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Comparison of Micro Needling with Topical Tranexamic Acid and Mesotherapy with Intradermal Tranexamic Acid in Treatment of Melasma

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ABSTRACT

Melasma is a common hyperpigmentation disorder that poses therapeutic challenges due to its recurrent and resistant nature. Microneedling showed superior and faster pigmentation reduction, with significant MASI score improvement and no adverse effects. **Objective:** To compare the effectiveness of intradermal Tranexamic Acid (TA) via mesotherapy versus topical TA delivered through microneedling in the treatment of melasma. **Methods:** In this prospective comparative study, 100 patients were divided into two equal groups. Group A received intradermal injections of TA (100 mg/mL), and Group B was treated with the same concentration of TA via microneedling using the Dr. PEN A6 device. Each group received three treatments at two-week intervals. Outcomes were assessed at Weeks 4, 8, 12, 16, and 20 using the Melasma Area and Severity Index (MASI) and standardized clinical photography. Statistical analysis was performed using repeated measures ANOVA, with a significance threshold of $p \leq 0.05$. **Results:** The mean age was 37.7 ± 6.1 years. Group B showed greater improvement in MASI scores compared to Group A, with a 32.5% vs 18.4% reduction at Week 4 ($p = 0.17$). Group B consistently showed statistically significant improvement at Weeks 12, 16, and 20 ($p < 0.05$), and a strong trend by Week 8 ($p = 0.001$). No adverse events were reported. **Conclusion:** TA is an effective treatment for melasma. Microneedling significantly enhances its efficacy, providing faster and greater pigmentation reduction with minimal side effects.

INTRODUCTION

Melasma is an acquired pigmentary disorder commonly affecting individuals with darker skin types, particularly Asians. It presents as symmetrical, light to dark brown macules with well-defined borders, predominantly on sun-exposed areas such as the cheeks, forehead, upper lip, and temples [1]. The condition significantly affects cosmetic appearance and quality of life. To objectively assess melasma severity, Maluki and Al-Sabak introduced the Modified Melasma Area and Severity Index (mMASI) in 2015, which evaluates the extent and darkness of pigmentation on each side of the face before and after treatment [2]. Although the exact pathogenesis of melasma remains unclear, several triggering factors have been identified, including hormonal influences (such as pregnancy or hormone therapy), Ultraviolet (UV) radiation, cosmetic products, phototoxic drugs, and anti-epileptic medications [3]. UV radiation may lead to pigmentation through photo-induced hormonal activity, inflammatory mediators, and growth factors that influence melanocyte activity [4]. A variety of treatment modalities have been

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explored ranging from topical depigmenting agents and chemical peels to dermabrasion and laser therapy but their results are often inconsistent or unsatisfactory [5, 6]. Tranexamic Acid (TA), a synthetic derivative of lysine, has emerged as a promising treatment option. It is used orally, topically, intradermally (mesotherapy), or via microneedling to inhibit melanogenesis. TA acts by reversibly blocking lysine binding sites on plasminogen, thereby inhibiting the conversion of plasminogen to plasmin, which reduces inflammation and vascular factors that stimulate melanin production. Given its potential, this study aims to compare the effectiveness of intradermal TA (mesotherapy) with that of microneedling-assisted topical TA application in the management of melasma [7, 8]. In recent years, Tranexamic Acid (TA) has emerged as a promising therapeutic option for melasma. Its proposed mechanisms of action include inhibition of melanocyte proliferation, reduction in melanin synthesis, decreased dermal vascularization, and suppression of mast cell activity within the dermis [9]. Transepidermal delivery of TA through microneedling, as well as localized intradermal microinjections (mesotherapy), have shown encouraging results in recent clinical studies [10-12]. However, there is limited direct comparative evidence evaluating the effectiveness of these two delivery methods.

This study aimed to address this gap by comparing the efficacy of intradermal TA (mesotherapy) and microneedling-assisted topical TA in the treatment of melasma.

METHODS

In Pakistan Emirates Military Hospital's Department of Dermatology, a prospective comparative study was carried out. The study spanned from January 2024 to June 2024, a period of six months. Adult males and females with moderate-to-severe bilaterally symmetrical melasma distribution, aged 18 to 50, were included in the target population. Diagnostic Tools for Melasma: Diagnosis of melasma was clinically confirmed using a Wood's lamp examination, which helped distinguish between epidermal and dermal melasma. Additionally, a detailed personal and medical history was taken to confirm the symmetrical distribution and moderate-to-severe classification of melasma. Consideration of comorbidities: participants with conditions that could potentially affect melasma outcomes were excluded. These included: pregnant or nursing women, patients taking oral contraceptives or hormone replacement therapy, individuals with bleeding disorders or using anticoagulants, patients with known allergies to tranexamic acid and those who had received any depigmenting treatment within the past month. Patients were selected from the Pakistan Emirates Military Hospital's Department of Dermatology after meeting the exclusion and inclusion criteria. The sample size was calculated based on a confidence level of 95%, a power of 80%, and a one-tailed test to detect a significant difference between the two treatment groups. The proportions were assumed as 0.18 for the microinjections group and 0.33 for the microneedling group. A 10% dropout rate was also considered in the final calculation. However, 200 patients were included in this investigation to allow for any variability. a sample size of 100 individuals, 50 in each treatment arm, who will present between January and June of 2024. To identify the type of melasma, a Wood's lamp examination was conducted following the acquisition of comprehensive personal and medical histories. Melasma severity was evaluated using a modified MASI grading system. Prior to treatment, the lesions of the patient were photographed in both treatment arms. About an hour before the procedure, an anaesthetic cream (5% lidocaine and 5% prilocaine) was applied with a closed dressing for maximum effectiveness. There were 100 mg/mL TXA ampoules used in the first treatment arm. The DR. PEN A6 microneedling machine was used to perform the microneedling technique, and a sterile disposable cartridge containing 36 needles was used. To cause localised bleeding, these needles were placed 2-4 mm into the targeted skin area. Making punctures in the skin in horizontal, vertical, and diagonal orientations was the needling technique. A total of 5 cc of TXA was applied topically on each patient during the microneedling treatment. After the microneedling process was finished, the skin was covered for 15 minutes with sterile gauze (SOAK) that contained 5 mL from each ampoule. Using a 1cc insulin syringe, intradermal injections of 100 mg/mL TA supplied in vials containing 100 mg/mL solutions were given to melasma lesions in the second treatment group. Every two weeks, TA injections under the skin were administered. To avoid cosmetic defects, one centimeter distances were measured with a ruler and marked with a washable marker. In order to produce a wheal-like area on the skin, 0.1 mL of solution was injected into each indicated site at an angle ranging from 5 to 15 degrees. Thirty minutes after the treatment, the areas were cleaned with an alcohol pad. After the process, ice packs were used. Weeks 0, 2, and 4 saw the conduct of the experiment three times at 2-week intervals. Weeks 4, 8, 12, 16, and 20 saw the comparison of the results. At every visit, clinical images were taken, and assessments were conducted to gauge the clinical response. These assessments included patient and physician global assessments, as well as modified Melasma Area Severity Index (MASI) scoring. The study was approved by the Institutional Review Board (IRB) of Pakistan Emirates Military Hospital. Ethical approval number: (A/28/ERC/35/24). All participants provided written informed consent, and the study was conducted in compliance with the Declaration of Helsinki guidelines. SPSS version 23.0 was used to analyse the data. To compare the demographic and clinical characteristics of the two groups, Chi-square and unpaired t-tests analyses

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were used. Every follow-up was conducted using the Mann-Whitney U test to evaluate changes in lesional counts. The percentage decrease in inflammatory, non-inflammatory, and overall acne counts in both groups was also evaluated using the Mann-Whitney U test. Less than 0.05 was the threshold for a statistically significant p-value.

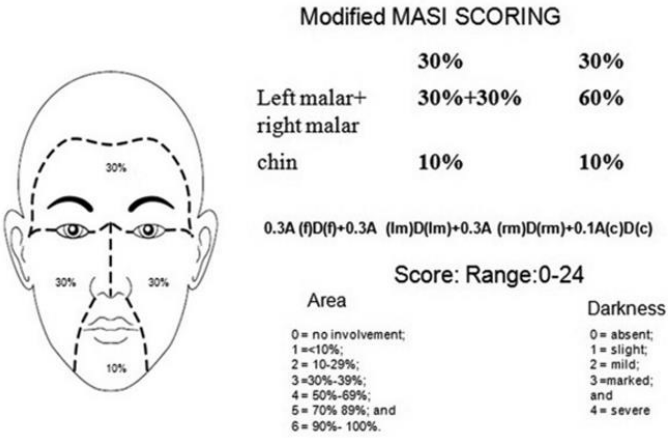

Figure 1: Modified MASI Scoring System

RESULTS

The distributions of the clinical parameters and demographic traits of melasma patients receiving treatment are shown in Table 1. A total of 100 people participated in the trial, 50 in each of the two treatment groups (Group B, microneedling) and Group A, mesotherapy. The mean age of the participants in both groups was 37.7 years; there was not any statistically significant difference (p=0.08) between the mean ages of Group A (37.2 years) and Group B (38.3 years). The distribution of sexes showed that 82% of participants were female overall, with 78% of them in Group A and 86% in Group B. This difference did not reach statistical significance (p=0.29). 60% of subjects had Type 4 skin, 40% had Type 5 skin, and the distributions of the two categories were similar (p=0.68). There was not any statistically significant difference (p=0.72) among the groups for the forms of melasma detected, which were 52% centrofacial, 46% malar, and 2% mandibular. 9 percent of the melasma patterns were epidermal, 12 percent were dermal, and 79 percent were mixed types. The distribution of patterns did not significantly differ across the groups (p=0.51). For both treatment groups mesotherapy (Group A) and microneedling (Group B) Table 2 shows the mean modified Melasma Area Severity Index (MASI) scores and improvement in percentage at various time points. Group A's mean MASI score at baseline (MASI b) was 8.94 ± 2.16, whereas Group B's mean score was 9.11 ± 4.10. At baseline, there was not any statistically significant difference between the groups (p=0.32). Group A demonstrated an 18.39% improvement after 4 weeks (MASI 1) with a mean score of 5.65 ± 1.68, while Group B demonstrated a 32.45% improvement at the same time with a mean score of 6.15 ± 2.52. There was no statistically significant difference in the groups' percentage improvement (p=0.17). Group B's mean score at 8 weeks (MASI 2) was 5.41 ± 2.41, indicating a 40.59% improvement, whereas Group A's mean score had dropped to 4.94 ± 1.73, indicating a 28.63% improvement. Given that the difference was statistically significant (p=0.001), microneedling was clearly more successful at this particular time. Group A's mean score at 12 weeks (MASI 3) was 4.76 ± 1.76, indicating a 31.32% improvement, whereas Group B's mean score at the same time was 5.21 ± 2.05, indicating a 42.71% improvement. The greater efficacy of microneedling was further supported by the statistical significance of this difference (p=0.01). Group A's mean MASI score at 16 weeks (MASI 4) was 4.56 ± 1.76, indicating a 34.21% improvement, while Group B's mean score at that same time was 5.06 ± 2.14, indicating a 44.41% improvement. The difference was still statistically significant (p=0.02), indicating the continued superiority of microneedling. At 20 weeks (MASI 5), Group B's mean score was 5.06 ± 2.14, indicating a 44.41% improvement, whereas Group A's mean score was 4.45 ± 1.69, indicating a 35.72% improvement. The difference's statistical significance (p=0.01) attests to the consistent superior outcomes of microneedling. In conclusion, all time points were found to exhibit consistent superior efficacy of microneedling over mesotherapy, with statistically significant differences observed at multiple intervals. Melasma severity improved and MASI scores decreased as a result of both treatments.

Table 1: The Distributions of Demographical Characteristics and Clinical Parameters of Patients in Treatment of Melisma (n=200)

Variables	Total Mean ± SD/Frequency (%)	Group A Mesotherapy Mean ± SD/ Frequency (%)	Group B Microneedling Mean ± SD/ Frequency (%)	p-value
Age (Years)				
Age	37.7 ± 8.6	37.2 ± 9.2	38.3 ± 8.1	0.54[a]
Sex				
Female	82 (82.0)	39 (78.0)	43 (86.0)	0.29[b]
Male	18 (18.0)	11 (22.0)	7 (14.0)	

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Fitzpatrick Skin Type				
Type 4	60 (60.0)	29 (58.0)	31 (62.0)	0.68[b]
Type 5	40 (40.0)	21 (42.0)	19 (38.0)	
Type of Melasma				
Centro facial	52 (52.0)	28 (56.0)	24 (48.0)	0.72[c]
Malar	46 (46.0)	21 (42.0)	25 (50.0)	
Mandibular	2 (2.0)	1 (2.0)	1 (2.0)	
Pattern of Melasma				
Epidermal	9 (9.0)	6 (12.0)	3 (6.0)	0.51[c]
Dermal	12 (12.0)	5 (10.0)	7 (14.0)	
Mixed	79 (79.0)	39 (78.0)	40 (80.0)	

*SD (Standard Deviation), a (unpaired t-test was applied to measure the level of significance), b (Chi-square test was applied to measure the level of significance), c (Fisher's exact test was applied to measure the level of significance).

Comparison of mean modified MASI scores and percentage improvement between Microneedling and Mesotherapy groups (n = 100) (Table 2).

Table 2: Mean modified Melasma Area Severity Index (MASI) Scores and Percentage Improvement of Both the Groups (n=100)

Variables	Group A (Mesotherapy) Mean ± SD/(%)	Group B (Microneedling) Mean ± SD/(%)	p-value
MASIb			
Percentage Improvement	8.94 ± 2.16	9.11 ± 4.10	0.32[a]
MASI 1 (4 Weeks)			
Mean	5.65 ± 1.68	6.15 ± 2.52	0.17[a]
Percentage Improvement	18.39%	32.45%	
MASI 2 (8 Weeks)			
Mean	4.94 ± 1.73	5.41 ± 2.41	0.001[a]
Percentage Improvement	28.63%	40.59%	
MASI 3 (12 Weeks)			
Mean	4.76 ± 1.76	5.21 ± 2.05	0.01[a]
Percentage Improvement	31.32%	42.71%	
MASI 4 (16 Weeks)			
Mean	4.56 ± 1.76	5.06 ± 2.14	0.02[a]
Percentage Improvement	34.21%	44.41%	
MASI 5 (20 Weeks)			
Mean	4.45 ± 1.69	5.06 ± 2.14	0.01[a]
Percentage Improvement	35.72%	44.41%	

*SD (standard deviation), a (unpaired t-test was applied to measure the level of significance).

The percentage improvement in Melasma Area Severity Index (MASI) ratings for both treatment groups microneedling (Group B) and mesotherapy (Group A) is shown in Table 3. Comparing Group A to Group B, the data shows that a greater percentage of patients in Group A had little to no improvement. In particular, just 8% of patients in Group B saw the same result as 12% of patients in Group A who did not exhibit any improvement. In terms of percentage improvement, 26% of individuals in Group A and 18% of individuals in Group B saw improvements of less than 25%. 44% of patients in Group A showed improvement in the range of 25% to 50%, while 48% of patients in Group B showed comparable improvements. 18% of Group A individuals and 24% of Group B individuals were in the improvement range of 51% to 75%. Remarkably, 2% of individuals in Group B and none of the individuals in Group A showed recovery between 76% and 100%. Mesotherapy (Group A) was less successful in creating higher percentages of improvement than microneedling (Group B), as evidenced by the statistically significant variations in improvement percentages between the two groups (p=0.001).

Table 3: Percentage improvement and adverse event of Melasma Area Severity Index (MASI) scores in both the groups (n=100)

Variables	Group A Mesotherapy Frequency (%)	Group B Microneedling Frequency (%)	p-value
Response (%)			
No Improvement	6 (12.0)	4 (8.0)	0.001[a]
<25	13 (26.0)	9 (18.0)	
25-50	22 (44.0)	24 (48.0)	
51-75	9 (18.0)	12 (24.0)	
76-100	-	1 (2.0)	
Adverse Event			
Itching	6 (12.0)	2 (4.0)	0.001[a]
Burning	4 (8.0)	2 (4.0)	
Erythema	8 (16.0)	5 (10.0)	

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No Adverse Events	32 (64.0)	41 (82.0)	

a (Chi-square test or Fisher's exact test was applied to measure the level of significance).

The frequency of side effects that patients in the two treatment groups microneedling (Group B) and mesotherapy (Group A) experienced is shown in Table 3. According to the data, Group A experienced unfavourable events more frequently than Group B. In particular, itching was reported by 12% of individuals in Group A and just 4% of individuals in Group B. Comparably, 8% of individuals in Group A and 4% in Group B reported experiencing burning sensations. In Group A, erythema was observed in 16% of individuals, while in Group B, it was observed in 10% of patients. Regarding total adverse events, 64% of individuals in Group A and 82% of individuals in Group B reported at least one adverse effect and no adverse event, respectively. Mesotherapy (Group A) was linked to a higher incidence of adverse effects than microneedling (Group B), as evidenced by the statistically significant (p=0.001) variations in the frequency of adverse events between the two groups. Figures 2 and 3 displayed the total PGA and PtGA scores for each group. Figure 2 illustrated the trends in Physician Global Assessment (PGA) and Patient Global Assessment (PtGA) scores across multiple follow-up visits in the mesotherapy group.

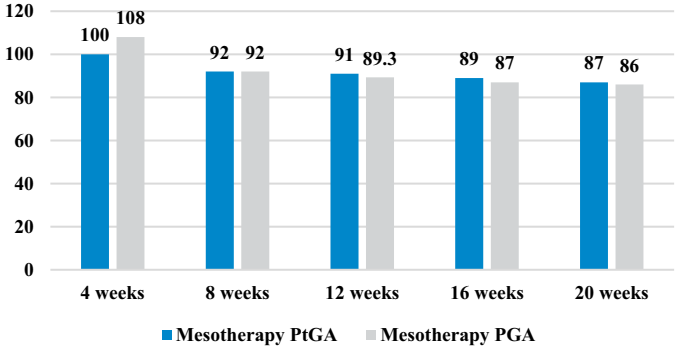

Figure 2: Total PGA and PtGA Scores at Different Visits in The Mesotherapy Group

Figure 3 displayed the progression of Physician Global Assessment (PGA) and Patient Global Assessment (PtGA) scores over the treatment period in the microneedling group.

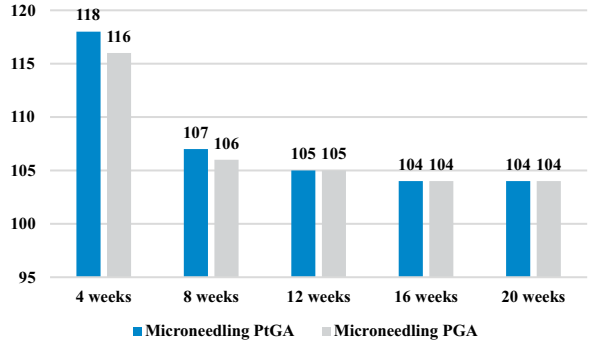

Figure 3: Total PGA and PtGA Scores at Different Visits in The Microneedling Group

DISCUSSION

The main uses of tranexamic acid are for its antihemorrhagic and antifibrinolytic properties. Topical trans-4-(aminomethyl) cyclohexanecarboxylic acid (trans-AMCHA, sometimes referred to as TA) is a plasmin inhibitor that has been demonstrated in recent studies to be able to prevent UV-induced pigmentation in animal models, including guinea pigs. By preventing plasminogen from attaching to keratinocytes, trans-AMCHA applied topically suppresses UV-induced plasmin activity in these cells. Melanocyte tyrosinase activity is subsequently decreased as a result of this action, which also lowers prostaglandin synthesis and free arachidonic acid [13]. Moreover, urokinase-type plasminogen activator, which is secreted by human keratinocytes, increases melanocyte activity in vitro. TA's ability to block this process may account for its effectiveness in lowering melasma linked to hyperpigmentation [14]. Treatment for both mixed and dermal kinds of melasma may benefit from intradermal injection of TA. Drug delivery with microneedle technology is almost painless and requires little physical intervention [15]. By making tiny holes in the skin, this method allows a wide range of medicinal substances including proteins to enter the body that would not normally be able to pass through healthy skin. Pistor offered localized microinjections, also referred to as "mesotherapy," for the first time in France [16]. In medicine, mesotherapy is a commonly used procedure that involves injecting 0.05 to 0.1 mL of highly diluted drug mixes or individual pharmaceuticals subcutaneously or intradermally into particular body parts that present health or cosmetic issues. This technique works with any intravenously injected chemical, but it does not work with alcoholic or greasy solvents. The main objective is to directly provide medication to the affected area, which minimises the need for oral medications and permits the use of lower amounts of medication. The microneedling tool is a simple, portable instrument with a handle that has a cylinder filled with tiny, 0.5–2 mm stainless steel needles. The needle-studded cylinder is rolled over the skin in different directions to create microchannels, which have therapeutic effects. The beauty industry uses this process, called "microneedling," to treat a variety of skin ailments, including as post-burn scars, acne, wrinkles, and pigmentation problems [17]. Additionally, it is applied as a component of collagen induction therapy for cosmetic rejuvenation [18]. In this study, we assessed the efficacy and safety of two different approaches to tranexamic acid (TA) administration for treating melasma: microneedling and localised microinjections (mesotherapy). The impact of both techniques was evaluated by comparing baseline, 4, 8, and 12-week treatment outcomes on the Melasma Area and Severity Index (MASI) scores, Patient Global Assessment (PtGA), and Physician Global Assessment (PGA) [19]. Over

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time, MASI scores, PtGA, and PGA significantly decreased for both treatment regimens. The improvement from microneedling was higher than from microinjections, although the difference was not statistically significant. It's possible that microneedling's increased effectiveness stems from its capacity to administer medicine more evenly and deeply into the skin. During the next three-month follow-up period, all assessment scores stabilized [20]. The study's small sample size might have hampered the practical implications of the findings. Furthermore, it's possible that the brief course of treatment did not adequately reflect the long-term safety and effectiveness of both topical therapies. The study population's lack of variety may have limited the data' generalizability to larger demographic groups. Moreover, there was no evaluation of the patients' adherence to the medication, which might have affected the results.

CONCLUSIONS

Tranexamic Acid (TA) shows promise as a safe, efficient, and therapeutic drug for the treatment of melasma in light of the findings. This drug is reasonably priced and easily obtained. It can be used in a clinical context and provides almost no downtime, low adverse effects, and rather quick outcomes. The more efficient and consistent drug administration made possible by the microchannels made by microneedling may be the reason for the better therapeutic response seen in the microneedling group.

Authors Contribution

Conceptualization: AF

Methodology: FKW, IG, WAK, NR, NUW

Formal analysis: NG

Writing, review and editing: AUB, BA

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors declare no conflict of interest.

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