

Exploring the Quality-of-Life Impact, Disease Burden, and Management Challenges of GPP: The Provider and Patient Perspective [Podcast]

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Abstract: Generalized pustular psoriasis (GPP) is a rare, chronic, and debilitating disease characterized by flares of widespread erythema, desquamation, and pustule formation. GPP flares can be accompanied by systemic symptoms including fever, fatigue, malaise, and skin pain; severe cases may be fatal if untreated. Although GPP may occur concurrently with plaque psoriasis, they represent two distinct inflammatory conditions. Patients with GPP experience a substantial burden of disease, and the impact of GPP on an individual's mental health and quality-of-life (QoL) goes far beyond skin pain and discomfort. The rarity of GPP may result in a misdiagnosis, as the sudden onset of skin pustules may be mistaken for a primary infection. Misdiagnosis with a subsequent delay in treatment has tremendous negative consequences for the affected patient. In September 2022, spesolimab became the first FDA-approved medication in the US for the treatment of GPP flares in adults. Spesolimab has since been approved by regulatory agencies in numerous countries, including Japan, Mainland China, and the EU. Prior to spesolimab, the clinical management of GPP relied on the off-label use of systemic or biologic therapies approved for plaque psoriasis or other inflammatory conditions. There is a need for increased education among healthcare providers regarding the clinical diagnosis, risk stratification, and therapeutic management of this rare disease, including the other novel GPP-specific therapies in development. In this podcast, two dermatologists and a patient who has plaque psoriasis and GPP discuss the clinical presentation, symptoms, disease burden, QoL impacts, diagnostic challenges, and therapeutic strategies for the management of GPP.

Keywords: generalized pustular psoriasis, GPP, pustules, quality-of-life, IL-36, spesolimab, plaque psoriasis, inflammatory skin disease

Guests: Dr Jason E Hawkes, Dr. Tina Bhutani, Dale V Reisner

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Dr. Jason E. Hawkes: Welcome to our listeners. I am Dr. Jason Hawkes, a board-certified medical dermatologist in the Greater Sacramento area. I specialize in the care and treatment of complex and chronic inflammatory skin diseases, including the management of psoriasis and patients living with generalized pustular psoriasis, or GPP. I would like to welcome and introduce Dale Reisner, a patient advocate with plaque psoriasis and GPP, as well as Dr. Tina Bhutani, my colleague and fellow medical dermatologist.

Today we will discuss the clinical presentation of GPP, the patient journey, diagnostic challenges, and novel management strategies from the perspective of the patient and provider. Tina and Dale, can each of you share some additional information regarding your background and experience with GPP?

Dr. Tina Bhutani: Hi everyone, my name is Dr. Tina Bhutani. I am an associate professor of dermatology at the University of California, San Francisco. Most of the patients that I see in clinic have complex skin conditions like psoriatic disease. I have seen and managed several patients with GPP in my career.

Dale V Reisner: Hello, my name is Dale Reisner and I have lived with plaque psoriasis and GPP for over 45 years. My psoriatic disease started when I was 17 years old. I live in Yankton, South Dakota, and have been married to my beautiful wife for over 36 years. She has also had to endure the negative impacts of my GPP and has been an incredible support to me. I am happy to be here today to share my experiences.

Dr. Jason E. Hawkes: Thank you both for being here. Today we are going to be discussing several topics, including the clinical presentation of GPP, its impact on patient's quality of life, challenges to the accurate and timely diagnosis of GPP, healthcare barriers impacting treatment, and the unmet needs related to the management of this pustular variant of psoriasis. Tina, could you start us off by providing a brief overview of GPP? [00:01:54]

Dr. Tina Bhutani: Sure, I am happy to start us off. GPP is a rare, potentially life-threatening skin condition that is characterized by sterile, monomorphic pustules across large areas of the body, within a background of erythema and desquamation. Systemic symptoms can also be associated with GPP, such as fever, fatigue, malaise, and skin pain.

This condition can occur as an isolated event or have periods of recurring worsening, known as GPP flares, which can result in hospitalization if not recognized or treated urgently.¹ Flares may be the result of a change in medications, an infection, pregnancy, hypocalcemia, or other environmental triggers that are not easily identified.

GPP shares some similarities with plaque psoriasis. However, they represent two distinct inflammatory conditions.² Because GPP is much less prevalent, physicians can face challenges in successfully diagnosing and treating GPP, and this can negatively impact patients who have GPP.

Dr. Jason E. Hawkes: Dale, as a patient with plaque psoriasis and GPP, can you tell us about the symptoms you experience during a typical GPP flare?

Dale V Reisner: I'd be happy to share my story. I have had plaque psoriasis since I was 17 years old, and it was not until years later, in 2005, that I was diagnosed with GPP.

I can tell when a GPP flare is starting. It begins to itch, followed by a warm feeling of the skin. I then get redness, and small pustules start to form within the redness. The skin then begins to feel painful. The intensity of the pain is usually a five out of ten, but goes up to eight out of ten on bad days. When the pustules dry up, it leaves an open sore that can crack and bleed. The pain feels like a paper cut multiplied by 10,000 spread out over the entire body.

When I am in a bad flare, GPP covers my body. As a result of my severe pain and there being limited GPP treatments, I was taking oral pain medication for many years.

Over the course of the last 10 to 15 years, I have had multiple hospitalizations. When I had my first GPP flare in 2005, I stayed in the hospital for nine days after developing a serious skin infection where my pustules were. [00:04:08]

Dr. Tina Bhutani: I think it's important to note that, like Dale, many patients with GPP have recurrent GPP flares throughout their life, and a severe flare may result in serious complications,³ such as a secondary infection, sepsis, organ failure and even death, if left untreated.

Like Dale, I have patients whose flares start as a single pustule, but if they do not start treatment urgently, these can quickly expand to thousands of pustules covering large parts of their body. They may also start to feel unwell or develop systemic symptoms such as fatigue, skin pain, or fever.

Dr. Jason E. Hawkes: Great points, Dale and Tina. You are describing some common GPP symptoms, as well as the potential consequences of a delayed diagnosis or inadequate disease management. These complications are not trivial, such as secondary organ failure, or an opportunistic infection resulting from the widespread skin barrier breakdown.

It's important to also note that a primary infection can trigger GPP,⁴ and this should be considered in the differential diagnosis, since an infection may result in pustule formation within the skin. Steps to rule out a primary versus secondary infection in patients presenting with acute GPP flares are essential for all treating providers.

Dr. Tina Bhutani: Dale, it sounds as though your disease is managed much better than it was in the past. Could you share more about your patient journey and efforts to find better GPP treatments?

Dale V Reisner: Sure. My initial struggle was really in getting an accurate diagnosis for my underlying condition. As I mentioned earlier, I have had plaque psoriasis for many years, which was recognized and diagnosed much earlier than my GPP.

I was evaluated by many dermatologists across the country, and many did not seem familiar with GPP or its proper management. At one point, a provider had me on seven different medications at once, with little success. I felt as if they were just throwing everything at the wall and hoping something would stick, or work for my disease. As a patient, I was frustrated and disheartened.

After that, I was referred to an excellent dermatologist who put me on a psoriasis biologic, which got both my plaque psoriasis and GPP under better control. However, I continued to struggle to find a plaque psoriasis biologic that works for a longer period of time, and also keeps my GPP under sufficient control. This has resulted in me switching from one biologic to another, sometimes because the drug stops working, or other times because I have had medical problems, such as fungal infections that required me to stop them. I am currently managing my condition with a combination of light therapy and apremilast.

I have accepted that my GPP will never fully be gone. I have always had residual pain and itchiness on parts of my body, and I know I could easily flare again, but at least it's manageable right now. It's hopeful knowing that there are specific GPP treatments available now and in development. [00:07:02]

Dr. Jason E. Hawkes: Thanks, Dale. Having to cycle through so many doctors and different treatments must have been challenging. Would you like to talk more about that experience and any additional challenges?

Dale V Reisner: My GPP was not under adequate control until a previous dermatologist assumed my psoriasis care. Compared to some of the other providers I had seen, I could tell that he understood my condition and felt confident that he knew what he was talking about. He also recognized that I had several coexisting conditions, including hypertension, diabetes, and elevated cholesterol. When he told me I needed to make certain lifestyle changes, or consider starting a specific medication, I did what he said because I trusted that he had my best interests at heart. I started walking and changed my lifestyle in 2015, and thankfully, I have been able to reverse those comorbidity conditions.

I stayed with that dermatologist until he retired. There was a new dermatologist that opened the door close to my home, but I would have preferred to stay with the former, despite the distance from home, he knew my history. I had full trust in his care. I did not want to have to start all over again with a new dermatologist. The bottom line is that you have to travel to see a specialist who is comfortable managing your GPP, especially if you live in a rural area like I do.

I have traveled more than 90 miles to receive appropriate care for my GPP. However, if I were to experience a severe GPP flare today, I would not be able to afford these travel costs, let alone the office visit and the medication costs, which add up over time. It is very challenging. [00:08:36]

Dr. Tina Bhutani: Dale, I am glad you mentioned several patient-related issues, such as the difficulty finding psoriasis specialists, rising healthcare costs, and easy access to specialty medications. This is not just a problem for patients with GPP, but rather systemic issues that need to be addressed across the entire healthcare system.

Medication co-pay, or patient assistance programs are examples of temporary efforts that can help patients afford specialty treatments. Increasing the accessibility of specialty medications for chronic or potentially life-threatening diseases like GPP is extremely important, because these treatments can significantly improve a patient's quality of life.⁵

GPP patients may require hospitalization for GPP flare management, pain control, or care for complications related to severe or untreated GPP.⁶ This can result in significant financial burden for patients. Furthermore, GPP care may also cause patients to miss work or disrupt critical family responsibilities, while they are treated in the hospital for a severe flare. In my experience, the early recognition and treatment of GPP can often prevent hospitalization, which is why disease education is so important.

Dr. Jason E. Hawkes: Thanks for sharing these great points regarding the GPP patient journey and struggle. Dale, can you share with us more about your experience living with GPP and its impact on your overall quality of life? [00:09:57]

Dale V Reisner: Living with GPP has been very difficult, and I could not have made it without the help of my wife. I had psoriasis before I met my wife, so we have always had these health challenges to deal with together. She plays a big role in the management of my GPP and helps me preserve some quality of life. For example, I know how lucky I am that she makes me feel loved despite the appearance of my skin. Intimacy can also be a challenge in a close relationship when there

is an underlying skin disease like GPP, though we have been able to navigate that together. I am sure there are GPP patients out there possibly worse off than I am, who do not have the support that I have because they are afraid to get close to others. I am very thankful to have a strong marriage, and for the support of my wife who is so caring and devoted to me.

However, I continue to struggle with simple daily activities such as opening doors or cans of food. We had to replace all the doorknobs in our house with handles because I cannot turn them when I had severe flares in my GPP or plaque psoriasis. The new handles allow me to push them down with my arms or elbow. I also limit my use of sharp knives for safety reasons, since I do not have much strength in my hands to grip the handles tightly enough. At times, it's difficult for me to tease out the GPP symptoms from my underlying plaque psoriasis.

There's also a profound psychological impact on me in between my GPP flares. I worry about when a new flare might occur and the financial impact that it might have on my family if I were to need urgent or emergency medical care.

Finally, it's my opinion that all patients living with GPP should consider joining a GPP patient support group or other social support groups, since the detrimental effects of this disease extends far beyond the skin of the patient. [00:11:49]

Dr. Tina Bhutani: Thank you, Dale. I want to add some additional information about what patients experience in between GPP flares. As you have noted, residual symptoms, such as itch or pain, may continue in the background even when most other symptoms of GPP are well controlled by medical treatments. These symptoms may occur in normal appearing skin, or within psoriasis plaques for those patients like you who have both GPP and plaque psoriasis.

Also, the unpredictability or anticipation of GPP flares can adversely affect the patient's mental health and potentially lead to debilitating, anxiety or depression.

It's also important to reiterate the chronic relapsing-remitting nature of GPP, and the need for effective maintenance therapy to help reduce residual symptoms, decrease the number of GPP flares, and reduce the psychological impact of this disease. Topical steroids are often insufficient to adequately control GPP, and other "as needed" treatment such as oral steroids are inappropriate, as they may ultimately lead to disease-worsening over time.⁷

Jason, now that we have heard Dale speak about his journey to a proper diagnosis and improved treatment, in your opinion, why is it so difficult to identify, diagnose, and manage patients with GPP?

Dr. Jason E. Hawkes: As Dale has explained, it can be difficult for patients with GPP to receive an accurate diagnosis or get appropriate medical treatments. First, I believe there's a general lack of awareness of GPP among physicians. Given its rarity, GPP only accounts for about 1% of all cases of psoriasis.⁸ A dermatologist or provider may only see a handful of GPP cases throughout their entire career. Dale's patient journey accentuates this, given his visits to multiple dermatologists before receiving a GPP diagnosis and being placed on a psoriasis biologic. His difficulty finding and accessing a specialist who is comfortable managing GPP is a common complaint from patients.

Second, GPP is a heterogeneous disease.⁶ These variations in the clinical presentation may also delay a GPP diagnosis. The patient's description of symptoms, skin manifestations, clinical findings at the time of their visit, and personal or family history of pre-existing plaque psoriasis may interfere with arriving at a correct diagnosis. For example, some GPP patients present with joint and muscle pain flares, while others may have other predominant symptoms such as itching or skin pain.⁹ Patients with GPP may be misdiagnosed as having adverse drug reactions or an underlying primary infection, resulting in the formation of widespread pustules and erythema.^{10,11} Unfortunately, there is no specific or commercially available test for the rapid diagnosis of GPP.

[00:14:29]:

Third, access to specialty medications in general is cumbersome and expensive for providers and patients. Most insurance companies require prior authorization for biologics and specialty medications before they will cover the prescribed medication. This is even more complicated when a payer requires the trial of one or more medications prior to the approval of a specialty medication, a process referred to as "step therapy". Overall, the prior authorization process frequently results in significant treatment delays for patients.

The cost of specialty treatments is another issue that patients often face, as Dale shared with us earlier, the economic burden for patients with GPP is about three times higher than

that of the general population and is 1.8 times higher than in patients diagnosed with plaque psoriasis. In-patient hospital stays and biologic medications make up most of these increased costs.¹²

Finally, a key factor in the delayed treatment of GPP is the lack of GPP-specific therapies and management guidelines. Prior to September 2022, GPP was primarily managed using off-label treatments approved for plaque psoriasis. Unfortunately, these treatments often fail because they were not intended for the treatment of GPP, and do not adequately block the elevated IL-36 signaling driving this chronic inflammatory condition.

Dale's history highlights the overall inadequacy and incomplete effectiveness of these plaque psoriasis medications repurposed for the off-label treatment of GPP. When GPP is not fully controlled, the patient is likely to experience subsequent disease flares. **[00:16:09]**

Dr. Tina Bhutani: I completely agree. The good news is that the first GPP-specific treatment is now available in the US, having been approved by the US FDA in September of 2022.¹³ It's called spesolimab, and is sold under the brand name SPEVIGO®. Spesolimab is now also approved by the regulatory agencies in many other countries, including Japan, Mainland China, and the European Union.¹⁴

GPP patients now have a safe, effective, targeted treatment option that has been shown to provide rapid and sustained control of GPP flares in adults.¹⁵ Spesolimab is currently administered via intravenous infusion, and subcutaneous delivery is being developed in the Effisayil™ 2 trial.¹⁶ Results from the trial showed that there was significant prevention of GPP flares for up to 48 weeks.¹⁷ This will further increase treatment accessibility, and the potential for long-term disease management.

Dr. Jason E. Hawkes: Thank you for that update, Tina. To close out what has been a very informative podcast, I'd like to collect any final thoughts or key takeaways for dermatologists, or patients living with GPP.

Dale V Reisner: One of my friends, who also has GPP, recently told me that he did not realize he could have a family in addition to his GPP. He had not considered having them both at the same time.

I like to say, "I may have GPP, but GPP does not have me", because I am not going to let GPP get in the way of what I want in life. I have always tried to have a positive outlook on life and have realized that I am my own best advocate for my health.

I want patients to know that it's possible to lead a fulfilling life, despite living with GPP. New, better treatments are now available for GPP. **[00:17:46]**

Dr. Tina Bhutani: First, I wanted to echo Dale's sentiments and optimism. His advice should be encouraging to other patients with GPP. I commend him on his determination to not give up and find the right doctor to treat his GPP.

As additional educational resources become available to raise awareness for this debilitating disease, improvements in diagnosing and managing GPP will likely follow.

The approval of spesolimab is a huge step forward in GPP-specific management. Hopefully, other treatments for GPP currently in development, and subcutaneous delivery of spesolimab, will be available to patients soon.

Dr. Jason E. Hawkes: Great points, Dale and Tina. I want to add that further education on GPP is needed for providers, patients, and the general population. GPP is a rare disease and most physicians may only see a few cases in their entire career, many of which may present in inpatient or emergency care settings.¹⁸ The availability of educational materials detailing what GPP is, its link with dysregulated, IL-36 signaling, and how this disease differs from plaque psoriasis, and other conditions that mimic pustular variants, have the potential to help reduce the time to a GPP diagnosis and the initiation of effective treatments.

I want to thank you, Tina and Dale, for participating in this conversation today. It has provided a valuable perspective on GPP, its impact on patients, and obstacles that interfere with the diagnosis and treatment of this chronic inflammatory condition. For anyone looking for more information on GPP, I hope listeners will review the previous podcasts in this podcast series, where we discuss the characteristics of GPP, as well as novel treatment strategies to better control disease flares, and improve the quality of life of affected patients.

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