

Treatment of genital lichen sclerosus with a synthetically thymosin substance— an administered field study

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Introduction:

Genital lichen sclerosus is a chronic inflammatory skin disorder of unknown cause. It runs its course in stages. The patients get better as time goes on. The case of new outbreaks of vulval lichen sclerosus is 14 per 100,000 per year. It can develop in people of all ages. The preferred spots in male are the genitals, the head of the penis (glans penis), around the meatus, and the foreskin. In females it is often the sulcus interlabialis that is infected, followed by the clitoris, labia minora, perineum, perianal zone, and labia majora. The medical picture in the early stages is characterized by porcelain-white, in parts confluent papules. The full picture demonstrates a firm atrophy with follicle hyperkeratosis, hypo- but also hyperpigmentation. In the late phase it may cause the inner lips of the vulva to shrink and disappear, the clitoris to become covered with scar tissue, and the opening of the vagina to narrow. Male patients experience phimoses and shrinking and narrowing of the small foreskin band (frenulum) and the urethra (the tube through which urine flows). The clinical symptoms are characterized by itching, burning and pain, dyspareunie (syn. *Algopareunie*), as well as pain during micturition (urination) and defaecation.

The histological examination secures the diagnoses. In the early stages you will find a normal wide epithelium with ortho hyperkeratosis with normal wide epithelium. The collagen connective tissue is homogenized, and on the upper dermis it is surrounded by lymph fluid. In the full stage you will see an epidermal atrophy, follicle hyperkeratosis with degeneration of the basal cell. Loss of elastic fibers occurs (1). The following text reports about the field study regarding efficiency and tolerance of Thymuskin® Sclero Discret in patients with genital lichen sclerosus during administration.

Patients and Methods:

Seventeen patients (2 men and 15 women), age 4-68 years old with long term medical records of genital lichen sclerosus were included in the study. The following criteria were assessed: erythema, scleroses, atrophy, erosion, ulceration, excoriation, burning, itching and pain as well as application, tolerance, skin penetration, feel, and fragrance. These factors were evaluated by the patients. The assessment of the healing process (efficiency) and tolerance were assessed by the doctor and patient. Thymuskin® Sclero Discret crème was applied twice daily by the patient. The above listed criteria were assessed initially (U1), after 4 weeks (U2) and 12 weeks (U3). In addition a skin thickness measurement was taken of the ulcus interlabialis during U3 with 20 MHz-sonography in all female patients.

Results:

The effectiveness was evaluated ranging from good to very good by 75% of all patients. 18% said the effectiveness was moderate. One patient did not experience any effectiveness. The tolerance was assessed from good to very good by all patients (see diagram 1). Application, distribution, absorption, feel and fragrance were assessed ranging from good to very good by all patients as well (see diagram 2). The clinical assessment showed a decline of erythema, the scleroses, as well as individual judgment of symptoms like itching, burning and pain. The assessment of the atrophy by the doctor showed a slight mean increase (see diagram 3 and case documentation case 1 and case 2). The skin thickness measurement showed increased and decreased values after the treatment. A distinct trend could not yet be completely defined (see diagram 4).

Discussion:

When discussing the pathogenesis of Lichen, some people may have a genetic tendency towards the disease. Also an overactive autoimmune system may play a role. The role of Borrelien infections is discussed paradoxically in the literature. A causative therapy is not known today. Possible therapies today to treat genital Lichen sclerosus are potent corticosteroids, which are given topically or directly into the effected area. Recently tacrolimus (immunosuppressive drug) and pimecrolimus (immunomodulating agent) were used with success. An important role is played by the local care of outbreak areas during symptom-free times. Thym-Uvocal crème, a highly purified calf thymic tissue was used successfully (2). Thymuskin® Sclero Discret is a synthetically produced thymus peptide identical to nature. In extensive, experimental research of thymus peptides different effective mechanisms could be demonstrated. First thymosins are able to activate the vitality of cells (3). In addition to that an increase of natural cell growth was proven (4). Further, the cell respiration was increased by 50% though thymosins (5). The principle behind low molecule thymus peptides with lichen sclerosus is mainly based on specific immune system modulation. The exact principle is not known in detail. Regarding the parameters we measured, one has to consider that the skin thickness depends on different pathogenetic factors. A decrease in inflammation caused by declination of the edema will lead to a reduction of skin thickness for example, and a decline of atrophy causes increasing thickness. The present results are in any case encouraging enough, especially in regards to the patient's increased life quality, to justify pursuing further case field studies with a larger test group.

Diagram 1:

Title: Assessment of effectiveness and tolerance by patient and doctor

y-axes: N/A

x-axes: effectiveness assessed by patient, effectiveness assessed by doctor, tolerance assessed by patient, tolerance assessed by doctor

Diagram 2:

Title: Product Properties

y-axes: 2:0= bad, 3= very good

x-axes: Application, Distribution, Absorption, Feel, Fragrance

Diagram 3:**Title:** Hospital**y-axes:** Mean Values**x-axes:** Erythema, Scleroses, Atrophy, Erosion, Ulceration, Excoriation, Itching, Burning, Pain**y-axes:** U1: 0 weeks= starting Point

U2: after 4 weeks

U3 after 12 weeks

Diagram 4:**Title:** Skin Thickness measurements**y-axes:** Skin Thickness in Millimeter [mm]**x-axes:** Time Frame**Pictures:****Title:** Case Documentation**Pic. 1:** Case 1: U1 (Starting Point 0)**Pic. 2:** U2 (after 12 weeks)**Pic. 3:** Case 2: U1 (Starting Point=0)**Pic. 4:** U2 (after 12 weeks)