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WHICH WORKS BETTER? MODIFIED KLIGMAN'S REGIMEN OR INTRALESIONAL TRANEXAMIC ACID FOR MELASMA

Dermatology

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ABSTRACT

This study investigates the efficacy and safety of intralesional tranexamic acid (TXA) compared to topical Kligman's regimen in treating facial melasma through a randomized controlled trial involving 20 participants at a tertiary care center in southern India. Participants were randomly assigned to receive either intradermal TXA injections or topical Kligman's therapy and were evaluated over 16 weeks using modified melasma area severity index (MASI) scores, physician's global assessment scale, and patient's global assessment scale. Statistical analysis showed that while both treatments significantly reduced MASI scores, intralesional tranexamic acid demonstrated a better response by the 16th week and also had less adverse effects like erythema, burning, and hypopigmentation. Intralesional TXA has more efficacy and superior safety profile, suggesting it as a viable alternative for patients who do not respond to or cannot tolerate Kligman's regimen due to its adverse effects on long term use.

KEYWORDS

Melasma, Tranexamic acid, Modified kligman's regimen, Hyperpigmentation

Introduction

Melasma is a common skin condition marked by dark brown, symmetrical patches of hyperpigmentation on areas of the face that are frequently exposed to the sun, such as the cheeks, forehead, upper lip, nose, and chin. Commonly affecting females, female-to-male ratio of about 4:11. This condition causes notable cosmetic issues and remains difficult to treat successfully. Current topical treatments for melasma, especially for dermal or mixed types, have not been entirely effective. Contributing factors to melasma include genetics, UV light exposure, pregnancy, hormone therapy, thyroid disorders, cosmetics, phototoxic medications, and antiepileptic drugs, with UV radiation being the primary exacerbating factor. UV light, along with photo-induced hormones, growth factors, chemical mediators, or inflammation that impact melanocytes, may play a role in UV-induced pigmentation and could be potential causes of melasma. Reported inflammatory mediators that enhance melanogenesis include interleukins (IL-1a, IL-1b, IL-6), tumor necrosis factor (TNF-a), eicosanoids (prostaglandins D2, E2, F2, and leukotriene B4), and histamine[2].

There are multiple treatment options available for this condition, including topical agents, lasers, chemical peels, microneedling, dermabrasion, and oral medications3. However, the chronic nature of the disease and its tendency to recur can be frustrating for both patients and physicians. Many of these treatments have significant side effects and often yield suboptimal results. Procedures like lasers, chemical peels, and dermabrasion require specialized skills and expensive equipment, making them costly and necessitating numerous clinic visits and follow-up appointments. This often leads to poor patient compliance. Therefore, there is a pressing need for a therapeutic drug that can enhance treatment outcomes without causing substantial adverse effects.

Kligman's modified melasma treatment consists of a triple combination therapy with fluocinolone acetonide 0.01%, hydroquinone 2%, and tretinoin 0.05%. This regimen is currently widely used and considered safe. However, long-term use of steroids in this combination can lead to side effects such as telangiectasia and atrophic skin changes, which are significant drawbacks.

Tranexamic acid (trans-4-aminomethylcyclohexane-carboxylic acid; TA) is a synthetic derivative of the amino acid lysine and functions as a plasmin inhibitor. It works by reversibly blocking lysine binding sites on plasminogen molecules, thus preventing the plasminogen activator (PA) from converting plasminogen into plasmin. The primary mechanism behind TA's hypopigmentation effects is its antiplasmin activity, and its structural similarity to tyrosine allows it to competitively inhibit tyrosinase. Additionally, plasmin converts the vascular endothelial growth factor (VEGF) into a diffusing form. Histological examinations reveal that TA plays a crucial role in reducing erythema, vascularity and the number of mast cells in the dermis.

Objectives

1. To compare the efficacy of intralesional tranexamic acid with modified kligman's formula in the management of melasma
2. To study the age & sex pattern of melasma

Materials and Methods

A prospective, randomized, open label study was conducted on 20 clinically diagnosed cases of melasma, attending the outpatient department of Navodaya medical college, hospital and research centre, Raichur, Karnataka from march 2024 to June 2024.

Patients age, sex, occupation and other data was collected. A detailed history was taken. Masi score was calculated before start and end of the study period.

Two groups were created and each group is assigned with ten people randomly.

One group is treated with intralesional tranexamic acid and the other with modified kligman's formula. Tranexamic acid (4mg/ml) is injected at 1cm intervals.

INCLUSION CRITERIA:

1. Patients of ages between 20-60 years and both sexes were included in the study

EXCLUSION CRITERIA:

1. known hypersensitivity to modified kligman's formula, and Tranexamic acid.
2. Pregnant/lactating females
3. History of abnormal wound healing
4. History of abnormal scarring.
5. Concurrent active disease to facial area

Ethical clearance

Prior to the commencement, the ethical clearance was obtained from Ethics and Research Committee.

Results

Group which is treated with modified kligman's regimen has cumulative improvement of 40 % in MASI score. Group which is treated with intralesional tranexamic acid has cumulative improvement of 48 % in MASI score (table 1). Images of the patient and MASI scores of the both groups were assessed (figure 1 & 2) and

group which was treated with intralesional tranexamic acid showed better results compared to group treated with topical modified kligman's regimen.

Discussion

Melasma is a hyper pigmentary disorder characterized by dark patches over the face which has a huge psychological impact on the patients4. Melasma is resulted from excess production of melanin due to UV radiation, hormonal changes, genetic factors and various other factors. Topical therapeutic options like corticosteroids often used in combination with hydroquinone and tretinoin, azelaic acid, kojic acid and glycolic acid, oral medications like tranexamic acid, chemical peels and laser therapies are currently available options in treatment of melasma. But these options are giving results which are not very consistent5 owing to disease chronicity, recurrence and multifactorial etiology, hence there is a need in developing new therapeutic options in treating melasma. In this study we endeavored to compare the therapeutic efficacy of topical modified kligman's regimen to intralesional tranexamic acid and in this study we found out intralesional tranexamic acid is marginally superior when compared to modified kligman's regimen. But this study has limitations of its own such as low sample size and generalizability. There is a huge lacuna in this topic which can be answered by more studies and our study attempts to fill the existing gaps.

Table 1 Comparison of MASI score between two groups

Group	Masi at 0 week	Masi at 16 weeks	improvement
Modified kligmann's regimen	8.42	5.052	40%
Intralesional tranexamic acid	7.86	4.087	48%

Table 2 Age and Sex distribution among melasma patients

Age in years	Males	Females	Total	Percentage
21 – 30	1	7	8	40%
31 – 40	2	8	10	50%
41 – 50	1	1	2	10%
total	4	16	20	

Figure 1 Patient treated with modified kligmans regimen

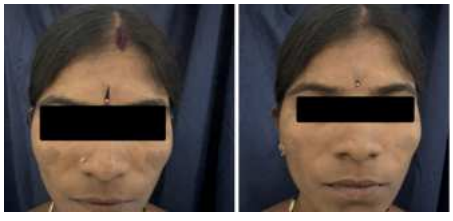

Figure 2 patient treated with intralesional tranexamic acid

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