Use of Topical Tacrolimus in Vitiligo

Authors: EA Tanghetti, MD, R. Brandt, PA-C, C. Hamann, BS; Center for Dermatology and Laser Surgery

Introduction

Vitiligo, an autoimmune disease, is a common pigmentation disorder of the hair and skin affecting up to 4% of the population world-wide. Common therapies include topical corticosteroids, topical or oral psoralens followed by UVA therapy (PUVA), and other phototherapies (UVB and narrow-band UVB). Tacrolimus ointment, a nonsteroidal topical immunomodulator, has demonstrated clinical efficacy in atopic dermatitis and should also be effective in other immunologically-mediated diseases such as vitiligo. A prospective case series of 15 patients treated with 0.1% tacrolimus ointment up to 9 months is presented.

Objective

To evaluate the efficacy and safety of twice daily applications of 0.1% tacrolimus ointment in pediatric and adult patients with vitiligo.

Methods

- Patients applied 0.1% tacrolimus ointment twice daily to depigmented skin areas as monotherapy.
- Concomitant medications for treatment of vitiligo were not allowed.
- Assessments for safety and efficacy occurred at baseline and approximately every 6 weeks during treatment.

Results

Patient Demographics/Baseline Characteristics

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Gender:	Male	5
	Female	10
Race/Ethnicity:	Asian	3
	White	6
	Hispanic	6
Age (yrs):	Mean	32
	Median (Range)	23 (4-73)
Disease Duration (yrs):	Mean	4.9
	Median (Range)	3 (1-20)

Safety Results

No adverse events were reported by patients or observed by physician during treatment with tacrolimus ointment.

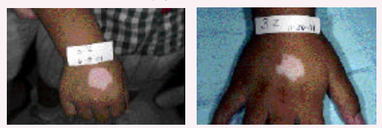
Patient Treatment Data

Pt. No.	Age (Yrs)	Location	Prior Treatment	Treatment Period	# Days	Treatment Response*
1	51	Face/neck	PUVA	Aug- Jan	172	>0 - 25
2	13	Forehead	Methoxsalen, Hydrocortisone Butyrate Cream	April - Jan	284	>75-100
3	11	L. knee/ankle	Triamcinolone Cream	Oct - Jan	119	>0 - 25
4	23	Hands/knees/elbows	None	Aug - Nov	79	>0 - 25
5	50	Hands	None	Aug - Sep	45	>0 - 25
6	13	Face	Hydrocortisone Butyrate Cream	Jun - Sep	114	>75 - 100
7	45	Face/neck	None	Jul - Dec	180	>75 - 100
8	4	R. dorsal hand	Fluticasone	Jun - Nov	176	>0 - 25
9	42	Face/neck	None	Jul - Oct	113	>50 - 75
10	23	Elbows/hands	Dihydroxyacetone, Hydrocortisone Valerate	Oct - Dec	67	>0 - 25
11	43	Neck/chest	Trioxsalen, PUVA	Oct - Dec	46	No Response
12	18	Face	PUVA	Nov- Jan	72	No Response
13	16	R. hand	Psoralen, topical steroid	Sep - Jan	156	>0 - 25
14	73	Forehead/face/hands	None	Oct - Dec	63	>0 - 25
15	61	Forehead/hands	Triamcinolone	Apr - Jan	283	>0 - 25

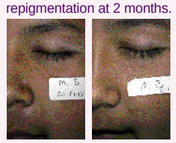
* Percent (%) repigmentation

Photographic Results

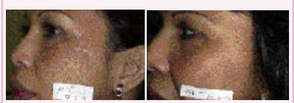
4 - year old Asian boy (Patient No.8) with 0-25% repigmentation at 5.5 months



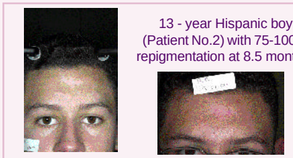
13 - year old Hispanic girl (Patient No.6) with 75-100% repigmentation at 2 months.



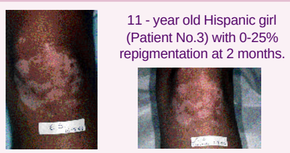
45 - year old Asian woman (Patient No.7) with 75-100% repigmentation at 5 months.



13 - year Hispanic boy (Patient No.2) with 75-100% repigmentation at 8.5 months.



11 - year old Hispanic girl (Patient No.3) with 0-25% repigmentation at 2 months.



Discussion

- Application site events commonly reported in atopic dermatitis patients were not observed in this prospective case series of vitiligo patients, possibly due to normal skin barrier function.
- 13 of 15 patients had at least partial improvement:
  - 3 had complete repigmentation
  - 1 had 50-75% repigmentation
  - 9 had 0-25% repigmentation
- The onset of response was typically noted within 6-8 weeks.
- The degree of response seemed to depend on the site of application and the season. Patients achieving the greatest benefit with tacrolimus ointment therapy had involvement of sun-exposed skin. This occurred with casual daily exposure during this period. Individuals with darker skin types, particularly with involvement of the head and neck, showed the best response. Our younger patients appeared to respond particularly well in this study. PUVA has been used successfully in vitiligo patients. Ultraviolet light (UVA and UVB) has been shown to alter immunologic function and could act in an additive or synergistic manner with topical tacrolimus in vitiligo. Specifically tacrolimus in combination with PUVA, narrowband UVB, Excimer laser intense pulsed narrow band UVB, and sunlight could enhance results and should be studied. Because there are precautions in tacrolimus ointment prescribing information that state “it is prudent for patients to minimize or avoid natural or artificial sunlight exposure,” the safety and efficacy of this use remain to be clarified and studied.

Conclusions

- Twice daily applications of 0.1% tacrolimus ointment was well tolerated for up to 9 months of treatment of vitiligo.
- Treatment with tacrolimus ointment resulted in at least partial repigmentation in the majority of patients with vitiligo.
- Patients achieving the greatest treatment response may have had additional benefit from natural sunlight exposure.
- Further clinical studies are warranted:
  - to determine which vitiligo patients are most likely to benefit from tacrolimus ointment.
  - to determine whether best treatment response is achieved with tacrolimus ointment monotherapy or with combination therapy.

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