent study observed that 25% of patients (1030/4141) who had a first relapse experienced at least one second relapse [17].

Vaccinating against shingles is the most effective method of preventing this infection and its complications. The original shingles vaccine, Zostavax® or Zoster Vaccine Live (ZVL), was approved in 2006; however, the effectiveness of ZVL in preventing shingles was found to be variable [18]. After more than a decade, a new, recombinant, shingles vaccine, *Shingrix*® (GlaxoSmith Kline), was introduced to the market. The shingles subunit vaccine (HZ/su) was approved by the Food and Drug Administration (FDA) in October 2017 for the prevention of shingles in adults aged 50 years and older and is now recommended as the preferred vaccine for shingles in immunocompetent adults in this age group by the Advisory Committee on Immunization Practices (ACIP) [19, 20].

It was demonstrated that, in all age groups studied, two doses of *Shingrix* were able to stimulate an intense cellular and humoral immune response. In particular, in the older population group, > 70 years, it was observed that the immune response persisted for at least seven years after vaccination [21, 22].

Despite the importance of RZV (recombinant zoster vaccine) specific guidelines for healthcare professionals, were only identified in ten countries due to the vaccine's novelty [23]. Vaccine administration is not without adverse effects, such as skin manifestations and including the risk of Shoulder Injury Related to Vaccine Administration (SIRVA). SIRVA is currently defined in the literature as "shoulder pain with limited range of motion (ROM) occurring within 48 h after vaccine receipt in individuals with no prior history of pain, inflammation, or dysfunction of the affected shoulder before vaccine administration" [24, 25].

The scientific discourse surrounding HZ continues to evolve, particularly concerning patients with comorbidities and immunocompromised states. The reactivation of VZV became a topic of interest during the COVID-19 pandemic, particularly in relation to vaccination. This led to numerous inquiries regarding different vaccination modalities and their potential skin and musculoskeletal consequences.

The aim of this scoping review is to explore the incidence of skin and articular complication, including SIRVA, in relation to *Shingrix* vaccination by analyzing the available evidence.

Materials and Methods

This scoping review was performed according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines [28, 29].

We performed a scoping review on available and published evidence on complications related to *Shingrix* administration. PubMed/MEDLINE and Google Scholar searches were performed for free-text words and medical subject heading terms related to "recombinant VZV vaccine", "zoster vaccination", "*Shingrix* vaccine", variously combined with "skin adverse effects" "arthritis", "arthralgia", "SIRVA", "VZV vaccine safety", "*Shingrix* adverse events", "post-marketing surveillance", "side effects", "adverse events". Case reports, case series, original studies, and reviews written in English and published online up to 31 January 2025 were selected and reviewed. Studies that did not explicitly reported articular complications in their full text or tables were not included. The final reference list was defined based on the relevance of each paper to the scope of this review.

Two independent reviewers (C.C. and A.C.) screened all identified titles and abstracts. All randomized controlled trials (RCTs), as well as prospective and retrospective cohort studies and case-control studies related to possible complications of shoulder pain following VZV vaccination, were included. Our search strategy identified 68 articles.

Results

An initial database search identified 1,326 records. After removing duplicates and screening for relevance, all 1,326 records were assessed by title and abstract. This process yielded 68 full-text articles for eligibility assessment. Upon full-text review, 67 articles were excluded for not focusing on skin or SIRVA (Shoulder Injury Related to Vaccine Administration) associated with the varicella-zoster virus (VZV) vaccine. Consequently, very few studies were selected and for SIRVA only a single study was identified that focused on post-vaccination SIRVA from VZV. However, this study was excluded from the analysis due to its inability to address the specific focus of the present investigation, namely the *Shingrix* vaccine. (see PRISMA flow diagram in Figure 1 for included and excluded studies).

Despite a comprehensive search of the available literature, we identified only Three article regarding skin manifestations and a single article addressing Shoulder Injury Related to Vaccine Administration (SIRVA) following Varicella Zoster Virus (VZV) vaccination. This highlights the significant paucity of evidence specifically concerning SIRVA in the context of VZV immunization. Most existing studies focus on other vaccine-related complications or different clinical scenarios, underscoring the limited data available to guide clinical management and prevention strategies for SIRVA after VZV vaccination.

Discussion

Overall Safety of Recombinant VZV Vaccination

The safety profile from clinical trials on the recombinant VZV vaccine, showed a high safety profile. First data emerging from a phase 3 clinical trial on hematologic patients, reported subsequent adverse events comprising mainly related to the expected reactogenicity profile of VZV, such as fever, VZV reactivation and injection sites reaction, with 47% of subjects in the vaccination group experiencing adverse events (AE) in the 30-day window after vaccination [13].

Another phase 3 clinical trial on adults immunosuppressed due to solid organ transplants, [14] showed a higher incidence of AE in the vaccine group compared with the placebo group, with pain being reported in over 90% of vaccinated individuals and other symptoms such as myalgia, shivering and headache being the other most frequently reported AEs.

Afterwards, during post-marketing surveillance, studies have collected more data on the safety profile of this vaccine formulation. Apart from the already reported local and systemic AEs such as pain, fever and asthenia, studies found other systemic AEs of note.

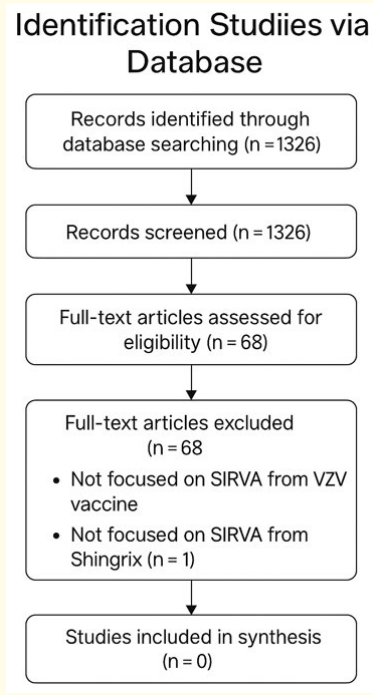

Figure 1: Flow chart of the screening process.

Data from the US population, [15] showed a higher risk of Guillain-Barré syndrome with *Shingrix* compared with other, live-VZV vaccine. In particular, the risk of developing Guillain-Barré was more than 2 times higher with the recombinant vaccine in the study by Goud R et al. A subsequent work by Nelson JC et al. [16], confirmed the presence of reported cases of Guillain-Barré syndrome (GBS) following recombinant VZV vaccination but saw no significant difference in the rate of this AE compared with other form of VZV vaccines.

In a recently published post-market surveillance analysis, Shu Y et al. [17] observed that GBS was among the most frequently reported serious AEs, around 8%. Moreover, among registered deaths, GBS was the second most reported cause of death (2 cases, 4.7%), following only cardiovascular complications.

In the subset of patients immunosuppressed due to medications for rheumatologic diseases, reports on flairs of arthritis began to emerge in clinical studies. In a 2020 work by Stevens E at al, [18] in a cohort of 403 patients, authors report 27 arthritis' flares (6.7 cases per 100 Patient-Years), all of mild entity and self-limiting. Data on these rheumatologic AEs were reported through the years, with rates ranging from 7 to 14% [19].

Furthermore, particular attention has been paid in case of combined vaccination, given that elderly patients may often suffer from multiple chronic diseases, which require vaccination. Recent clinical studies have confirmed that RZV can be co-administered with other vaccines, such as, for example, with the 13-valent pneumococcal conjugate vaccine (PCV13) or PPV23, while maintaining a high immunogenicity and safety [26].

Study	*Population*	*Main Adverse Events*	*Overall AE Incidence*
Dagnew et al. (2019)	Hematologic malignancy patients	Fever, VZV reactivation, injection site reactions	47% within 30 days post-vaccination
Vink et al. (2020)	Renal transplant recipients	Pain (>90%), myalgia, chills, headache	Higher in vaccine group vs placebo
Stevens et al. (2020)	Rheumatic disease patients (n=403)	27 arthritis flares (6.7 per 100 PY)	All were mild and self-limiting
Källmark et al. (2024)	RA patients on JAK inhibitors	Arthritis flares (7-14%)	No severe adverse events reported

Table 1: Summary of adverse events in immunocompromised populations receiving Shingrix® vaccination, including patients with hematologic malignancies, organ transplants, and autoimmune rheumatic diseases.

Recombinant VZV Vaccination and skin manifestations

In a study from Orru S et al [27] were enrolled, in a period between April and October 2020, 72 patients, of which 32 had skin symptoms in the thoracic and 27 in the cervical dermatomes. Most of the vaccinated cases had no history of previous episodes of HZ or immune defects or deficiencies. In 50 (69.4%) cases skin manifestations occurred after the first dose of RZV and in 22 (30.6%) cases after the second. Skin manifestations described included erythema, macules, papules, vesicles, pustules, hemorrhagic vesicles and crusts, where vesicles were more frequent in VZV PCR-positive subjects while macules were reported only in VZV-negative PCR cases. Skin manifestations were often associated with severe pain, but also with itching and paresthesia. VZV-positive cases. In 25 out of 27 VZV-positive cases it was confirmed the classic form of HZ. While no cases of HZ disseminatus or HZ sine herpete were described.

Of the 45 VZV-negative cases: 9 were classified as HSV, 2 as rash, 2 as eczema and finally 1 as folliculitis.

The authors conclude that dermatomal rashes, observed in the first week after the first vaccination or shortly after the second, positive to VZV PCR, can be ascribed to Wild Type VZV demonstrating that HZ can still occur after both doses, therefore the vaccine is not able to provide complete protection at this time.

A review of spontaneously reported post-marketing data by Pirrotta P., et al. evaluated adverse events suggestive of herpes zoster (HZ) and non-HZ vesicular and bullous skin eruptions, occurring after RZV. Of the 2423 reports of adverse events (AEs) suggestive of HZ or HZ complications, 645 met the criteria of possible vaccination failure but only two reports were laboratory-confirmed cases, while 643 reports remained only suspected cases based on the presence of clinical symptoms of HZ and time to onset post-vaccination.

Suspected cases were still included in the analysis, but these cases were not clinically confirmed. In fact, the reporting rate of vaccine failures was low (2.0 cases per 100,000 RZV doses distributed), in line with what was reported in clinical trials.

There were 810 reports suggestive of other vesicular and bullous (non-HZ) skin eruptions (ESM 3). Most skin manifestations were diagnosed as non-allergic and not localized to the injection site. A possible explanation may be that the elderly are more susceptible to dermatoses and hypersensitivity skin reactions, including vesicular or pustular reactions.

A total of 102 cases of non-injection site hypersensitivity rash were reported, including: vesicular rash (n = 51), vesicles (n = 38), pustules (n = 9), pustular rash (n = 5), and anaphylaxis (n = 1). Of these, 12 were rated as serious. The majority (n = 87) were delayed-type hypersensitivity reactions. Delayed hypersensitivity reactions to vaccines have been previosly described and range from persistent local itchy nodules to systemic rashes. Onset usually occurs within a few days, but may be delayed for weeks [28]. Although they are usually rare and often delayed hypersensitivity, which requires evaluation if they persist for more than a week [29].

In addition, local reactions at the injection site were reported in 72 cases, which were evaluated as reactogenic events.

436 reports of non-injection site rashes were classified as other etiologies, being related to other viral infections. The reported cases referred to the presence of: blisters (n = 120), vesicular rash (n = 80), pustular rash (n = 10), acne (n = 3;).

1928 spontaneous reports referred to cases of VZV reactivation. The observed incidence of HZ cases following RZV vaccination was lower than the background incidence in the general population.

Possible biological mechanisms hypothesized in HZ reactivation are that RZV vaccination may cause immune exhaustion as a consequence of chronic T-cell stimulation and produces poor control of infections; on the other hand the intense cytokine production and massive inflammation that occur in response to RZV vaccination may increase the risk of VZV reactivation.

Others are anecdotal cases of a bullous reaction, interpreted as a fixed drug reaction and a case of reactivation of herpes zoster after vaccination.

A patient, affected by Crohn's disease and previously treated with infliximab, showed a bullous rash on the left arm and axilla 2 days after receiving the second dose of *Shingrix* vaccine.

A PCR test for herpes simplex virus (HSV) 1, HSV 2, and VZV was performed on a bullous lesion and was negative. A biopsy was also performed, revealing epidermal necrosis associated with an inflammatory finding consisting primarily of eosinophils and scattered neutrophils. The findings were consistent with a fixed drug-induced bullous eruption.

The appearance of the bullous skin manifestation has been interpreted as a delayed hypersensitivity reaction due to T-cell hyperactivation [30].

Another patient with progressive interstitial pulmonary fibrosis, treated with antifibrotic therapy (Nintedanib), who had undergone autologous non myeloablative haemopoietic stem cell transplantation five months earlier, developed flu-like symptoms and itchy blisters spread across the body 10 days after the first vaccination; the lesions were tested and were positive for VZV by PCR. The VZV IgG were positive while IgM were negative before vaccination. The patient was treated with intravenous acyclovir and achieved complete remission within a week [31].

Recombinant VZV Vaccination and arthralgia

In a review by Tavares-Da-Silva et al, [20] authors collected, through data given by the manufacturer, 4639 reports, a reporting rate of 49.8 reports per 100'000 doses distributed. Among these reports, 3.0% were about cases of arthralgia following *Shingrix* administration (3.3 reports per 100'000 doses distributed). Most of the cases were reportedly mild, while 7.8% of reported arthralgia cases were reported as serious (0.3 reports per 100'000 doses distributed).

Most recent post-marketing surveillance reports, [21] do not report arthralgia as a frequent adverse event; however, they combined muscular and skeletal disorders, with musculoskeletal pain accounting for 736 cases among serious adverse events, making up around 40% of all serious AE reports. Similarly, a work by Costantino M et al, [22] analyzing an Italian cohort, reported a rate of "Joint/Muscle Pain" of around 15% in adult individuals immunized with the recombinant vaccine, with female sex being more affected compared with male sex. Another work by Stefanizzi et al, [23] reported arthromyalgia as the third most common systemic reaction after fever and asthenia, with a rate of 5.7 per 100 completed follow-ups. All reported episodes were self-limiting. (Table 2)

Recombinant VZV Vaccination and SIRVA

Shoulder injury related to vaccine administration (SIRVA), is a recently descripted vaccine-related adverse event. First described following influenza vaccination, [24] it became more thoroughly reported during the COVID-19 pandemic and the subsequent race to SARS-CoV2 vaccination [25]. SIRVA is described as a shoulder injury that can include a variety of conditions such as adhesive capsulitis, tendinitis, and subacromi-al-subdeltoid bursitis.

Type of Event	*Reference*	*Incidence / Reporting Rate*	*Notes*
Arthralgia	Tavares-Da-Silva et al. (2020)	3.0% of reports (3.3/100,000 doses)	7.8% were serious (0.3/100,000 doses)
Musculoskeletal pain	Shu et al. (2025)	736 serious cases (≈40% of all serious AEs)	Combined musculoskeletal category
Joint/Muscle pain	Costantino et al. (2024)	≈15%	More frequent in females
Arthromyalgia	Stefanizzi et al. (2024)	5.7 per 100 completed follow-ups	All episodes self-limiting

Table 2: Reported articular adverse events following Shingrix® vaccination based on post-marketing surveillance studies and clinical data. The majority of events were mild and self-limiting, though a minority were classified as serious.

SIRVA is considered a phenomenon related to improper vaccine delivery. To reduce the risk of SIRVA, researchers suggest an appropriate delivery technique for intramuscular vaccination as well as the use of needles with adequate length [26].

Hirai et al. [27] describe a case of SIRVA following Zoster vaccine administration. At the present time, this appears to be the only case of SIRVA reported following VZV vaccination. (Table 3 - Table 4)

Event	*Reference*	*Reported Cases*	*Notes*
SIRVA	Hirai et al. (2022)	1 case	Only reported case after Shingrix® administration
Guillain-Barré Syndrome	Goud et al. (2021)	Increased risk (>2x vs ZVL)	Observed in Medicare population
Guillain-Barré (no excess)	Nelson et al. (2023)	No significant difference	Conflicting evidence
GBS among fatalities	Shu et al. (2025)	2 cases (4.7% of deaths)	Second most common cause of death post-vaccination

Table 3: Overview of rare complications following Shingrix® administration, including Guillain-Barré Syndrome (GBS) and the only reported case of Shoulder Injury Related to Vaccine Administration (SIRVA).

Feature	*ZVL (Zostavax®)*	*Shingrix® (HZ/su)*
Type	Live-attenuated vaccine	Recombinant, adjuvanted vaccine
Target age	≥60 years	≥50 years
ACIP recommendation	No longer preferred	Preferred
Efficacy	Variable	High efficacy
Reactogenicity	Lower	Higher
GBS association	Lower risk	Potentially increased (some studies)

Table 4: Comparison of characteristics between the live-attenuated herpes zoster vaccine (Zostavax®) and the recombinant adjuvanted vaccine (Shingrix®), highlighting efficacy, target populations, and risk profiles.

Limitations

Is important to acknowledge the limitations of this scoping review. Firstly, the extant evidence on SIRVAs in the aftermath of *Shingrix*® vaccination is extremely limited, partly due to the recent release of the vaccine.

Secondly, heterogeneity in the reporting of adverse events across studies introduces variability into the data, potentially undermining the consistency and comparability of results.

Furthermore, the utilization of published literature inherently excludes unpublished data, reports of adverse events that have not been formally studied, and reports in languages other than English.

In conclusion, given that this was a scoping review, the objective was to map the existing evidence rather than to assess the quality or risk of bias of individual studies. It is evident that, despite the fact that this approach is adequate for the identification of research gaps and the summarization of the extant literature, it does not permit definitive conclusions to be drawn on causality or incidence rates.

Conclusions

Although the recombinant VZV vaccine represents a significant advance in the prevention of Herpes Zoster and its potentially debilitating complications, growing evidence suggests that its safety profile - although robust - deserves continued scrutiny, particularly in relation to musculoskeletal and joint adverse events. Nowadays, it becomes imperative not only to monitor well-known side effects, but also to shed light on underreported complications such as SIRVA and post-vaccination arthralgia.

Supplementary Materials: none.

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