Niosomal Gel: A Revolutionary Approach for the Treatment of Psoriasis

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Abstract

Psoriasis is a chronic autoimmune skin disease that poses challenges in terms of effective and safe treatment options. In recent years, niosomal gel formulations have emerged as a revolutionary approach for psoriasis treatment. These formulations offer enhanced drug delivery, improved bioavailability, and reduced side effects compared to conventional topical treatments. Niosomal gels are nanovesicular carrier systems composed of non-ionic surfactants that encapsulate drugs within their lipid bilayers. They allow for controlled drug release, improved stability, and enhanced penetration through the skin.

This article provides an overview of psoriasis, its challenges, and the limitations of current treatment options. It introduces niosomal gel formulations as a promising solution, highlighting their advantages such as enhanced drug delivery, increased bioavailability, reduced side effects, and improved patient compliance. The development and optimization of niosomal gels involve key steps like niosome preparation, characterization, formulation optimization, and stability and efficacy evaluation. The article emphasizes the importance of stability studies, in vitro and in vivo evaluations, and compares niosomal gels with conventional treatments and other drug delivery systems.

Clinical studies have demonstrated the efficacy of niosomal gel formulations in psoriasis treatment, showing better clinical outcomes compared to placebo and conventional gels. The article concludes by discussing future directions and the potential of combining niosomal gels with other treatment modalities to enhance efficacy and improve the quality of life for psoriasis patients.

***Keywords**: Psoriasis, niosomal gel, topical drug delivery, enhanced drug delivery, bioavailability, reduced side effects, patient compliance*

Introduction

Psoriasis is a chronic autoimmune skin disease that affects millions of people worldwide. The search for effective and safe treatments for psoriasis has led researchers to explore innovative formulations and delivery systems. One such breakthrough in the field of topical drug delivery is the development of niosomal gel formulations. Niosomal gels have shown promising results in the treatment of psoriasis, offering enhanced drug delivery, improved efficacy, and reduced side effects. The etiology of psoriasis is believed to be multifactorial, involving genetic predisposition, immune system dysfunction, and environmental triggers.

Psoriasis presents itself in various forms, with plaque psoriasis being the most common type. Plaque psoriasis appears as raised, inflamed areas of skin covered with silvery-white scales, typically occurring on the scalp, elbows, knees, and lower back. Other forms of psoriasis include guttate psoriasis, characterized by small, drop-like lesions, pustular psoriasis, featuring pus-filled blisters, and inverse psoriasis, affecting skin folds such as the groin and armpits.

The pathophysiology of psoriasis involves an overactive immune response. In a healthy individual, skin cells go through a natural cycle of growth and shedding over a period of about a month. However, in psoriasis, this process accelerates to a mere few days. The immune system mistakenly activates T cells, a type of white blood cell, triggering the release of inflammatory substances and causing rapid cell turnover. As a result, the skin cells pile up on the surface, leading to the characteristic redness, scaling, and thickening associated with psoriasis.

While the exact triggers for psoriasis flare-ups vary from person to person, several factors have been identified as potential contributors. These include stress, certain medications, infections, injury to the skin, hormonal changes, and even weather conditions. Additionally, genetic factors are believed to play a role, as psoriasis tends to run in families. However, it is important to note that not everyone with a genetic predisposition will develop the disease.

Living with psoriasis can have a significant impact on an individual’s quality of life. Beyond the physical discomfort and visibility of the skin lesions, psoriasis is associated with social stigma, self-esteem issues, and an increased risk of developing other health conditions such as psoriatic arthritis, cardiovascular disease, and depression. Therefore, it is crucial to raise awareness about psoriasis, promote early diagnosis, and ensure appropriate management to improve the well-being of those affected by this chronic condition.

In this paper, we will delve deeper into the different aspects of psoriasis, including its clinical manifestations, underlying mechanisms, diagnostic approaches, available treatment options, and strategies for coping with the disease. By exploring the current knowledge and advancements in the field, we aim to provide a comprehensive understanding of psoriasis and

contribute to the ongoing efforts to improve the lives of individuals affected by this challenging condition.

Understanding Psoriasis and its Challenges

Psoriasis is characterized by the rapid growth of skin cells, resulting in the formation of thick, red, and scaly patches on the skin. It is caused by an overactive immune system that mistakenly attacks healthy skin cells. The exact cause of psoriasis is still unknown, but it is believed to be a combination of genetic and environmental factors.

The current treatment options for psoriasis include topical creams, phototherapy, systemic medications, and biologic agents. However, these treatments have limitations such as poor drug penetration, low bioavailability, and potential side effects. Therefore, there is a need for innovative and effective topical delivery systems that can overcome these challenges and provide better outcomes for patients. One of the primary challenges of psoriasis lies in its unpredictable nature. The disease can go through periods of remission and flare-ups, making it difficult to predict when symptoms will worsen or improve. This unpredictability can lead to heightened anxiety and stress for individuals, as they navigate the uncertainty of managing their condition on a day-to-day basis.

The visible nature of psoriasis lesions poses another challenge. The red, scaly patches often appear on exposed areas such as the scalp, face, hands, and legs, making them difficult to hide. This visibility can result in social stigma, discrimination, and feelings of self-consciousness. Individuals with psoriasis may experience lowered self-esteem, depression, and anxiety, affecting their overall quality of life and interpersonal relationships.

Psoriasis also presents physical challenges, as the symptoms can be uncomfortable and even painful. The itching and burning sensations associated with psoriasis can be distressing, hindering sleep and daily activities. Additionally, the presence of psoriasis lesions may restrict movement, causing discomfort and difficulty in performing routine tasks.

Furthermore, psoriasis is not limited to skin involvement alone. It is increasingly recognized as a systemic disease, with potential links to other health conditions. Psoriatic arthritis, a type of inflammatory arthritis, commonly coexists with psoriasis. This adds an additional layer of complexity to the disease, as joint pain and stiffness can further impact mobility and overall well-being.

Treatment of psoriasis poses its own set of challenges. While various treatment options are available, including topical medications, phototherapy, systemic drugs, and biologics, finding the most suitable approach for each individual can be a trial-and-error process. Response to treatment varies, and some therapies may have associated side effects that need careful consideration.

Furthermore, access to appropriate care and treatment can be a challenge for some individuals. Factors such as cost, availability of specialized dermatologists, and insurance coverage may limit access to effective treatments, hindering optimal disease management.

To address these challenges, a comprehensive approach is needed. It involves patient education and support, fostering a supportive and understanding society, and advancing research and treatment options. Increasing awareness about psoriasis can help combat social stigma and promote acceptance. Providing resources, support groups, and mental health services can assist individuals in coping with the psychological impact of the disease. Continued research efforts are vital for uncovering the underlying mechanisms of psoriasis and developing more effective, personalized treatments.

Introduction to Niosomal Gel Formulations

Niosomal gels are a type of nanovesicular carrier system that can encapsulate both hydrophilic and hydrophobic drugs. These vesicles are composed of non-ionic surfactants and can entrap drugs within their lipid bilayers. The unique structure of niosomes allows for controlled release of the drug, improved stability, and enhanced penetration through the skin.

Niosomal gel formulations have gained attention as a potential solution for the treatment of psoriasis. These formulations can address the limitations of conventional topical treatments by improving drug penetration, reducing systemic exposure, and enhancing patient compliance. The development of niosomal gels for psoriasis treatment offers a promising alternative for patients who are seeking safe and effective therapies. Niosomes have shown great potential. They can encapsulate various anti-inflammatory agents, such as corticosteroids or calcineurin inhibitors, which are commonly used to manage psoriasis symptoms. By encapsulating these drugs within niosomes, their stability is enhanced, and they can be delivered directly to the affected skin layers, improving drug penetration and reducing systemic side effects.

The targeted delivery provided by niosomes allows for a localized therapeutic effect, minimizing the exposure of healthy skin to the medication and potentially reducing the risk of adverse reactions. This localized approach may also enhance the efficacy of the treatment by ensuring higher concentrations of the drug reach the psoriatic lesions.

Moreover, niosomes can be modified to enhance their interaction with the skin and improve drug absorption. Surface modifications with ligands or peptides can facilitate the active targeting of specific cells or receptors involved in psoriasis pathogenesis. This targeted delivery approach holds promise for delivering drugs that specifically modulate the immune response or target key inflammatory pathways involved in psoriasis development.

Although niosomes for psoriasis treatment are still in the early stages of development, preclinical studies have demonstrated their potential efficacy and safety. Further research and

clinical trials are necessary to evaluate their long-term effectiveness, compare them to existing treatment modalities, and ensure their safety profile.

Advantages of Niosomal Gel Formulations

One of the primary advantages of niosomes is their ability to encapsulate both hydrophilic and lipophilic drugs. Psoriasis is a complex disease with multiple inflammatory pathways involved. The encapsulation of different classes of drugs within niosomes allows for combination therapy, where multiple drugs with different mechanisms of action can be delivered simultaneously. This approach provides the opportunity for synergistic effects and enhanced therapeutic outcomes.

Niosomes also offer improved stability and controlled release of drugs. Psoriasis is a chronic condition that requires long-term treatment. The stability of drugs within niosomes ensures their integrity during storage and transportation, preserving their therapeutic efficacy. Additionally, niosomes can provide sustained and controlled release of drugs, maintaining therapeutic drug levels over an extended period. This controlled release profile helps in reducing the frequency of dosing, enhancing patient compliance, and improving overall treatment outcomes.

The ability of niosomes to penetrate the skin layers is another advantage in the treatment of psoriasis. Psoriatic lesions are characterized by an abnormal skin barrier function, allowing for enhanced drug permeation. Niosomes can encapsulate drugs and deliver them directly to the affected skin layers, promoting deeper penetration and better targeting of the lesions. This localized delivery reduces the systemic exposure of drugs, minimizing potential side effects on healthy tissues and organs.

Furthermore, niosomes can be tailored to improve their interaction with the skin and enhance drug absorption. Surface modifications with ligands or peptides can facilitate active targeting of specific receptors or cells involved in psoriasis pathogenesis. This targeted delivery approach holds the potential for improved efficacy by delivering drugs precisely to the sites where they are most needed.

In terms of safety, niosomes are generally considered biocompatible and biodegradable. They have shown low toxicity and minimal irritation, making them suitable for topical application in the treatment of psoriasis. This favorable safety profile is crucial for long-term use and patient acceptance.

Here are some important advantages of niosomes -

1. **Enhanced Drug Delivery:** Niosomal gels have been shown to improve the permeation of drugs through the skin. The vesicular structure of niosomes allows for efficient encapsulation and controlled release of the drug, leading to enhanced drug delivery to the target site.

2. **Increased Bioavailability:** The use of niosomal gels can increase the bioavailability of drugs by overcoming the low solubility and poor absorption issues associated with certain drugs. The encapsulation of drugs within niosomes protects them from degradation, resulting in improved drug stability and bioavailability.

3. **Reduced Side Effects:** One of the major advantages of niosomal gels is their ability to minimize systemic exposure and reduce the risk of systemic side effects. The localized delivery of drugs to the affected area minimizes the exposure of healthy tissues to the drug, resulting in reduced side effects.

4. **Improved Patient Compliance:** Niosomal gels offer a convenient and easy-to-use formulation for patients. The gel-based formulation allows for easy application and absorption, promoting patient compliance and adherence to the treatment regimen.

Development and Optimization of Niosomal Gel Formulations

The development and optimization of niosomal gel formulations for psoriasis treatment involve several key steps. These include the preparation of niosomes, characterization of the vesicles, optimization of the formulation, and evaluation of the stability and efficacy of the final product.

The preparation of niosomes involves the hydration of lipid layers using non-ionic surfactants. The choice of surfactants, their concentration, and the method of preparation play a crucial role in the formation and stability of niosomes. Various techniques such as lipid layer hydration, reverse-phase evaporation, and thin-film hydration can be employed for the preparation of niosomes.

Characterization of niosomes is essential to determine their size, shape, surface charge, and entrapment efficiency. Techniques such as dynamic light scattering, transmission electron microscopy, and zeta potential analysis can be used to assess the physicochemical properties of niosomes. These characterization studies provide valuable information about the stability and suitability of the niosomal formulation for further development.

Optimization of the formulation involves the selection of the most suitable surfactant, lipid composition, and drug-to-lipid ratio. Factors such as vesicle size, entrapment efficiency, and drug release kinetics are optimized to achieve the desired therapeutic effect. Various optimization techniques such as factorial design, response surface methodology, and Taguchi design can be employed to optimize the niosomal gel formulation.

Niosomal gels combine the advantages of niosomes, which are vesicular structures composed of non-ionic surfactants, with the desirable properties of gel formulations. This innovative

approach offers numerous benefits and holds promise for various applications in the pharmaceutical field.

The development of niosomal gel formulations begins with the preparation of niosomes. Niosomes are formed by hydrating a mixture of non-ionic surfactants with an aqueous phase. The resulting vesicles can encapsulate hydrophilic and lipophilic drugs, providing versatility in drug delivery. These niosomes can then be incorporated into a gel matrix, resulting in a niosomal gel formulation.

One of the key advantages of niosomal gels is their ability to enhance the stability and controlled release of drugs. The gel matrix provides physical stability to the niosomes, preventing their aggregation and maintaining their structural integrity. This stability is crucial for maintaining the encapsulated drug's efficacy during storage and transportation.

Additionally, the gel matrix allows for controlled release of the encapsulated drug over an extended period. The niosomal gel formulation offers sustained release characteristics, enabling a prolonged therapeutic effect and reducing the frequency of dosing. This controlled release profile is especially beneficial for drugs with a narrow therapeutic index or those requiring continuous administration.

Niosomal gels also possess excellent skin penetration capabilities, making them suitable for topical applications. The gel matrix, in combination with the niosomes, facilitates the efficient penetration of drugs into the skin layers. This enhanced permeation can be particularly advantageous in the treatment of skin diseases, such as psoriasis or dermatitis, where targeted delivery to specific skin layers is desired.

Furthermore, the niosomal gel formulation allows for the incorporation of both hydrophilic and lipophilic drugs. This characteristic opens up possibilities for combination therapy, where multiple drugs with different solubilities and mechanisms of action can be delivered simultaneously. The versatility of niosomal gels in accommodating diverse drug types expands their potential applications in various therapeutic areas.

The development of niosomal gels also offers opportunities for customization and optimization. The composition and characteristics of niosomes, such as size, charge, and surface modifications, can be tailored to meet specific requirements. This customization allows for the optimization of drug release kinetics, targeting capabilities, and stability of the formulation. By optimizing these parameters, the efficacy and safety of the niosomal gel can be enhanced.

In terms of formulation considerations, niosomal gels should be developed to ensure optimal physical and chemical stability. Proper selection of surfactants and lipids, as well as optimization of their concentrations, is crucial to achieve stable niosomes. The gel matrix should be carefully designed to provide suitable rheological properties, such as viscosity and spreadability, to ensure ease of application and patient compliance.

The safety profile of niosomal gels is an important aspect to consider during development. Non-ionic surfactants commonly used in niosomal formulations are generally regarded as safe and exhibit low toxicity. However, thorough evaluation of the compatibility and potential irritation of the gel formulation with the skin is necessary to ensure its safety for topical application.

Evaluation of Stability and Efficacy

Stability studies are conducted to assess the physical and chemical stability of niosomal gel formulations. Factors such as temperature, pH, and storage conditions can influence the stability of niosomes. Techniques such as differential scanning calorimetry, X-ray diffraction, and Fourier-transform infrared spectroscopy are used to evaluate the stability of the formulation.

The efficacy of niosomal gel formulations is evaluated through in vitro and in vivo studies. In vitro studies involve the assessment of drug release, skin permeation, and deposition using techniques such as Franz diffusion cells and tape stripping. These studies provide valuable insights into the drug release kinetics and penetration of niosomal gels through the skin.

In vivo studies are conducted to evaluate the therapeutic efficacy and safety of niosomal gel formulations. Animal models and human volunteers can be used to assess the anti-psoriatic activity, skin irritation, and tolerability of the formulation. Histopathological examination, psoriasis area severity index (PASI) scoring, and physician’s global assessment are commonly used to evaluate the efficacy of niosomal gel formulations.

One of the primary evaluations of niosomal gel formulations is the assessment of their physical characteristics. This includes the determination of particle size distribution, zeta potential, morphology, and rheological properties. Techniques such as dynamic light scattering, scanning electron microscopy, and rheological measurements are commonly employed for these evaluations. Understanding the physical attributes of niosomal gels helps in optimizing their formulation and assessing their suitability for topical application.

The encapsulation efficiency of the niosomal gel formulation is another important parameter to evaluate. It determines the percentage of the drug that is successfully entrapped within the niosomes. Various methods such as centrifugation, dialysis, or ultrafiltration can be employed to measure the encapsulation efficiency. A high encapsulation efficiency indicates the formulation’s ability to retain a significant amount of the drug, enhancing its therapeutic efficacy.

Furthermore, stability studies are performed to evaluate the formulation’s robustness and shelf-life. These studies involve subjecting the niosomal gel formulation to various stress conditions, including temperature, humidity, and light. By monitoring the physical, chemical,

and biological parameters over a defined period, stability studies help determine the formulation's shelf-life and storage requirements. Common parameters evaluated during stability studies include drug content, particle size, zeta potential, drug release, and physical appearance.

During stability studies, accelerated stability testing is often conducted by subjecting the formulation to elevated temperatures, typically 40°C or higher. This accelerated aging helps simulate the long-term storage conditions and assesses the formulation's stability under extreme conditions. Additionally, real-time stability studies are performed at ambient temperature to monitor the formulation's stability over an extended period, typically up to 12 months or more.

In addition to physical and chemical evaluations, stability studies also encompass microbiological assessments. Microbial growth is a concern, especially for topical formulations. Therefore, the niosomal gel formulation undergoes microbial testing to ensure that it meets the required microbiological standards. These tests include the evaluation of microbial content, sterility, and preservative efficacy.

To ensure the accuracy and reliability of the evaluation and stability studies, it is crucial to follow appropriate protocols and guidelines set by regulatory authorities. These guidelines outline the specific tests, acceptance criteria, and recommended storage conditions for stability studies. Adhering to these guidelines enables the generation of reliable data that can be used to support regulatory submissions and ensure the safety and efficacy of the niosomal gel formulation.

Comparison with Conventional Treatments

Niosomal gel formulations have shown significant advantages over conventional topical treatments for psoriasis. Compared to creams and ointments, niosomal gels offer improved drug penetration, enhanced bioavailability, and reduced side effects. Furthermore, niosomal gels have the potential to overcome the limitations of systemic medications by providing localized drug delivery with minimal systemic exposure.

Compared to other novel drug delivery systems such as liposomes and nanoparticles, niosomal gels have several advantages. Niosomes are easier to prepare, cost-effective, and have a higher stability compared to liposomes. Additionally, the use of non-ionic surfactants in niosomal formulations reduces the risk of toxicity and immunogenicity associated with nanoparticles.

Niosomal gel formulations have emerged as a promising approach for the treatment of psoriasis, offering several advantages over conventional methods. Let's compare the benefits of niosomal gel formulations with traditional treatment modalities in managing psoriasis:

- **Enhanced Drug Penetration:**

Niosomal gels provide improved skin penetration capabilities compared to conventional creams or ointments. The niosomal vesicles facilitate the targeted delivery of drugs to the affected skin layers, ensuring deeper penetration and better targeting of psoriatic lesions.

- **Controlled Drug Release**:

Niosomal gels offer sustained and controlled drug release, providing a prolonged therapeutic effect. This controlled release profile helps in reducing the frequency of application, improving patient compliance, and optimizing drug utilization compared to conventional topical formulations.

- **Localized Therapy:**

Niosomal gels enable localized therapy, delivering drugs directly to the psoriatic lesions while minimizing exposure to healthy skin. This targeted delivery reduces the risk of systemic side effects associated with conventional systemic therapies such as oral medications or injections.

- **Combination Therapy:**

Niosomal gels allow for the encapsulation of multiple drugs with different mechanisms of action. This feature enables combination therapy, where anti-inflammatory agents, immunosuppressants, or other drugs can be simultaneously delivered in a single formulation. Such combination therapy provides synergistic effects and enhances the therapeutic outcomes compared to single-drug conventional treatments.

- **Stability and Shelf-Life:**

Niosomal gel formulations exhibit improved stability compared to conventional creams or ointments. The gel matrix provides physical stability to the niosomes, preventing their aggregation and maintaining their structural integrity during storage. This stability ensures the formulation's efficacy and extends its shelf-life.

- **Reduced Systemic Side Effects:**

By delivering drugs directly to the affected skin layers, niosomal gels minimize systemic exposure and reduce the risk of systemic side effects associated with conventional systemic therapies. This localized approach enhances the safety profile and improves patient comfort during treatment.

- **Customization and Optimization:**

  Niosomal gel formulations offer opportunities for customization and optimization. The composition and characteristics of niosomes can be tailored to meet specific requirements, such as surface modifications for targeted delivery. This customization allows for optimized drug release kinetics, stability, and enhanced therapeutic efficacy.

- **Patient Compliance:**

  The ease of application and pleasant sensory attributes of niosomal gels contribute to improved patient compliance compared to conventional treatments. The gel formulation provides a smooth and non-greasy texture, ensuring better acceptance and adherence to the treatment regimen

Clinical Studies and Evidence of Efficacy

Clinical studies have demonstrated the efficacy of niosomal gel formulations in the treatment of psoriasis. For example, a study conducted by Lakshmi et al. Evaluated the efficacy of niosomal methotrexate gel in the treatment of localized psoriasis. The niosomal gel formulation showed better clinical efficacy compared to placebo and a marketed methotrexate gel. The reduction in the psoriasis area severity index (PASI) score and improvement in the physician's global assessment further supported the efficacy of niosomal methotrexate gel.

Another study by Verma et al. Investigated the use of niosomal gel containing calcipotriol and betamethasone dipropionate in the treatment of psoriasis. The niosomal gel formulation showed improved drug penetration and enhanced therapeutic efficacy compared to conventional gels. The reduction in erythema, infiltration, and scaling scores demonstrated the clinical efficacy of the niosomal gel.

Future Directions and Conclusion

Niosomal gel formulations hold great promise for the treatment of psoriasis and other dermatologic disorders. Further research and development in this field can lead to the discovery of novel drugs, optimization of formulation parameters, and improvement in therapeutic outcomes. The combination of niosomal gels with other treatment modalities such as phototherapy and biologics can potentially enhance the overall efficacy and reduce the recurrence of psoriasis.

The use of niosomal gel formulations in the treatment of psoriasis holds great promise and offers several advantages over conventional methods. Throughout this discussion, we have explored the benefits of niosomal gels in terms of enhanced drug penetration, controlled

release, localized therapy, combination therapy, stability, reduced systemic side effects, customization, and patient compliance.

Niosomal gel formulations have shown the ability to improve drug penetration through the skin layers, allowing for targeted delivery to psoriatic lesions. This enhanced penetration provides a more effective and efficient treatment approach compared to conventional creams or ointments.

The controlled release profile of niosomal gels ensures a sustained therapeutic effect and reduces the frequency of application. This feature improves patient compliance and enhances treatment outcomes by optimizing drug utilization.

Moreover, niosomal gels offer the advantage of localized therapy, delivering drugs directly to the affected skin areas while minimizing exposure to healthy skin. This targeted approach reduces the risk of systemic side effects associated with conventional systemic therapies, enhancing the safety profile of the treatment.

The ability of niosomal gels to encapsulate multiple drugs with different mechanisms of action allows for combination therapy. This approach provides synergistic effects and improves therapeutic outcomes, offering a more comprehensive treatment approach compared to single-drug conventional treatments.

The stability of niosomal gel formulations ensures the integrity and efficacy of the encapsulated drugs during storage and transportation. This stability extends the shelf-life of the formulation and ensures its effectiveness over an extended period.

Furthermore, the customization and optimization capabilities of niosomal gels offer opportunities to tailor the formulation to specific requirements. This customization allows for improved drug release kinetics, targeted delivery, and enhanced therapeutic efficacy, contributing to personalized treatment approaches.

Patient compliance is crucial in the successful management of psoriasis. The pleasant sensory attributes and ease of application of niosomal gels promote better patient acceptance and adherence to the treatment regimen. This improves overall treatment outcomes and patient satisfaction.

In conclusion, the use of niosomal gel formulations in the treatment of psoriasis represents a promising advancement in pharmaceutical research and development. The advantages discussed highlight the potential of niosomal gels to overcome the limitations of conventional methods and provide a more effective and patient-friendly treatment option. However, it is important to note that further research, including clinical trials, is necessary to validate the clinical efficacy, safety, and long-term benefits of niosomal gel formulations in the management of psoriasis. Nonetheless, the encouraging results and benefits observed thus far

indicate that niosomal gels have the potential to revolutionize the treatment of psoriasis and improve the quality of life for patients.

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