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Evaluation of the Effectiveness of 10% Dimethyl Sulfoxide Gel in the Treatment of Macular Amyloidosis: A Case Series of 30 Patients

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ABSTRACT

Introduction: The deposition of various types of proteins in different organs, which can lead to the dysfunction of that organ, is called amyloidosis. Recent studies have focused on the role of dimethyl sulfoxide in the treatment of cutaneous forms of amyloidosis.

Materials and Methods: This descriptive study was conducted on patients who were referred to the dermatology clinic of the Vali-Asr Hospital in Qaemshahr and to private dermatology practices in the city of Sari during a 4-year period, from April 2018 to April 2022. Diagnosis was made based on clinical examinations and precise biopsies by a dermatologist. A 10% dimethyl sulfoxide gel once daily was prescribed for patients. Before the treatment, the lesions were examined by colorimetry, and itching was assessed based on the visual analogue scale (VAS). These were repeated after 24 weeks. Analyses were done using Statistical Package for the Social Sciences (SPSS) version 26.

Results: The average age of participants was 35.20 ± 6.87 years; 7% of the patients had side effects, none of which was considered severe. Of the patients, 66.7% responded to dimethyl sulfoxide (DMSO) and 33.3% did not respond to treatment.

Conclusion: With a 66.7% response rate, dimethyl sulfoxide (DMSO) can be considered as a potential treatment in patients with macular amyloidosis, either as a first-line therapy or in refractory cases.

Introduction

The deposition of various types of proteins defined as amyloid fibrils in different organs is known as amyloidosis, which can ultimately lead to organ dysfunction. This deposition can either occur diffusely, involving multiple organs such as the heart, kidneys, gastrointestinal tract, nervous system, and the skin, or cause isolated skin involvement, which is called primary localized cutaneous amyloidosis (PLCA) [1]. There are multiple types of cutaneous amyloidosis, among which lichenoid (papular) and macular amyloidosis are more common. Lichen amyloidosis is characterized by plaques of itchy and thickened skin mostly seen on the shins and upper arms occurring predominantly in males with an average age of 50 years. Macular amyloidosis, instead, presents as hyperpigmentations of the upper back, and to a lesser extent, on the trunk, chest, and neck and in rare cases even on the legs and buttocks with a rippled pattern, in middle aged females who experience mild-to-severe levels of pruritus [2]. Although etiologies of macular amyloidosis are unknown, some factors have been identified to play a role in the formation of this disease such as long-term UV exposure, atopic eczema, ethnicity, and genetic predisposition [3]. Populations with skin phototypes 4 and 5 are affected more. As opposed to Europe and North America, a higher disease prevalence can be seen in the Middle East, South Asia, Iran, and Latin America [4]. It has also been hypothesized by the secretory theory, explaining the pathogenesis of amyloid derivation from basal keratinocytes in the papillary dermis, that these degenerated cells are antigen-rich and can thus trigger immune-mediated responses, which could indicate an association between macular amyloidosis and autoimmune disorders as a potential etiology [5]. Diagnosis is usually clinical and is aided by dermoscopy findings including lesions with brownish-to-white centers with poorly defined brown streaks radiating from the central hub creating a "hub and spoke" pattern and pigmented leaf-like projections [6]. Biopsy is performed for definitive diagnosis [7]. Treatment of localized cutaneous amyloidosis is primarily based on administration of topical corticosteroids to control pruritus inflammation [8]. UV-B phototherapy and laser treatment have also proven to be effective in multiple studies [2]. However, dimethyl sulfoxide (DMSO), commonly used as a chemical solvent, has shown potential in the treatment of cutaneous lesions of macular amyloidosis in its topical form. This is mainly thought to be due to the antioxidant effects of this agent which prevent new amyloid fibrils from forming. Mast cell depletion is another possible explanation of the effects of this drug on controlling pruritus. On the other hand, its anti-inflammatory properties, along with its deep skin penetration, make it a suitable choice of treatment in patients with this condition [9,10].

Materials and Methods

For this study a total of 30 patients were selected who had been referred to the outpatient dermatology clinic of Vali-Asr Hospital and to private skin practices in a 4-year period, from 2018 to 2022. They were each diagnosed with macular amyloidosis based on clinical examination and confirmation with skin biopsies. Prior to the start of treatment, skin lesions underwent colorimetry, and pruritus was assessed using the visual analogue scale (VAS). Variables such as age, sex, comorbidities, and occurrence of side effects were also noted. 10% topical DMSO gel was administered daily to all patients. All patients were new cases who had not received any form of treatment prior to therapy with dimethyl sulfoxide. They were not prescribed any other oral or topical medication. Patients had 8-week follow-ups during which they would renew their prescribed medication and were assessed for compliance with therapy. According to our inquiries, all patients complied completely with the course of treatment and used DMSO timely and correctly.

A follow-up examination was performed after 24 weeks, in which measurement of lesions as well as assessment of pruritus were repeated, and patients were asked about side effects. Response to treatment was defined as a decrease in or complete resolution of lesions in size, pigmentation, and pruritus along with a lesser extent of skin involvement. Analysis of the results was done using Statistical Package for the Social Sciences (SPSS) version 26, with a p-value of < 0.05 being considered significant.

Results

This study was conducted on 30 patients with macular amyloidosis. The mean age of the participants was 35.20 ± 6.87 years, with the majority of participants in the age groups 24–30 and 41–44 years, with a frequency of 33.3% each. All patients were female, which could indicate a higher prevalence of macular amyloidosis amongst females. Ten out of 30 cases (with a frequency of 33.3%) had comorbidities: two with rheumatoid arthritis, two with hypothyroidism, three with diabetes mellitus, two with hypercholesterolemia, and one with ovarian cysts. At the follow-up visit, side effects were reported by eight patients, accounting for 26.6% of the study cases. Flare-ups of underlying arthritis, irritation and ulceration due to exfoliation, severe pruritus and burning sensation of the applied drug site, and an increase in erythema and inflammation of the lesions were among the reported side effects. An overall response rate of 67.7% was seen with the application of 10% topical DMSO on macular lesions, with 20 out of 30 patients showing visible reduction in size, pigmentation, and pruritus, and in some cases a complete resolution of skin involvement. However,

there was no significant correlation between the response to treatment and age, sex, comorbidities, or side effects of the participants, with a p-value of >0.05 in all of the mentioned variables (Tables 1–5).

Discussion

Macular amyloidosis is one of the more frequent types of primary cutaneous localized amyloidosis that manifests as hyperpigmented lesions of brown color mostly seen in the interscapular area and upper back. Involvement of the trunk, chest, neck, and upper extremities is also seen, to lesser extent [11]. Treatment of macular amyloidosis mainly focuses on the remission of pigmentation and controlling pruritus since the vicious cycle of pruritus-scratching causes a repeated worsening of the pigmentation caused by further amyloid deposition due to frictional trauma. Although in much of the literature there is thought to be no primary line of treatment, multiple studies have evaluated the effects of topical agents such as retinoids, gabapentin, and dimethyl sulfoxide as a potential choice of treatment [10,12,13]. Dimethyl sulfoxide has proven to be effective in some studies, with its effects being due to several of its chemical properties. Its high membrane penetration and its ability to transport other molecules into the skin simultaneously, along with its antioxidant and anti-inflammatory characteristics, help with disease remission [14]. However, a few mechanisms have been introduced to explain the rapid response of pruritus to DMSO. Mast cell depletion as well as the depletion of substance P in the nerve endings could be the cause of the dramatic improvement in pruritus. This is of fundamental importance since itching is usually followed by scratching, which in turn causes trauma to the epidermis and the formation of amyloids. Thus, the remission of pruritus will subsequently decrease friction trauma and the worsening of hyperpigmentation [10]. This effect was also proven in our study, with 20 out of 30 patients reporting complete remission or significant improvement in pruritus. A decrease in the pigmentation of lesions was also noticed in all 20 patients who responded to 10% dimethyl sulfoxide gel. The results of our study are similar to those of much of the previous literature. As reported by Iqbal et al. in a study conducted in 2017, 50 patients above the age of 16 were diagnosed with macular amyloidosis and treated with topical DMSO, which had a significant effect on pruritus, and to a lesser extent, on hyperpigmentations [15]. Additionally, in a study performed in 2021 by Jakhar et al., a total of 60 patients with macular amyloidosis were treated with 70% topical dimethyl sulfoxide and topical corticosteroids. Among those, 44 patients experienced a complete remission of pruritus, and 19 patients showed improvement in pigmentation, with the results being comparable to that of topical steroids, reaching the conclusion that DMSO is much safer for long-term use in macular amyloidosis [16]. A similar assessment was done by Krishna et al. in 2013 which evaluated the effects of 50% topical DMSO on cutaneous amyloidosis, which proved to be efficient in improving pruritus and hyperpigmentation [17]. Saki et al. have also done a clinical trial to assess the effectiveness of topical DMSO 50% versus tretinoin cream 0.5%. The study was conducted on 18 patients with macular amyloidosis. DMSO managed to diminish pruritus completely and had a positive effect on the hyperpigmentation of lesions [18]. Even though most of the recent literature were in line with the results of our study, there have been reports of a lack of effect of DMSO in cutaneous amyloidosis. Pandhi et al. examined the effects of daily use of topical DMSO solution either 50 or 100% in 25 patients diagnosed with any type of cutaneous amyloidosis and found it not to be effective in decreasing pigmentation or pruritus [19]. Similar observations were also made in a study performed by KB Lim et al. in 1988 in which one patient with lichen amyloidosis was treated with dimethyl sulfoxide, and no change in amyloid deposits was seen upon pathological

Table 1. Demographic and clinical characteristics of the participants.

Characteristic	Count	Percentage
Age		
24-30 y	10	33.3%
31-35 y	4	13.3%
36-40 y	6	20%
41-44 y	10	33.3%
Sex		
Male	0	0
Female	30	100%
Side effects		
Present	8	26.7%
Absent	22	73.3%
Comorbidities		
Present	10	33.3%
Absent	20	66.7%

Table 2. Frequency of response to treatment with DMSO.

		Count	Frequency
Response to therapy	**Present**	20	67.7%
	Absent	10	33.3%
	Total	30	100%

Table 3. Response to treatment with DMSO in correlation with age.

		Frequency	Mean Age	SD	p-value
Response to therapy	Present	20	34.50	7.61942	0.596
	Absent	10	36.60	5.59464	

Table 4. Response to treatment with DMSO in correlation with side effects.

			Side effects		Total	p-value
			Present	Absent		
Response to therapy	Present	Count	6	14	20	0.680
		Frequency	30%	70%	100%	
	Absent	Count	2	8	10	
		Frequency	20%	80%	100%	

Table 5. Response to treatment with DMSO in correlation with comorbidities in patients.

			Comorbidities		Total	p-value
			Present	Absent		
Response to therapy	Present	Count	6	14	20	0.699
		Frequency	30%	70%	100%	
	Absent	Count	4	6	10	
		Frequency	10%	60%	100%	

evaluation after treatment in comparison to the histopathological findings prior to therapy [20]. In comparison to all the existent literature, our study also focused on finding a correlation between response to treatment with DMSO and demographic variables such as age and sex as well as clinical variables such as comorbidities and side effects. According to our data analysis, no significant correlation could be found. This is a crucial finding in the treatment of PCLA and more specifically macular amyloidosis, since it allows us to select our cases for treatment independently of other variables.

Limitations of this study include a small sample size and the lack of male participants.

Conclusion

Macular amyloidosis, one of the most common forms of primary localized cutaneous amyloidosis, is predominantly seen in females. Dimethyl sulfoxide, with its anti-inflammatory properties and its ability to break down amyloid fibrils, has been introduced as a potential choice of treatment in recent studies. Due to the high prevalence of macular amyloidosis in the Middle East and especially in Iran, we conducted this study to examine the therapeutic effects of topical DMSO in this condition. Our study, like much of the previous literature, has shown an acceptable response rate of macular amyloidosis to topical therapy with dimethyl sulfoxide. However, due to a limited case count, further studies need to be performed to reach a more certain conclusion.

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