Sermorelin Medical Evidence

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Abstract

Sermorelin, a synthetic peptide, has gained attention as a promising therapeutic option for stimulating the body's natural production of growth hormone (GH). By enhancing the body's endogenous secretion of GH, Sermorelin offers numerous medical benefits, particularly due to the critical role of growth hormone in regulating cellular regeneration, metabolism, and overall physiological development. Current research often compares Sermorelin therapy with traditional growth hormone replacement therapy (GHRT). Unlike GHRT, which involves direct administration of growth hormone, Sermorelin stimulates the pituitary gland to produce more GH, thereby reducing the risk of side effects commonly associated with GHRT.

This white paper delves into the physiological and psychological effects of Sermorelin, evaluating its effectiveness as a safer alternative to conventional hormone replacement therapies. It also explores its potential for improved safety, reduced side effects, and better patient outcomes, offering a comprehensive overview of this innovative approach to hormone regulation.

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Introduction

Sermorelin is a synthetic peptide developed in the United States during the early 1980s and gained approval by the U.S. Food and Drug Administration (FDA) in 1997 for treating growth hormone deficiencies in children, but it is also used off-label by adults. Even though it is a synthetic compound, it is based on a natural substance in the human body.
Sermorelin works by mimicking the action of growth hormone-releasing hormone (GHRH), which stimulates the pituitary gland to produce and secrete more of the natural growth hormone.

Human growth hormone, also known as somatotropin, is a natural hormone released by the pituitary gland and it has both direct and indirect mechanisms of action. This hormone encourages the growth of nearly every tissue and organ in the body. One of the most prominent effects of GH is the growth of cartilage and bone, particularly during adolescence. Since growth hormone upregulates the production of insulin-like growth factor-1, growth hormone plays a role in metabolism.

By improving the body's endogenous production of GH, Sermorelin promotes functions such as tissue repair, muscle growth, and metabolic regulation, thus offering a more natural approach compared to direct growth hormone replacement therapies. The therapy with Sermorelin may improve cognitive performance among other functions.
As of 2008, Sermorelin has been discontinued by the manufacturer and is no longer available in the United States as an FDA-approved medication, but is sold and dispensed as peptide therapy instead. Difficulties in the manufacturing process of the active ingredient led to the discontinuation of Sermorelin. Safety issues weren't the reason for discontinuing this medication.

Problem Statement

Growth hormone replacement therapy is a common pharmaceutical approach in cases where a patient has a lack of growth hormones. The therapy does effectively increase the concentration of serum growth hormones, but it also may lead to adverse effects. These include abnormal changes to the physiology of a patient, among others. With this in mind, research needs to focus on alternative options that patients can use to offer a safer approach to restoring optimal growth hormone levels.

Literature Review

This white paper reviewed papers and studies by R.F. Walker, M.V. Vitiello, Y. Chang, J.T. Sigalos, and A. Prakash, which provide a comprehensive comparison of Sermorelin and growth hormone replacement. These papers focus on the efficacy, safety, and physiological effects of Sermorelin in patients with growth hormone deficiency.
While Walker's research focuses on mechanism through which Sermorelin stimulates the release of GH, Vitiello explores positive effects of this compound on cognition and sleep quality.

Moreover, we reviewed findings from O. Khorram, L. Gelander, and E. Corpas who explored the impact of Sermorelin and related growth hormone-releasing hormone analogs on several aspects of physiological health.

Research by Y. Chang et al. explored the potential therapeutic role of Sermorelin in patients with recurrent gliomas and provides insight into its potential anti-tumor properties.
Additionally, J.T. Sigalos et al. examined the use of Sermorelin in combination with GH-releasing peptides to increase IGF-1 levels. These papers emphasize Sermorelin's ability to treat conditions related to muscle wasting and metabolic dysfunction.
Older, yet relevant papers by A. Prakash and K.L. Goa evaluated the effectiveness of Sermorelin as a diagnostic tool for growth hormone deficiency in children.
Overall, the literature reviewed in this whitepaper provides a detailed exploration of Sermorelin's potential as a therapeutic alternative to GHRT.

Methodology

The main purpose of this whitepaper is to evaluate evidence regarding the effects of Sermorelin on growth hormone regulation and its broader physiological and psychological influences. The studies and pieces of research from this whitepaper focus on Sermorelin's abilities to stimulate the production of growth hormone in the body, improve sleep quality and cognitive functioning, and provide potential therapeutic benefits in patients with growth hormone deficiency. The whitepaper also investigates the therapeutic potential of this peptide in specialized contexts such as its use in treating recurrent gliomas. The goal is to shed more light on the outcomes associated with Sermorelin in diverse populations.

Results/Findings

R.F. Walker's research compares the efficacy of Sermorelin with traditional growth hormone replacement therapy (GHRT), emphasizing the risks associated with GHRT, such as serious side effects, abnormal physiological changes, and legal issues. The study focuses on evaluating these two treatment options for patients with growth hormone deficiency. Walker explains the mechanisms behind Sermorelin's effectiveness, noting that it stimulates the pituitary gland to naturally release growth hormone rather than triggering IGF-1 production in the liver, as GHRT does. This results in a lower risk of side effects, and overdosing is much more difficult to achieve compared to GHRT. Sermorelin also promotes an intermittent release of growth hormone, aligning more closely with the body's natural rhythms.

M.V. Vitiello's research highlights the positive effects of Sermorelin on sleep and cognition, as somatotropic hormones are linked to cognitive function improvements that, in turn, benefit sleep quality.

Y. Chang et al. explored the potential of Sermorelin in treating recurrent gliomas. Their study, involving 1,018 glioma patients, demonstrated that Sermorelin was most effective in high-grade gliomas, particularly in those with IDH-wildtype and 1p/19q non-codeletion status. The researchers found that Sermorelin may inhibit tumor cell proliferation by blocking the cell cycle.

J.T. Sigalos and colleagues studied the combination of Sermorelin with GH-releasing peptides, finding that it increased serum insulin-like growth factor-1 (IGF-1) levels. This combination therapy was particularly useful in men with wasting conditions, offering an effective way to raise growth hormone levels and improve muscle mass.

Although research on Sermorelin is still relatively limited, older studies provide valuable insights. For instance, A. Prakash and K.L. Goa's paper found Sermorelin to be a well-tolerated analog of growth hormone-releasing hormone (GHRH) and useful as a diagnostic tool for growth hormone deficiency. Their research also suggested that subcutaneous Sermorelin could promote growth in pre-pubertal children with idiopathic growth hormone deficiency.

E. Corpas et al. conducted a clinical trial to evaluate whether GHRH injections could restore growth hormone and IGF-1 levels in older men to match those of younger men. Their results showed that short-term administration of GHRH successfully reversed age-related reductions in growth hormone and IGF-1, suggesting potential long-term improvements in body composition with continued treatment.

O. Khorram et al. conducted a 5-month randomized, placebo-controlled trial on 19 participants aged 55-71, testing the effects of GHRH analogs. The study found significant increases in nocturnal GH and serum IGF-1 levels in both men and women, but men experienced greater anabolic benefits, including improvements in insulin sensitivity, libido, and quality of life. Skin thickness increased in both genders, while lean body mass improved only in men. The study underscored the need for further research to understand the gender differences in response to GHRH treatment.

L. Gelander et al. examined the short-term effects of 1 mg Sermorelin and GHRH 1-40 injections on growth hormone, IGF-1, and other hormones in children with pulsatile growth hormone secretion. Both peptides significantly increased GH levels, but Sermorelin was associated with slight acute rises in prolactin, FSH, and LH, suggesting that it mimics the body's natural GHRH responses.

This white paper offers an in-depth analysis of the existing literature on Sermorelin, highlighting its efficacy, safety, and potential applications across various patient populations. While more research is needed to fully understand its long-term effects, current evidence suggests Sermorelin is a viable alternative to GHRT, offering benefits with fewer risks.

Discussion

The studies and evidence reviewed in this white paper highlight the effects of Sermorelin on various cognitive and physiological functions. Research indicates that Sermorelin can stimulate the natural production of growth hormone (GH), leading to improvements in cognitive function, sleep quality, and overall well-being in individuals with growth hormone deficiency. Its ability to mimic the body's natural GH-releasing process offers a safer alternative to GH replacement therapy (GHRT), which can cause more severe side effects.

Evidence also suggests that Sermorelin may be effective in treating specific conditions, such as recurrent gliomas, by inhibiting tumor growth. In aging populations, it has the potential to reverse age-related declines in GH levels, positively influencing skin thickness, body composition, and lean muscle mass.

However, it's important to note that the production of Sermorelin has been discontinued by its manufacturer, which has significantly limited the availability of studies and clinical data. Most of the research on Sermorelin is from older studies, which provide valuable insights into its effectiveness, but the lack of new research leaves significant gaps in our understanding of its long-term safety and efficacy.

Despite these limitations, Sermorelin is associated with a favorable safety profile compared to GHRT, with a lower risk of adverse reactions such as overdose and hormonal imbalances. However, the benefits of Sermorelin on muscle mass, sleep, and well-being may diminish over time without continued treatment.

Looking ahead, there is substantial room for further research. Future studies should focus on investigating the long-term effects of Sermorelin on patients to better understand its potential as a therapeutic option.

Conclusion

We conclude that Sermorelin shows significant potential as a treatment for growth hormone deficiencies and related conditions. Its ability to naturally stimulate growth hormone production, coupled with a more favorable safety profile compared to traditional growth hormone replacement therapy (GHRT), makes it an appealing option for many patients.

Unlike GHRT, which often stimulates the liver to produce insulin-like growth factor 1 (IGF-1), Sermorelin does not rely on this pathway, reducing the risk of IGF-1-related side effects.

Research has demonstrated that Sermorelin contributes to improvements in body composition, cognitive function, and sleep quality, particularly in older adults and those with specific health concerns such as recurrent gliomas. These positive effects stem from Sermorelin’s capacity to mimic the body's natural growth hormone-releasing process, promoting a more balanced and gradual increase in hormone levels. However, it is important to note that the beneficial effects of Sermorelin may diminish over time without continuous treatment.

Despite its promising potential, there is a significant need for more research to fully understand the long-term therapeutic effects of Sermorelin. The discontinuation of its production has resulted in a limited body of evidence, with much of the available research being older. This gap in more recent studies creates uncertainty about its long-term safety, efficacy, and broader applications.

In conclusion, while Sermorelin presents a safer and more natural alternative to GHRT, further clinical trials and research are essential to fully elucidate its benefits, sustainability, and potential in treating various growth hormone-related conditions.

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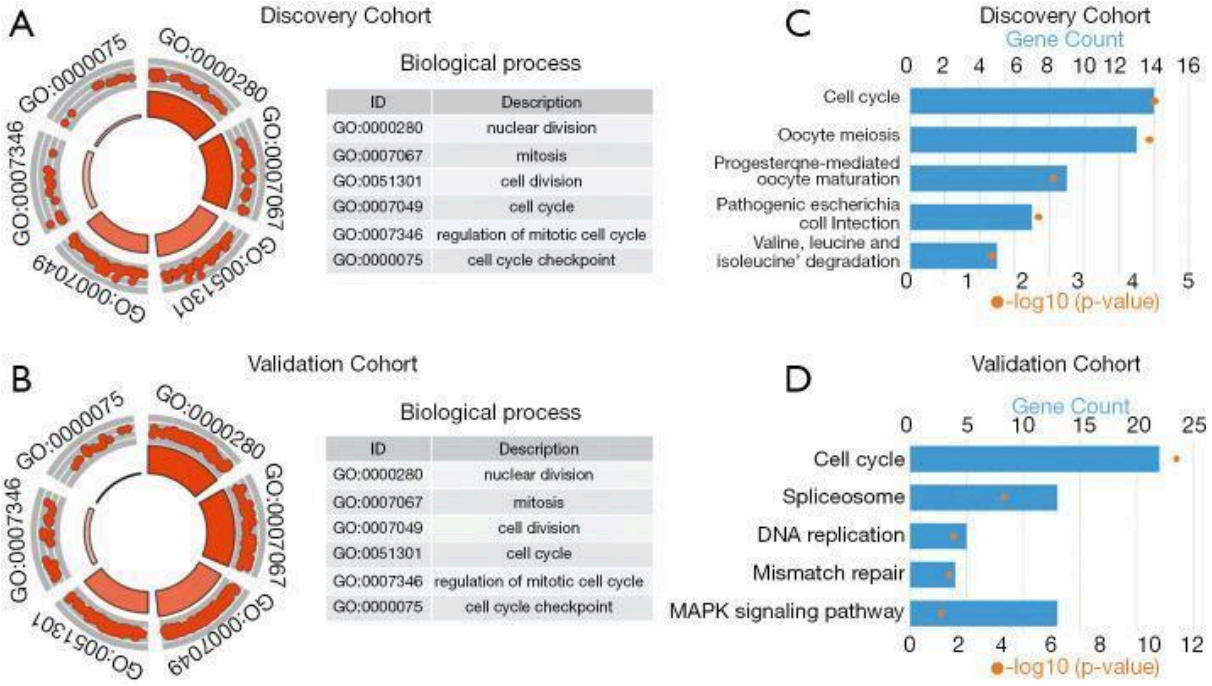
Appendices



Sermorelin is closely linked to cell proliferation functions.
Chang Y, Huang R, Zhai Y, et al. A potentially effective drug for patients with recurrent glioma: sermorelin. *Ann Transl Med*. 2021;9(5):406. doi:10.21037/atm-20-6561

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Conflicts of Interest

At the time of creating this whitepaper, there were no notable conflicts of interest.

Contact Information

Queries and questions regarding the content of this whitepaper should be directed to the authors.