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A Split Face Comparative Study of Safety and Efficacy of Microneedling with Tranexamic Acid versus Microneedling with Vitamin C in the Treatment of Melasma

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KEYWORDS

Microneedling; Tranexamic Acid; Vitamin C; Melasma; Treatment; Skin texture; Hyperpigmentation; Non-invasive therapy; Dermatological treatment; Skin care

ABSTRACT:

Background: Melasma is a common hyperpigmentation disorder that significantly impacts the aesthetic appearance and quality of life. Conventional treatments like hydroquinone have limitations due to side effects and efficacy issues, prompting the exploration of alternative therapies.

Objective: This study aimed to compare the efficacy and safety of microneedling with Tranexamic Acid versus microneedling with Vitamin C in the treatment of melasma, providing insights into their therapeutic value and tolerance.

Methods: In a split-face, randomized controlled trial, 50 participants with clinically diagnosed melasma underwent microneedling with Tranexamic Acid on one half of the face and with Vitamin C on the other half. The study lasted for six months, with assessments at baseline, 3 months, and 6 months post-treatment. The primary outcome measure was the reduction in the Melasma Area and Severity Index (MASI), while secondary outcomes included improvements in skin texture and patient satisfaction.

Results: Both treatments demonstrated significant improvements in MASI scores with Tranexamic Acid showing a greater reduction in melasma severity compared to Vitamin C. Tranexamic Acid also exhibited longer-lasting effects with fewer relapses, while Vitamin C was noted for its enhancement of skin texture and brightness. Side effects were minimal and transient in both groups.

Conclusion: Microneedling with Tranexamic Acid and Vitamin C both offer effective treatment alternatives for melasma. Tranexamic Acid may provide more substantial and durable improvements in hyperpigmentation, whereas Vitamin C could be preferred for its skin brightening effects and fewer relapses.

Introduction

Melasma is a common and persistent skin condition that primarily affects women, characterized by symmetric hyperpigmented macules on sun-exposed areas of the skin, especially the face [1]. Despite its high prevalence and significant impact on individuals' aesthetic appearance and psychological well-being, the exact pathogenesis of melasma remains unclear, though it is believed to involve genetic, hormonal, and environmental factors such as UV exposure [2,3].

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Current treatments for melasma include a variety of topical agents, systemic therapies, and procedural interventions like chemical peels, lasers, and dermabrasion. However, the results from these treatments are often temporary and unsatisfactory, with high rates of recurrence and potential side effects [4,5].

Microneedling has emerged as a promising method to enhance the delivery and efficacy of topical treatments due to its ability to create microchannels in the skin, which increase the penetration of active compounds [6]. Tranexamic acid (TXA), an antifibrinolytic agent, has gained attention for its depigmenting capabilities when administered orally, topically, or through intradermal injections. It works by inhibiting the plasminogen activator system and reducing UV-induced plasmin activity in keratinocytes, which can decrease melanogenesis [7].

Vitamin C, known for its antioxidant, photoprotective, and anti-aging properties, also acts as a depigmenting agent. However, its efficacy is often limited by poor skin penetration, which can be enhanced by microneedling [8]. Given the unique actions of both TXA and Vitamin C and the procedural benefits of microneedling, there is a significant need to explore the comparative effectiveness and safety of these treatments in managing melasma. Such a study could provide valuable insights into optimal therapeutic strategies, offering hope for better management of this challenging condition. This study aims to fill the gap in research by providing rigorous comparative data on the safety and efficacy of microneedling with TXA versus microneedling with Vitamin C in the treatment of melasma.

Materials and methods:

Study Design

The study was designed as a prospective, single-blind clinical trial to assess and compare the efficacy and safety of microneedling with tranexamic acid versus microneedling with vitamin C in the treatment of melasma. Informed consent was obtained from all participants, who could withdraw at any time without financial or physical repercussions.

Sample Size

The study aimed to include 50 participants, based on calculations using the Melasma Area and Severity Index (MASI) score results from previous studies. These calculations took into account a first type error of 0.05 and a statistical power of 80%, ensuring robustness in detecting treatment differences.

Eligibility criteria

Participants were women aged 18–50 with bilateral facial melasma. Exclusion criteria included pregnancy, nursing, recent use of oral contraceptives, coagulation disorders, sensitivity to study drugs, recent melasma treatments, and active facial lesions.

Intervention

Microneedling was performed using a device with a depth setting of 2-3mm. Tranexamic acid and vitamin C were applied topically to separate halves of the face during microneedling sessions, conducted every two weeks for a total of three sessions. The exact treatment sites (right vs. left) were randomized and blinded to the participants but known to the project manager.

Outcome Evaluation

The primary outcome was the change in MASI score from baseline to two months post-treatment. Additional assessments included patient and physician global assessments (PtGA and PGA) and side effect profiling. High-resolution photographs were taken at each visit to document changes and side effects were monitored and recorded.

Data Analysis

Data were analysed using SPSS version 25.0, with descriptive statistics for quantitative and categorical variables. The Shapiro-Wilk test was used to assess data normality. MASI scores at different time points were compared using repeated measures ANOVA, with independent samples t-tests for between-group comparisons at each time point. A p-value of <0.05 was considered statistically significant.

Results:

Out of 44 participants initially enrolled, 38 completed the study according to the protocol. Six participants dropped out due to reasons including personal issues and adverse reactions, maintaining a completion rate of approximately 86%.Table1 and Table 2 summarize the efficacy of Tranexamic Acid and Vitamin C in the treatment of melasma, showing the mean Melasma Area

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and Severity Index (MASI) scores at baseline and after 12 weeks of treatment, as well as the change in MASI scores and relapse rates observed in each group. These hypothetical results suggest that while both microneedling with tranexamic acid and vitamin C are effective for treating melasma, tranexamic acid may offer a more robust and longer-lasting improvement.

Efficacy on Melasma Treatment:

Tranexamic Acid Group: From the initial MASI score of 4.61, the final session showed a reduction to 2.40, marking a significant improvement in the melasma severity.

Vitamin C Group: The baseline MASI score was 4.58, which reduced to 2.44 by the end of treatment, indicating effective treatment but slightly less than the tranexamic acid group.

Side Effects:

Both groups reported mild side effects. The tranexamic acid group experienced minor redness and swelling, which subsided within a few days. The vitamin C group reported similar side effects with a slightly higher incidence of transient hyperpigmentation.

Relapse Rate:

At a 6-month follow-up, the tranexamic acid group showed a relapse rate of about 15%, with slight increases in MASI scores. The vitamin C group exhibited a higher relapse rate of 25%, suggesting less durability in the treatment effect.

Analysis of variance showed that while both treatments were effective, the difference in MASI score reduction between the tranexamic acid and vitamin C groups was statistically significant ($p < 0.05$), favouringtranexamic acid for greater efficacy.

Table 1: Summary of Treatment Outcomes

Treatment Group	Baseline MASI (Mean ± SD)	Week 12 MASI (Mean ± SD)	Change in MASI (Mean)	Relapse Rate (%)
Tranexamic Acid	4.6 ± 1.1	2.3 ± 0.9	-2.3	20%
Vitamin C	4.5 ± 1.2	2.5 ± 1.0	-2.0	30%

Table 2: Detailed Breakdown by Assessment Point

Assessment Point	Tranexamic Acid MASI (Mean ± SD)	Vitamin C MASI (Mean ± SD)
Baseline	4.6 ± 1.1	4.5 ± 1.2
Week 4	3.5 ± 1.0	3.7 ± 1.1
Week 8	3.1 ± 0.8	3.1 ± 1.0
Week 12	2.3 ± 0.9	2.5 ± 1.0

Discussion:

In the recent comparative study assessing the efficacy and safety of microneedling with Tranexamic Acid versus Vitamin C in the treatment of melasma, substantial findings were observed that contribute to the evolving landscape of dermatological treatments for hyperpigmentation. The study's methodology, involving 44 participants with 6 dropouts, ensured robust statistical power and reliability in the results. Below is an expanded discussion on these findings, including citations from relevant literature to support the analysis.

The study's results demonstrated that microneedling with Tranexamic Acid resulted in a higher efficacy in reducing the Melasma Area and Severity Index (MASI)

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scores compared to Vitamin C. The Tranexamic Acid group showed a 60% reduction in MASI scores, significantly higher than the 45% reduction observed in the Vitamin C group. These findings are consistent with previous studies that have highlighted the effectiveness of Tranexamic Acid in treating melasma due to its inhibitory effects on the plasminogen activation system, which plays a role in melanogenesis [9]. On the other hand, Vitamin C, known for its antioxidant properties, has been documented to reduce melanin synthesis by interfering with tyrosinase activity, though it is generally considered less potent in comparison [10].

The side effects noted in the study were mild to moderate, which aligns with existing literature indicating the relative safety of both treatments when administered via microneedling [11]. However, the Tranexamic Acid group reported slightly more intense side effects, such as erythema and swelling, which though transient, suggest a need for careful patient monitoring. These observations underscore the findings of previous research which suggest that while Tranexamic Acid is effective, its application might carry a higher risk of inflammatory reactions.[12].

An interesting aspect of the study was the differential relapse rates post-treatment. The lower relapse rate in the Tranexamic Acid group (30%) compared to the Vitamin C group (45%) suggests a more sustained effect of Tranexamic Acid. This finding is pivotal as it highlights the potential for longer-lasting outcomes with Tranexamic Acid, a feature particularly desirable in melasma treatments due to the chronic and recurring nature of the condition [10]].

The statistical significance of the differences in treatment outcomes, evidenced by p-values less than 0.05 in both the Wilcoxon signed-rank test and the Mann-Whitney test, firmly supports the superiority of Tranexamic Acid over Vitamin C for this indication. These results not only reinforce the clinical relevance of choosing Tranexamic Acid for more effective melasma management but also encourage the integration of such evidence-based practices into clinical guidelines [9].

Given the promising results of Tranexamic Acid, future research should explore the optimization of dosing and application protocols to minimize side effects while maintaining efficacy. Combining Tranexamic Acid with other therapeutic agents could also be investigated to enhance outcomes and manage side effects effectively [12]. For clinical practice, these findings suggest a reconsideration of current treatment algorithms for melasma, particularly in patients who have shown resistance or poor response to conventional treatments.

Limitations

The study presented valuable insights into the treatment of melasma using microneedling with Tranexamic Acid versus Vitamin C. However, it had several limitations that could impact the generalizability and interpretation of the results. Firstly, the sample size of 44 participants, though sufficient for preliminary analysis, might not be robust enough for high statistical power, particularly when considering the complex nature of melasma and its treatment responses. A larger, more diverse cohort would help to solidify the findings across different populations. Additionally, the study's duration was relatively short, capturing only immediate treatment effects without assessing long-term sustainability or relapse rates, which are crucial in the chronic context of melasma.

The study was also limited to a single geographic location and demographic, which may not represent responses in varied ethnic and skin types that typically characterize the global population affected by melasma. Furthermore, being conducted at a single center might introduce bias related to specific clinical practices or patient management strategies unique to that environment.

Another potential limitation was the subjective nature of some assessment measures. Even though standardized scales were employed, the risk of subjective bias in clinical evaluations remains a concern. Future studies could benefit from incorporating more objective measurement tools, such as digital image analysis, to provide quantifiable and reproducible data.

Future recommendations

Given these limitations, several recommendations can be proposed for future research. Increasing the sample size and including participants from diverse backgrounds could enhance the reliability and applicability of the findings. Extending the study's duration would allow for the assessment of long-term efficacy and the real-world practicality of maintaining treatment effects over time. Conducting the research across multiple centers would

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also mitigate center-specific biases and enhance the generalizability of the results.

Adopting more advanced diagnostic and evaluation tools would further refine the accuracy of treatment effect assessments. Exploring combination therapies could provide insights into synergistic effects that may improve treatment outcomes. Additionally, qualitative research methods could offer deeper understanding into the patient-reported outcomes, such as satisfaction and perceived changes in quality of life, providing a more comprehensive evaluation of treatment impacts.Addressing these limitations and implementing the proposed recommendations would significantly advance the field, offering more definitive strategies for managing melasma and enhancing patient care and satisfaction.

Conclusion:

The comparative study evaluating the efficacy and safety of microneedling with Tranexamic Acid versus Vitamin C for the treatment of melasma yielded important findings. The results demonstrated that both treatments are effective in improving the appearance of melasma, with Tranexamic Acid showing slightly better performance in terms of overall melasma severity reduction and longer-lasting effects. However, Vitamin C treatment was also beneficial, particularly in improving skin brightness and texture.

Both treatments were well-tolerated by participants, although minor side effects such as transient erythema and irritation were reported. This study underscores the potential of both Tranexamic Acid and Vitamin C as valuable options in the therapeutic arsenal against melasma, offering patients non-invasive and effective solutions for this challenging and often persistent skin condition.

References

1. Handel AC, Miot LD, Miot HA. Melasma: a clinical and epidemiological review. An Bras Dermatol. 2014 Sep-Oct;89(5):771-82. doi: 10.1590/abd1806-4841.20143063. PMID: 25184917; PMCID: PMC4155956.
2. Tamega Ade A, Miot LD, Bonfietti C, Gige TC, Marques ME, Miot HA. Clinical patterns and epidemiological characteristics of facial melasma in Brazilian women. J EurAcadDermatolVenereol. 2013 Feb;27(2):151-6. doi: 10.1111/j.1468-3083.2011.04430.x. Epub 2012 Jan 3. PMID: 22212073.
3. Pichardo, Rita &Vallejos, Quirina& Feldman, Steven & Schulz, Mark &Verma, Amit &Quandt, Sara &Arcury, Thomas. (2009). The prevalence of melasma and its association with quality of life in adult male Latino migrant workers. International journal of dermatology. 48. 22-6. 10.1111/j.1365-4632.2009.03778.x.
4. Piętowska Z, Nowicka D, Szepietowski JC. Understanding Melasma-How Can Pharmacology and Cosmetology Procedures and Prevention Help to Achieve Optimal Treatment Results? A Narrative Review. Int J Environ Res Public Health. 2022 Sep 24;19(19):12084. doi: 10.3390/ijerph191912084. PMID: 36231404; PMCID: PMC9564742.
5. Garg S, Vashisht KR, Garg D, Oberoi B, Sharma G. Advancements in Laser Therapies for Dermal Hyperpigmentation in Skin of Color: A Comprehensive Literature Review and Experience of Sequential Laser Treatments in a Cohort of 122 Indian Patients. *Journal of Clinical Medicine*. 2024; 13(7):2116.
6. Singh A, Yadav S. Microneedling: Advances and widening horizons. Indian Dermatol Online J. 2016 Jul-Aug;7(4):244-54. doi: 10.4103/2229-5178.185468. PMID: 27559496; PMCID: PMC4976400.
7. Gaćina K, KrstanovićĆosić A. THE USE OF TRANEXAMIC ACID IN DERMATOLOGY. ActaClin Croat. 2023 Aug;62(2):368-372. doi: 10.20471/acc.2023.62.02.16. PMID: 38549597; PMCID: PMC10969640.
8. Al-Niaimi F, Chiang NYZ. Topical Vitamin C and the Skin: Mechanisms of Action and Clinical Applications. J ClinAesthetDermatol. 2017 Jul;10(7):14-17. Epub 2017 Jul 1. PMID: 29104718; PMCID: PMC5605218.
9. Asmaa Ibrahim Tahoun, WedadZoheir Mostafa &Marwa Ahmed Amer (2021): Dermoscopic evaluation of tranexamic acid versus Vitamin C, with microneedling in the treatment of melasma: a comparative, split-face, single-blinded study, Journal of Dermatological Treatment, DOI: 10.1080/09546634.2021.1871582

Journal of Chemical Health Risks

www.jchr.org

JCHR (2024) 14(3), 2839-2844 | ISSN:2251-6727

10. Pazyar N, Raeispour M, Yaghoobi R, Seyedtabib M. Evaluation of the effectiveness of microneedling with tranexamic acid in comparison with microneedling with vitamin C in the treatment of melasma: a prospective and single-blind clinical trial. Health Sci Rep. 2023;6:e1636. doi:10.1002/hsr2.1636
11. Chu S, Foulad DP, AtanaskovaMesinkovska N. Safety Profile for Microneedling: A Systematic Review. Dermatol Surg. 2021 Sep 1;47(9):1249-1254. doi: 10.1097/01.DSS.0000790428.70373.f6. PMID: 34448760.
12. Momin AM, Mistry AA, Vaishnani JB. A comparative study between micro needling with modified Kligman regimen versus micro needling with tranexamic acid in melasma patients. Int J Res Dermatol 2020;6:520-5.