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Review Article

India launches Shingrix Zoster Vaccine- April 2023 Will Governments (GOI & States) Save a Million Elderly Annually from Painful Shingles

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Abstract

Shingles (Herpes zoster) are caused by the reactivation of the varicella zoster virus (VZV), the same virus that causes chickenpox. Commonly seen among persons over 50 years though can occur at any age. Most people have only one episode of the illness in their lifetime, however, second episodes are not uncommon and third episodes very rare and multiple episodes are possible.

In India, we see about a million cases each year giving an incidence of 705 per million population per year. In USA approximately 1 out of 3 people develop herpes zoster during their lifetime Shingles, and about half of people over age 80 have had shingles.

Most people with shingles have one or more Fluid-filled blisters, usually on just one side of the body or face, and in a small area, the most common place to occur is in a band around one side of the waistline. The rashes often follow the distribution of nerves in the skin, a pattern called a dermatome. Shingles occurs more commonly on the chest and back but can involve the arms and legs. Fortunately, shingles is not communicable to others. In 2 to 4 weeks, the blisters and pimples heal, but the tingling or a pins-and-needles feeling, itching, burning, and a deep pain due to the post-herpetic neuralgia, a severe painful condition persists for months. There is no cure for shingles, but treatment can help ease symptoms until the condition improves. Several antiviral medicines like acyclovir, valacyclovir, and famciclovir are used to treat shingles and shorten the length and severity of the illness. Pain present for 90 days or more after HZ rash onset is known as PHN which is the most common complication of HZ. Postherpetic neuralgia is very rare in people under 50 and the pain often resolves within a few weeks. It is a debilitating complication that is challenging to treat and is responsible for most of the HZ-related burden of disease in older people, as the pain reduces more slowly in people over 70, and the pain can bother for months or even a year after their shingles attack.

This article is based on primary cases seen by the author since 2007 to March 2023 and review of the literature, in the context of the launch of Shingrix Zoster Vaccine Recombinant, Adjuvanted vaccine in India on Monday the 16 April 2023 for the persons over 50 years. India has 260 million adults above 50 years of age at risk of shingles and its complications and this vaccine given in 2 doses becomes a boon for such population providing protection for 10 years.

While there is no specific immunization program in India for senior citizens, the author tried to suggest how we can reach these 260 million people in the next 5 years and an annual cohort of 10 million each year, thereafter.

Materials & Methods: An autobiographical case and two of sisters suffering Shingles over last 15 years, made me to experience the shingles rashes and most importantly the post-herpetic neuralgia. This is supplemented by literature review of global and Indian scenario.

Keywords: shingles; herpes zoster, rashes; post-herpetic neuralgia;burden; epidemiology;economics, administrative data; shingrix zoster vaccine ; recombinant; adjuvanted

Introduction

Shingles or Herpes Zoster (HZ) are caused by the reactivation of the varicella zoster virus (VZV), virus that causes chickenpox. Herpes zoster is being commonly seen among persons over 50 years though can occur at any age. Most people have only one episode of the illness in their lifetime, however, multiple episodes are possible [1]. In India it has been given various names like Janeu (sacred thread), Brahmsutri , Sarpa Suttu(Kannada-snake like blisters), Nagin Gulakrallu (Telugu),mainly due to the stripe of blisters pattern it clinically manifests over the skin on the torso the body.

Magnitude of the problem: As everyone infected with the varicella zoster virus is at risk of developing shingles, the condition is relatively common, particularly in older adults. In India, we see about a million cases each year giving an incidence of 705 per million population or 7 cases per 10,000 people each year. Shingles occurs in 20 to 30 percent of people at some point in their lives, and about half of people over age 80 have had shingles. In USA 1 out of 3 people develop herpes zoster during their lifetime.

Clinical presentation: Usually, shingles develops on just one side of the body or face, and in a small area. The most common place for shingles to occur is in a band around one side of the waistline. Pre-domal symptoms include a mild fever, itching, tingling, burning and pain over the site's rashes appear after 4-5 days. Most people with shingles have multiple fluid-filled blisters, that often follow the distribution of nerves in the skin. This distribution pattern is called a dermatome. Shingles occurs more commonly on the chest and back but can involve the arms and legs. In 2 to 4 weeks, the blisters and pimples heal. They rarely come back.

Though the pain from shingles lasts for 2 to 4 weeks, one may have tingling or a pins-and-needles feeling, itching, burning, and a deep pain called the post-herpetic neuralgia, a severe paining condition persists for months or even years. Age and weak immune system increase the risk of getting shingles.

Pain present for 90 days or more after HZ rash onset is known as PHN which is the most common complication of HZ. Postherpetic neuralgia is very rare in people under 50 and the pain often resolves within a few weeks. It is a debilitating complication that is challenging to treat and is responsible for most of the HZ-related burden of disease in older people, as the pain reduces more slowly in people over 70, and the pain can bother for months or even a year after their shingles attack.

Epidemiology: Although anyone who has had chickenpox can get shingles, the risk of developing shingles increases with age, as most people get shingles in their 50s or later in life. In Inda women are more susceptible than men. Adults over 50 years of age and those suffering from chronic conditions such as diabetes, heart disease, Kidney disease, HIV/AIDS, Cancer, TB, are at an increased risk of Shingles and its complications because of weakened immunity. Shingles is not communicable to others. Only an individual suffers and despite close contact with the patient others cannot contract chickenpox from him/her, except if they have not been infected earlier. Shingles occurs in nearly a quarter of patients receiving immunosuppressive treatment for blood cancers or Covid 19.

There is no cure for shingles, but treatment can help ease your symptoms until the condition improves. Several antiviral medicines like acyclovir, valacyclovir, and famciclovir are used to treat shingles and shorten the length and severity of the illness. These medicines are most effective the sooner one takes after the rash appears. Regularly bathing with cool or lukewarm water may reduce shingles symptoms. Bathing in hot water is not recommended. Adding 1-2 cups of colloidal oatmeal or corn-starch to some lukewarm water in the bathtub and soaking in it for at least 15-20 minutes helps a lot. A seroprevalence study in Indian subjects showed that by the age of 40, more than 90% had virus in their body and were vulnerable for Shingles [1].Shingles can be prevented by taking proper vaccine.

Shingrix was approved by the US Food and Drug Administration (FDA) for the prevention of shingles in adults 50 years of age or older in 2017, followed by the European Commission in 2018 for the same age cohorts. GlaxoSmithKline Pharmaceuticals Ltd. (GSK) announced the launch of Shingrix Zoster Vaccine Recombinant, Adjuvanted) in India on Monday the 16 April 2023 for the same age cohorts.

Shingrix is the world's first non-live, recombinant subunit vaccine to be given intramuscularly in 2 doses and manufacturer claims the vaccine can protect for 10 years India's 260 million adults above 50 years of age at risk of shingles and its complications. Some people can still get shingles after getting the shingles vaccine, will have milder symptoms and a shorter duration illness.

GSK India launched its globally top-selling shingles vaccine Shingrix in India, at INR 12500 (150 US $) one-third of the US price of about $450 for two doses [3].

Case Reports:

1. **Autobiography:** I had seen on an average 2 cases per year since I started practice in public sector in 1968 July. It was only in 2007, at the age of 61 years I had, the first-hand experience of suffering from Shingles and experience it's post herpetic

neuralgia. It had started a mild fever, itching, tingling, burning and pain over the right upper side of the chest.
On 4th day of onset of listed symptoms, I noticed a single stripe of blisters that wrapped around the right side of my chest over thoracic ribs no 3-6. I had sought the treatment from a private dermatologist in New Delhi. She had put me on antiviral oral drugs for one-week, local application of smoothening powders and analgesics. Though the blisters healed over 2 weeks, the neurologic pain bothered for well over 2 months.

2. **My sister's case:** It was in May 2021 my sister Kusuma aged 62 years had Shingles over her nape of neck, upper part of left side chest including breast and back, after pro-dermal symptoms of malaise, fever, itching, tingling, burning and pain for 6 days. She had sough treatment of general practitioner initially, and then sought my opinion. She again was put on antiviral tablets of FabiFlu (Favipiravir) 200 mg twice daily, Crotorax (anti-pruritic lotion) local application for 15 days and antihistamine tablet for controlling itching twice daily for one week and once night next week. She suffered unusual period of post-herpetic neuralgia for over 4 months.

3. **Veena's Case:** This is a case of a lady around 63 years, just recovering from a recent episode of Backache/Sciatica. Current complaint of back ache while standing and walking relieved by rest or sitting for few minutes for about 6 months. Within 2 weeks of this recurrence of sciatica she had an attack of Shingles (herpes Zoster) painful rashes on left lumbar and hip and buttock region. A band of blisters were seen on left buttocks. There were red patches of skin covered in bumps that turned into fluid-filled, oozing blisters. The rashes were preceded by headache, fever, fatigue, light sensitivity and upset stomach for a week's time. After 3 weeks the blisters dried up, crust over, and the scabs clear up. She had suffered a lot of neurological pain for nearly 3 months. That Shingles episode had triggered silent Sciatica due to low immunity following Cancer therapy. Key history of importance included her having been diagnosed as early case of Breast cancer and treated by left sided mastectomy, and radiotherapy in one of the best Cancer Hospital in Bangalore. She had faced the entire episode positively and was doing well leading almost a normal life, till six months ago. Nearly a decade ago she had first episode of Sciatica, cured by Unani treatment.

Discussions:

Shingles is caused by varicella zoster virus (VZV), the same virus that causes chickenpox. After a person recovers from chickenpox, the virus stays dormant in their body, and can reactivate later, causing shingles. Some people can have shingles more than once in lifetime. Direct contact with the fluid from a patient's rash blisters can spread VZV to people who have never had chickenpox or never received the chickenpox vaccine. If they get infected, they will develop chickenpox, not shingles. They could then develop shingles later in life. The risk of spreading VZV to others is low if affected person covers the shingles rash. People with shingles cannot spread the virus before their rash blisters appear or after the rash crusts. People with chickenpox are more likely to spread VZV than people with shingles.

A 2022 retrospective study compared 394,677 people over the age of 50 years who had contracted COVID-19 with those who had not yet had COVID-19. The study found that a COVID-19 diagnosis in people over 50 years old was associated with a significantly increased risk of developing shingles. The study found that people aged 50 years or older with COVID-19 had a 15% higher risk of developing shingles than those without COVID-19. If a person has had chickenpox, they can develop shingles later in life. This is because the VZV remains dormant in their body and can reactivate later, causing shingles. A person's immune system prevents shingles from developing by continually tackling the VZV. Maintaining sufficient levels of VZV-specific T-cell immunity is important for suppressing shingles. The study states that an infection with the SARS-CoV-2 virus can result in T-cell immune dysfunction, which may trigger the latent VZV reactivation, causing shingles [2].

Nationwide community-based data are sparse for India. A few studies have shown HSV-2 seroprevalences among STD clinic attendees ranging from 43% to 83%, and lower prevalence in population-based cross-sectional studies from 7.9% to 14.6% [4]. A longitudinal population-based survey in Andhra Pradesh, India, in two rounds: 2004–2005 and 2010–2011, that collected Sociodemographic and behavioural, and dried blood spots tested for HSV-2 and Treponema pallidum IgG. The results 12 617 adults participated at baseline with 8494 at follow-up showed an Incidence of HSV-2 and syphilis per 1000 person-years was 25.6 and 3.00. Incidence of HSV-2 was higher in women vs men (31.1 vs 20.2) and in rural vs urban residents (31.1 vs 19.0) ($p<0.05$ for both). STI Sero-incidence increased in a stepwise fashion with age and was associated with spousal seropositivity for both sexes (incidence rate ratio (IRR) 2.59 to 6.78). Within couples the rate of transmission per 1000 couple-years from men to women vs women to men was higher for HSV-2 (193.3 vs 119.0) compared with syphilis (27.6 vs 198.8), $p<0.05$ for both [5].

A cross sectional clinic-epidemiological study (detailed history, examination, HIV screening and Tzanck smear were carried out in all cases) on all consecutive cases of herpes zoster reporting to the Dermatology Outpatient Department at a Tertiary Care Hospital in Bangalore from 01 Jun 2013 to 31 May 2014. The results showed 84 cases of herpes zoster with a mean age of 30 years. Majority (39%) of cases were seen in the 21–30-year age group. Thoracic segments were involved in 65.4%, cervical in 11.9%, cranial in 11.5%, lumbar in 8.3% and sacral segments in 3.5%. 63% of cases had zoster associated pain. One case had motor involvement.3.57% of the patients were HIV positive [6].

A prospective, hospital based, observational study involving 170 clinically diagnosed cases, in Indore, Madhya Pradesh, India reported Male to female ratio of 2.1: 1 (mostly due to care seeking bias). Maximum cases were seen in the age group of 51 - 60 years (22.9 %), followed by 31 - 40 and 61 - 70 (18.8 % each). Left side involvement was more common. Pain in the affected dermatome was the most common prodromal symptom. Fever and myalgia were the most reported constitutional symptoms. Less than half (80) patients had history of varicella. Thoracic dermatomes were the most involved followed by cranial, cervical, lumbar, and sacral dermatomes. Little over a

quarter (28.2%-48) patients had associated risk factors for herpes zoster infection. Complications secondary to herpes zoster infection developed in less than a quarter (40-23.5%) patient. Patients who developed complications had a significantly higher mean age than those who didn't. Post herpetic neuralgia was seen in 14.2 % patients [7].

A systematically conducted literature search of 27 studies, published between January 2011 and May 2020, reporting 3124 HZ clinical cases, indicated a high proportion in older adults (>50 years of age: 15.0–81.3%). Thoracic dermatome was consistently reported as the most frequent site affected by HZ (38.9–71.0%). Post-herpetic neuralgia and secondary bacterial infections were the two most frequent complications (10.2–54.7% and 3.5–21.0%, respectively). Despite the paucity of data and gaps in the reporting of HZ cases, available evidence indicate that the disease causes an important burden to older adults in India, suggesting that preventive strategies, along with recommendations to vaccination, can help mitigate the burden of HZ [8].

A cross-sectional study to determine the seroprevalence of herpes simplex virus type 1 and type 2 (HSV-1 & 2) IgG antibodies and their association with potential infection risk factors among Jordanians indicated an HSV-1 seroprevalence of 75.3% and that of HSV-2 was 2.9%. A total of 759 serum samples were collected (January to February 2020) and analysed by enzyme-linked immunosorbent assay and estimates for population seropositivity were determined by weighting the age-specific seroprevalence by the size of the population in each age stratum. After adjustment for possible confounders, regression analysis revealed higher seroprevalence with increase in age ($p < 0.005$) and low household income ($p = 0.002$). No significant differences in HSV-2 seroprevalence were observed in association with age, gender, family size, educational level, and socioeconomic status, may be due to low seropositivity [2].

The seroprevalence of herpes simplex virus-1 was 84.9% (95% confidence interval (CI): 78.4–90.0%) in Filipino men and 48.3% (95% CI: 43.6–53.0%) in Indian men. The seroprevalence of herpes simplex virus-2 was 8.3% (95% CI: 4.6–13.7%) in Filipinos and 3.7% (95% CI: 2.2–5.9%) in Indians. This study indicated that the seroprevalence rates of herpes simplex virus-2 in Filipino and Indian men living in Qatar were like those found in host countries. However, the seroprevalence of herpes simplex virus-1 in Indians, was substantially lower than that of other countries in Asia and developing countries worldwide [3].

Prevention:

The spread of Shingles from a patient can be minimized by, Covering the rashes with a clean soft sterile cloth. Avoid touching or scratching the rash. Washing hands often. Affected person need to avoid contact until rash crusts with pregnant women who have never had chickenpox or the chickenpox vaccine; premature or low birth weight infants; and people with weakened immune systems, due to receiving immunosuppressive medications or undergoing chemotherapy, organ transplant recipients, and people with human immunodeficiency virus (HIV) infection.

Shingles can be prevented by the chickenpox vaccine if the vaccine is administered before the individual gets chickenpox. If primary infection has already occurred, there are shingles vaccines that reduce the risk of developing shingles or developing severe shingles if the disease occurs, namely a live attenuated virus vaccine, Zostavax, and an adjuvanted subunit vaccine, Shingrix [1].

Know side effects include tiredness, muscle pain, a headache, shivering, fever, stomach pain, or nausea. Some people may experience these side effects that prevent them from doing regular activities, and wane away on their own in about 2 to 3 days.

A review by Cochrane concluded that Zostavax was useful for preventing shingles for at least three years. This equates to about 50% relative risk reduction. The vaccine reduced rates of persistent, severe pain after shingles by 66% in people who contracted shingles despite vaccination. Vaccine efficacy was maintained through four years of follow up. It has been recommended that people with primary or acquired immunodeficiency should not receive the live vaccine.[8]

Vaccine is Produced locally so what?

While India can boast of producing Shingrix vaccine locally, costing (US$ 150 for 2 doses) one third of the western world market, people at risk do not get protected automatically. The country doesn't have specific vaccine programs for elderly. However, there are multiple opportunities to introduce the vaccination starting with at high-risk population of i) immune-compromised, elderly (over 60 years).

Around a million of the population will experience herpes zoster (HZ), in India each year and a million (10%) of whom develop postherpetic neuralgia (PHN). Together, these illnesses produce a significant economic burden to the healthcare system as an average cost works around 100 US dollars (around a lakh INR) despite anti-viral being produced in India and are much cheaper than western world.

Plan of action suggested:

1. The National Programme for the Health Care for the Elderly (NPHCE) is an articulation of the International and national commitments of the Government of India for any person being a citizen of India, attained the age of sixty years or above. As one of the objectives of this initiative is to provide an easy access to promotional, preventive, curative and rehabilitative services to the elderly through community based primary health care approach, providing Shingrix vaccine to all beneficiaries must be made mandatory as soon as possible. The funding must be from the program for below poverty (BPL) elderly, and all above poverty families (APL) be made to pay for it.
2. Health Insurance: Nearly 950 million individuals (or 215 million families) are eligible for health insurance. However, the actual coverage is low (25%) since not all households eligible for government-subsidized insurance are covered at present. There are overlaps between different health insurance schemes. Around 75% of Indians pay for medical services from their pocket.

The plan should aim to cover the backlog of 10 billion (7%) 65 years and above individuals and immunocompromised (people who have cancer and are on chemotherapy, or who have had a kidney or heart transplant, and are taking medication to keep their transplant). population in next 2 years (2023-24 & 2024-25), and about 30 million (20%) between 50-65 years in next 2 years (2025-26 &2026-27). After 2027 there will be an annual cohort of 15 billion each year to cover. Covid 19 vaccinations empowerment and experience in 2021 & 2022 have enabled the primary health care centres and government dispensaries for this task. The private practitioners in urban towns and cities may provide starting in current year on payment. All Insurance plans starting this year must cover (just like USA where 96% of commercially insured members cover) SHINGRIX.

The vaccine must be procured at negotiated rate by Government of India and supplied to all states under UIP. The GOI procurement process is well equipped to handle this purchase and logistics due to recent covid 19 vaccination achievement, the best in the world.

The current political environment is very favourable due to ensuing general election in 2024.This should one of the key agenda and promise of all the parties for the same.

Conclusion:

Nationwide community-based data for Shingles incidence are sparse for India.

Even the significant number of cases of herpes zoster reported in Urban India, the disease causes a substantial burden to older adults in India.

In view of the growing elderly population in India, the finding of greater proportion of cases in >50 years of age holds importance.

Implementation of preventive strategies especially Shingrix vaccination along with guidance to primary healthcare practitioners can help prevent the disease and complications in vulnerable population.

Launching of Shingrix vaccine by GSK India has provided the best opportunity.

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