

## SPECIAL ARTICLE

# Anti-Herpes zoster vaccination in patients with dermatologic diseases: a position statement from the Italian SIDeMaST group of sexually transmitted, infectious and tropical diseases

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## ABSTRACT

Herpes zoster (HZ) is a condition caused by the reactivation of varicella-zoster virus (VZV), the virus responsible for chickenpox, which is the clinical manifestation of the primary infection. Congenital or acquired immune system deficiencies, as well as the physiological decline in immune response occurring in the elderly, known as immune senescence, can allow VZV reactivation and, consequently, HZ. One out of 3 people develops HZ during their lifetime. Moreover, thirty percent of the affected subjects develop post-herpetic neuralgia, the most frequent complication after HZ skin rash. Patients with dermatological conditions characterized by alteration of the immune system, such as systemic lupus erythematosus, psoriasis, atopic dermatitis, bullous diseases, and cutaneous lymphomas, are at higher risk of developing HZ and post-herpetic neuralgia, even when their disease is in remission. In the present work, we described the currently available vaccinations against HZ and provided recommendations for the vaccination against HZ in patients with dermatological diseases.

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KEY WORDS: Herpes zoster; Vaccination; Prevention and control.

**H**erpes zoster (HZ), commonly known as “shingles” is a condition caused by the reactivation of varicella-zoster virus (VZV), while Varicella, also known as “chickenpox”, represents the clinical manifestation of the primary VZV infection.<sup>1, 2</sup>

The pathogenesis of the disease contemplates the penetration of VZV through the airways (the rhinopharynx

is the first site of entrance) with subsequent replication in the lymphatic tissue of the head and neck and access to the bloodstream causing viremia. Next, the virus undergoes a second replication cycle in the liver and spleen, and through the second viremia, occurring almost 15 days after the primary infection, it reaches its primary target, the skin, where the final replication phase occurs. Cutaneous lesions are the

result of a direct viral cytolytic effect on epidermal cells and probably also of an indirect immune-mediated effect. The cutaneous eruption of chickenpox is at first macular, becoming maculopapular in a few hours and, subsequently, it evolves into characteristic vesicles with a surrounding area of erythema, often associated with pruritus. Thereafter, skin lesions become pustular and crusted. The virus accomplishes a retrograde movement from the skin, within nervous fibers, reaching the spinal posterior sensory ganglia and the ganglia of the central nervous system, where it remains lifelong latent. In spinal and cranial sensory ganglia, the VZV activity is usually controlled by humoral and cell-mediated immunity. However, congenital or acquired immune system deficiencies can allow VZV reactivation and replication, causing inflammation in the involved ganglion; in this case, a reverse viral route occurs within nervous fibers from the ganglia to the periphery, the skin, where cutaneous lesions happen with a unilateral distribution in the dermatomes innervated by the involved ganglion.<sup>1, 2</sup> Especially in the elderly, the physiological decline in immune response, known as immune-senescence, causes a higher susceptibility towards infections in general and towards reactivation of latent viruses, including VZV.<sup>3</sup> HZ shows predilection towards mid-and-lower thoracic dermatomes (T3-T12), upper lumbar dermatomes (L1-L2), and ophthalmic dermatomes (V-1). The cutaneous eruption of HZ is usually preceded by general malaise and fatigue. The acute phase of HZ is characterized by macules and papules evolving into confluent vesicles in a few days, with subsequent crust formation. Vesicles can persist for up to two weeks; in the meantime, new vesicles tend to form in crops. In the elderly, clinical manifestations of HZ are typically intense and prolonged. The exanthem of HZ is associated with intense, burning, neuropathic shooting pain, and paresthesia, and the skin may be tender to the touch. Pruritus is less frequent. It is rare for more than one dermatome to be involved, but when this does occur two or three adjacent dermatomes are affected. In the acute phase of HZ satellite adenopathy, mild fever and headache can occur.<sup>1, 2</sup> In some cases, VZV reactivation can occur without skin lesions (zoster sine herpete): in this particular form of HZ, chronic pain with dermatomal distribution, in the absence of any skin rash, is the only symptom indicative of viral reactivation, which can be documented by measuring VZV DNA in serum or saliva.<sup>4</sup>

### Herpes zoster: complications

The most frequent complication of HZ, occurring in up to 30% of affected subjects, is post-herpetic neuralgia, char-

acterized by persistent pain, lasting more than 3 months, localized in the dermatome that was previously affected by the HZ skin rash.<sup>5</sup>

The pain of post-herpetic neuralgia has been described as stinging, cutting, or sharp and burning, sometimes accompanied by dysesthesia. It can be intermittent or constant and can be very disabling. It may persist for months, years, or a lifetime, negatively impacting the patient's quality of life.

Localized chronic itching and/or dysesthesia are also common at the site of skin rash, as well as secondary bacterial infections.<sup>1</sup> Ophthalmic HZ, resulting from viral reactivation into the ganglion of Gasser, affects the innervation area of the ophthalmic branch of the trigeminal nerve, possibly causing acute and chronic ocular complications and even blindness. VZV reactivation in the geniculate ganglion can cause paralysis of the facial nerve with ear pain, and sometimes hearing loss and vertigo, accompanied by a vesicular rash of the pharynx, the external auditory canal, and other facial regions (Ramsay-Hunt Syndrome). Also, ageusia may affect the anterior two-thirds of the tongue. In severely immunocompromised patients or patients with underlying health conditions (diabetes, bronchopneumopathy, heart disease, chronic kidney failure) or pre-existing dermatological conditions, hematogenous viral dissemination can occur, leading to diffuse cutaneous varicelliform type rash (disseminated zoster). In these individuals, second attacks, which are virtually unknown in the immunocompetent, are sometimes observed. Central nervous system complications are rare but possible: among these, meningoencephalitis, transverse myelitis, and retinal necrosis must be mentioned. Also, persistent infection of the cerebral arteries can cause hemiplegia from unifocal or multifocal vasculopathy with infarctions and hemorrhages in the cortical and subcortical areas, mostly with fatal outcomes.<sup>1-5</sup>

### Epidemiology of Herpes zoster

One out of 3 people develops HZ during their lifetime; every year in the USA one million episodes of HZ are recorded,<sup>6</sup> most of them in presumably immunocompetent individuals.<sup>7</sup> A recent Italian study reported a yearly incidence of 6.5 HZ cases (95% confidence interval: 5.99-6.95) per 1000 individuals, increasing to 9.2 cases in subjects over 75 years old. In this study, over 10% of patients developed post-herpetic neuralgia, especially subjects over 75 years of age.<sup>8</sup> Another Italian study on HZ-associated hospitalizations found that HZ is not a rare cause of hospitalization

(10 per 10,000 subjects/year), though from 2003 to 2018 the number of hospitalizations for HZ has reduced, in line with other European data. Notably, the hospitalization rate for HZ is 20 times higher in subjects over 80 years of age than in those younger than 50, suggesting that older people should be given priority for anti-HZ vaccination.<sup>9</sup>

### Herpes zoster available vaccinations

Currently, two vaccines are available for the prevention of HZ and post-herpetic neuralgia:<sup>10, 11</sup>

- a live attenuated virus vaccine, which contains an attenuated form of VZV, which is administered in a single dose;
- a recombinant vaccine (RZV), which contains the most abundant surface protein of VZV, namely glycoprotein E, together with an adjuvant system that stimulates the immune response. Two doses are administered, 2-6 months apart.<sup>10</sup>

### Categories of individuals to whom anti-herpes zoster vaccinations are addressed

The Italian National Vaccine Prevention Plan 2023-2025, approved in the State-Regions Conference in August 2, 2023, provides HZ vaccination for free, in adults starting from 65 years of age. Additionally, in case of chronic diseases that may increase the risk of HZ (diabetes mellitus, chronic obstructive pulmonary disease [COPD], diseases requiring the use of immunosuppressive therapy), the anti-HZ vaccination is offered for people aged 50 years and over.<sup>10</sup>

On October 20, 2021, the Advisory Committee on Immunization Practices (ACIP), an American commission composed of a group of experts in medicine and Public Health, recommended the use of the recombinant vaccine (RZV) for the prevention of HZ and its complications, also in adults aged 19 or over, if they are or will be immunosuppressed due to a disease or therapy.<sup>11</sup>

The live attenuated HZ virus vaccine is recommended in Italy in people over the age of 65, or people over 50 if affected by diabetes mellitus, cardiovascular disease (excluding isolated hypertension), chronic obstructive pulmonary disease, bronchial asthma, cystic fibrosis, and any chronic condition that can increase the risk of developing HZ and can aggravate its clinical manifestations. This vaccine reduces the risk of developing HZ by 51% and of post-herpetic neuralgia by 66%; however, its effectiveness decreases with age; as other live attenuated vaccines, it is not recommended in immunocompromised people.<sup>12</sup>

RZV is indicated in people of 50 years or more and frail subjects aged 19 or over, presenting conditions of increased risk of HZ (diabetes mellitus, cardiovascular diseases, chronic respiratory diseases such as bronchial asthma, immunocompromised state, chronic kidney failure) and in subjects with previous episodes of HZ (4% of patients with HZ complained of relapsing episodes), especially those affected by severe forms of HZ. This vaccine, not containing a live virus, can also be administered to immunocompromised subjects or to individuals who are going to start immunosuppressive therapy.<sup>12</sup> In the vaccine's clinical trial (Zoster Efficacy Study in Adults 50 Years of Age or Older [ZOE-50] and Zoster Efficacy Study in Adults 70 Years of Age or Older [ZOE-70]),<sup>13</sup> RZV showed >90% efficacy in preventing HZ, regardless of age and comorbidities, with persistent effectiveness of up to 7 years in 90.9% of individuals. The RZV vaccine was also associated with a significant reduction of HZ complications, such as post-herpetic neuralgia,<sup>5</sup> vasculitis, stroke, disseminated zoster, ophthalmic complications, neurological diseases, and hospitalizations related to HZ.<sup>13</sup>

The choice of the vaccine type is based not only on the clinical conditions of the subject but also on the different national and regional policies that may vary among different countries and also among different Italian regions.<sup>10-12</sup>

### Dermatological patients at risk for Herpes zoster

Patients with dermatological conditions at increased risk of developing HZ comprise those affected by alteration of the immune system, such as systemic lupus erythematosus, psoriasis, atopic dermatitis, autoimmune bullous diseases, and cutaneous lymphomas. These patients are at higher risk of developing HZ and post-herpetic neuralgia, even when their disease is in remission; the administration of immunosuppressive therapies, nearly always necessary in these patients, further increases this risk.<sup>14-16</sup> Therefore, these patients should be protected from HZ with absolute priority, especially if subjected to therapies that further suppress their immune systems.<sup>14-16</sup> Several authors studied the risk of HZ following different pharmacological therapies for chronic skin diseases. An Israeli study on more than 22,000 psoriatic patients, found that those treated with cyclosporin, methotrexate, acitretin, and corticosteroids had a significantly higher incidence rate of HZ, compared to patients treated with anti-TNF $\alpha$ .<sup>17</sup> Among the evaluated anti-TNF $\alpha$  biological drugs (etanercept, infliximab, and adalimumab) none was associated with an increased risk of developing HZ.<sup>17</sup> A recent meta-



analysis reported that monotherapy of anti-TNF $\alpha$  biologic drugs (for example adalimumab, etanercept, infliximab), anti-CD20 (rituximab), and anti-IL12/23 (ustekinumab) or methotrexate did not increase the incidence rate of HZ.<sup>18</sup> Similarly, IL-17 inhibitor drugs (e.g., secukinumab, ixekizumab, brodalumab, bimekizumab),<sup>19</sup> as well as inhibitors of IL-23 (e.g., guselkumab, risankizumab, tildrakizumab) were not associated with an increased risk of HZ compared to other therapies or placebo.<sup>20</sup> Conversely, a recent systematic review of 41 studies on HZ in psoriatic patients showed an increased risk of developing HZ in patients treated with systemic corticosteroids, Janus kinase (JAK) inhibitors, and combinations of biologic drugs and traditional drugs, compared to patients who are not treated with these medications.<sup>21</sup>

Indeed, in patients with atopic dermatitis and in those with psoriatic arthritis who are candidates for therapy with JAK inhibitors (e.g., upadacitinib), anti-HZ vaccination is recommended, according to the drug's technical data sheet, before starting to take the drug.<sup>22</sup>

Finally, a recent study of over 130,000 patients with psoriasis and psoriatic arthritis, found no increased incidence of HZ in patients taking apremilast in monotherapy,<sup>6</sup> while an increased incidence of HZ was found in patients on polytherapy with biologics and other immunomodulatory drugs.<sup>23</sup>

### Anti-Herpes zoster vaccination in patients with skin diseases

A recent systematic review focusing on the recommendations of anti-HZ vaccination in psoriatic patients with and without arthropathy highlighted that:

- live attenuated HZ vaccine can be administered to patients with psoriasis and psoriatic arthritis over 50 years of age, if not receiving systemic therapy or if receiving only low-dose immunosuppressants (methotrexate <0.4 mg/kg/week or prednisone <20 mg/day). This vaccine should not be administered to patients with psoriasis or psoriatic arthritis taking moderate/high levels of traditional anti-inflammatory drugs (methotrexate, hydroxychloroquine) and biologics;<sup>21</sup>

- the recombinant HZ vaccine (RZV) is preferable, when available, in patients with psoriasis and psoriatic arthritis compared to the live attenuated vaccine; RZV should be administered before initiation of systemic immunosuppressive therapy; however, it can be administered safely even during the use of traditional anti-inflammatory drugs and biological drugs. This vaccine should therefore

be recommended to all patients with psoriasis and psoriatic arthritis over 50 years of age and in psoriatic patients under age 50 if they are on treatment with tofacitinib, systemic corticosteroids, or combinations of systemic drugs.<sup>21</sup>

Indeed, the severity of psoriatic disease and the intake of multiple therapies increase the overall incidence of HZ and therefore justify the use of the anti-HZ vaccine. Based on the evidence of safety and efficacy of the RZV vaccine patients with psoriasis<sup>21</sup> and also in different categories of immunocompromised patients, including patients after hematopoietic stem celltransplants,<sup>24</sup> kidney transplant recipients,<sup>25</sup> patients with malignant solid tumors undergoing chemotherapy,<sup>26</sup> patients with hematological malignancies<sup>27</sup> and patients living with human immunodeficiency virus infection,<sup>28</sup> the Italian Society of Dermatology and Sexually Transmitted Diseases suggests to extend the indication to undergo anti-HZ vaccination with RZV to all patients suffering from diseases of the skin and mucous membranes which may alter the efficiency of the immune system (both for the nature of the disease itself or for the related pharmacological treatments): psoriasis, atopic dermatitis, systemic lupus erythematosus, connective tissue disease, autoimmune bullous diseases, lymphomas and other chronic inflammatory diseases that require treatment with immunosuppressive drugs. Furthermore, in dermatologic patients, the frequent need for multiple pharmacological treatments to achieve complete disease control, or the severe disease by itself, justifies the use of anti-HZ vaccination for the prevention of HZ and its complications.<sup>8</sup>

### Conclusions

In conclusion, anti-HZ vaccination through the VZV live attenuated vaccine or, preferably, the recombinant HZ vaccine (RZV), should be recommended to all patients suffering from chronic diseases of the skin and mucous membranes impairing the efficiency of the immune system. Dermatologists should have an educational role towards their patients not only to treat the diseases for which they seek treatment but also to prevent the diseases from which they may suffer in the future. In this way, it will be possible to fully improve the current and future quality of life of the patients and also of their caregivers.

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#### Conflicts of interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

#### Authors' contributions

All authors read and approved the final version of the manuscript.

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