

Pseudocatalase - Outcome of Rational Survey

Dennis P. West, Ph.D., F.CCP.
Professor of Dermatology
Northwestern University

To assess pseudocatalase and calcium (PCAT) treatment outcomes for a usual care, geographically diverse patient population, we conducted a retrospective, uncontrolled, nationwide survey of vitiligo patients using a freshly-prepared, extemporaneously formulated, topical PCAT cream obtained by doctor's prescription. This survey was partially supported by the National Vitiligo Foundation. We attempted to contact over 850 patients via a mail survey during a two month period. Of the 250 patients that replied, 193 patients were currently using PCAT for at least two months. 158 patients indicated compliance with their PCAT treatment. The age range was 4-74 years (mean=34). Race was characterized as Caucasian (n=187), Hispanic (n=19), African American (n=14), Asian (n=20) and Other (n=10). Duration of vitiligo ranged from 0.25-56 years (mean=11.2 years). Vitiligo distribution was generalized in 233 patients, focal in 6 patients and facial in 11 patients.

PCAT treatment ranged from 2-28 months (mean=8). Of these 250 patients, 189 stated the vitiligo was unstable and they were actively losing pigment at the initiation of their PCAT treatment. Of the 189 patients, 78 patients believed that vitiligo actively stopped spreading after the application of PCAT. 83 people believed that PCAT did not affect the spreading of the vitiligo. 66 patients applied PCAT to the entire body surface, while 92 patients applied to only the vitiliginous areas. Light exposure varied considerably. Most patients (n=114) used sunlight on a consistent basis. Other sources included PUVA (n=30), UVB narrowband / broadband (31), UVA/UVB (n=10) and none (n=48). Of 244 patients reporting, 87 patients (36%) stated they have relatives with vitiligo. 61 of these 87 patients (76%) reported repigmentation and 19 patients (24%) reported no repigmentation (7 patients did not answer). 157 patients out of 244 (64%) reported that they do not have relatives with vitiligo. 84 of these 157 patients (56%) reported repigmentation and 65 patients (44%) reported no repigmentation (8 patients did not answer).

In those that stabilized pigment loss (n=78) the mean time to stabilize pigment loss was 7 weeks (range= 1-32). Of the patients that applied PCAT to the entire body, those reporting, repigmentation (n=48), the mean time to first sign of repigmentation was reported as 10.42 weeks (range =148 wks). Of the patients that applied PCAT only to vitiliginous areas and reported repigmentation (n=57), the mean time to first sign of repigmentation was reported as 8.5 weeks (range = 1-52wks).

Comments: PCAT is available by doctor's prescription as a freshly prepared, extemporaneous formulation containing USP-designated ingredients: calcium chloride, manganese chloride and sodium bicarbonate. PCAT functions to remove increased skin levels of hydrogen peroxide. When successful detoxification of epidermal hydrogen peroxide occurs, tissue biopsies have demonstrated that the stressed epidermis is able to recover.

1. This is our second annual national survey of outcomes and results continue to be consistent with reported literature. In an open-label case study series of 33 selected patients, Schallreuter et. al. showed that by applying topical PCAT, combined with short term UVB light exposure, 90% of the group experienced repigmentation. Stabilization of pigment loss was achieved in all patients using this regimen in these specially selected patients.

2. Our national survey results continue to show no clear-cut indication of which light source (sunlight versus artificial light) may be optimal in combination with PCAT.

Safety of topical PCAT has been substantiated by monitoring for serum manganese and calcium and, to date, after ten years of clinical use, there have been no reports of altered homeostasis in patients using it on a long-term basis. Efficacy of topical PCAT is such that it appears to be reliable in stopping the progression of pigment loss in a majority of nonsegmental active vitiligo patients.

Despite a lack of independent, blinded clinical trials, topical PCAT in conjunction with a light source, may prove to be a safe and effective approach to stabilizing active vitiligo as well as to promote repigmentation from the light source. It will be important to the vitiligo patient population that an effective commercializable product is developed and that double-blind multi-center clinical trials be performed. Currently at Northwestern University a single-center double-blind trial is underway and is funded by the National Vitiligo Foundation. The same study design is concurrently being conducted as a study in Australia.

Supported by National Vitiligo Foundation

References:

1. Schallreuter KU, Moore J, Tobin DJ. Pseudocatalase: a successful mechanism for removal of epidermal hydrogen peroxide in the skin of patients with vitiligo. *Br J Dermatol*. 1998; 139:16(Suppl. 51).
2. Schallreuter, KU, Wood JM, Lemke KR, Levenig C. Treatment of vitiligo with a topical application of pseudocatalase and calcium in combination with short-term UVB exposure: a case study on 33 patients. *Dermatol*. 1995; 190:223-229.