Original Article

Evaluation of the Efficiency of Microneedling with PRP Versus Microneedling with Tranexamic Acid in the Treatment of Melisma

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ABSTRACT

Background: Melasma, characterized by irregular skin hyperpigmentation, presents a therapeutic challenge with limited universal solutions. Platelet-rich plasma (PRP) and Tranexamic Acid (TXA), coupled with microneedling, offer promising avenues for treatment. This clinical trial sought to compare the efficacy and adverse effects of microneedling with PRP versus TXA in managing melasma.

Methods: The study was a single-blind, randomized controlled trial from May 2022 to Apr 2023 and enrolled 23 female melasma patients. Using the coin toss method, patients were randomly assigned to receive microneedling with PRP on one side and microneedling with TXA on the other. Evaluation parameters included Melasma Area and Severity Index (MASI) scores, melasma improvement grading, patient satisfaction, and treatment-related side effects, monitored over three sessions at 3-week intervals.

Results: Both microneedling approaches demonstrated effectiveness, with the PRP group exhibiting significantly lower MASI scores at the 6th and 9th wk. However, no significant distinctions were observed in improvement grading or patient satisfaction between the PRP and TXA groups. Side effects were minimal, limited to transient burning and mild pain during the procedure.

Conclusion: Microneedling with PRP and TXA emerged as a safe and effective treatment for melasma. While the PRP group showed potential superiority in MASI scores, comprehensive considerations, including patient preferences and long-term outcomes, are crucial. Larger, multi-center studies with extended follow-up periods are warranted for a more nuanced understanding of these treatments in melasma management.

KEYWORDS
Melasma; Platelet-rich plasma; Tranexamic acid; Microneedling; Clinical trial

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INTRODUCTION

Melasma is a commonly acquired hypomelanosis characterized by a disturbance in the melanogenic process [1]. It manifests as irregularly bordered patches or macules ranging from light to dark brown, often forming a symmetrical pattern on the face [2]. The forehead, cheeks,

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chin, perioral region, and neck are most commonly affected [3]. Melasma significantly impacts an individual's appearance, compromising quality of life [4]. The primary etiology and pathogenesis of melasma remain incompletely understood, appearing to be multifactorial with genetic and acquired factors, including pregnancy, hormonal medication use, sun exposure, anticoagulant drugs, and thyroid disorders, contributing to its onset [5].

Unfortunately, treating melasma is challenging as the disease's pathogenesis remains unclear [6]. Common therapeutic approaches include medication, chemical peels, and lasers, but no universal effective global treatment for this condition exists [7]. Recent studies in the field of dermatology and plastic surgery have highlighted the role of Platelet-Rich Plasma (PRP) in pigmented dermatoses. PRP is an autologous blood derivative concentrated through centrifugation, reaching a platelet concentration 3 to 5 times higher than baseline [8]. Another medication gaining attention in melasma treatment is Tranexamic Acid (TXA), an antifibrinolytic drug used as a depigmenting agent [9]. TXA can be administered orally, topically, intradermally, or intravenously [10].

Nowadays, microneedling is a relatively new, simple, safe, effective, and minimally invasive therapeutic approach. This method involves creating microchannels that, instead of damaging the epidermis, generate controlled wounds in the skin. These injuries lead to minimal superficial bleeding and, through the release of various growth factors such as Platelet-Derived Growth Factor (PDGF), Transforming Growth Factors alpha and beta (TGF-α and TGF-β), tissue-activating protein, Fibroblast Growth Factor (FGF), contribute to the cascade healing of wounds. Additionally, by passing through the branching layer and directly delivering drugs to the skin's blood vessels, microneedling enhances drug penetration through the skin barrier [11]. As microneedling is a simple and tolerable method for patients compared to intradermal drug injections, ensuring uniform drug delivery through the creation of microchannels, it has gained popularity. Microneedling, utilizing both Platelet-Rich Plasma (PRP) and Tranexamic Acid (TXA), is a safe and effective treatment for melasma.

Therefore, we aimed to compare the impact of microneedling with PRP to microneedling with TXA in the treatment of melasma, taking a step towards evaluating both methods concerning effectiveness and adverse effects.

MATERIALS AND METHODS

Participants and study design

This study was conducted as a single-blind, randomized, controlled clinical trial. The study was conducted from May 2022 to Apr 2023 at the dermatology clinic of Jundishapur University of Medical Sciences in Ahvaz, southern. The study population consisted of patients diagnosed with melasma. Twenty-three patients with melasma were enrolled in the study based on inclusion and exclusion criteria.

Inclusion criteria included women aged 18-50 yr, patients with symmetric and bilateral facial melasma, and informed consent of the patient to participate in the study. Exclusion criteria include pregnant women and lactating mothers, use of oral contraceptive pills during the last 12 months and the study, the presence of any history of coagulation disorders and thrombotic problems, use of anticoagulants and anticonvulsants, and the presence of sensitivity to the studied drugs and topical lidocaine, history of melasma treatment in the past month, active herpes simplex lesions on the face and facial warts. In this study, both sides of the face (right and left side) of the patients were examined separately. For randomization, two treatment methods, A and B, were used; in treatment method A, microneedling treatment with tranexamic acid was performed for the right side of the patient's face, and microneedling treatment with PRP was performed for the left side. In treatment method B, microneedling treatment with PRP was performed on the right side of the patient's face, and microneedling treatment with tranexamic acid was performed on the left side. The patients were placed in treatment groups A and B using the coin toss method. The patients were unaware of how to allocate the treatment to the right and left side of the face, but the therapist was aware.

Procedures

Initially, photographs of the patient's lesions were taken before the commencement of the treatment. For enhanced efficacy, patients applied a topical

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anesthetic cream (containing 5% lidocaine and 5% prilocaine) with occlusive dressing approximately one hour before the treatment. The NPRP model kit of Standard Company (Noavaran Salamat Arjang) was used to prepare the PRP solution in this study. First, 20 cc of peripheral blood was taken from the patient and placed in sterile tubes containing the anticoagulant sodium citrate. Then, the blood was centrifuged at 1600 rpm for 12 min, and then plasma and buffy coat were transferred to the second tube without anticoagulant. Magda was centrifuged again for 7 min at 3500 rpm. The bottom 1/3 of the tube is platelet-rich plasma (PRP). The top 2/3 of the tube contents were discarded, and 0.9 ml of PRP was prepared in an insulin syringe containing 0.1 ml of calcium gluconate (activator). Tranexamic Acid (TXA) ampoules were also used in the form of ampoules of 500 mg/5 ml.

The microneedling procedure was performed using the A7 microneedling device with a single-use sterile cartridge containing 36 needles at a depth of 1.5 to 2 mm. The goal was to achieve pinpoint bleeding in the affected microneedling area, performed in horizontal, vertical, and oblique directions. During the micro-needling procedure, two ccs of Tranexamic Acid (TXA) and two ccs of Platelet-Rich Plasma (PRP) were directly applied to the skin for each side of the face. Immediately after completing microneedling, one cc of each of the mentioned substances was placed on the skin with sterile gauze for 15 min. Necessary recommendations for sun protection were provided to the patients. This procedure was performed in 3 sessions with a 3-week interval (wk 0, 3, and 6).

Variables and outcomes

Demographic characteristics of patients, including age, gender, family history, skin phenotype, type of melasma, and affected areas, were recorded. In the first visit, after taking the history, each patient was examined with a Wood's lamp, and the type of melasma (epidermal, dermal, mixed) was determined. If the melasma spot intensified under the light of the Wood's lamp, it was considered epidermal and otherwise dermal. If part of the lesion is aggravated and part is unclear, it is considered mixed. The primary outcome in this study included the improvement of melasma, evaluated using the MASI (Melasma Area and Severity Index) score and grading of melasma improvement. MASI score is calculated based on area A (Area), darkness D (Darkness), and homogeneity H of hyperpigmentation. The right side of the forehead, the right side of the cheek, and the right side of the chin are calculated as 15%, 30%, and 5% of the entire face, respectively. Similar areas on the left side are also calculated similarly to include 100% of the face. The evaluation score of A in each area is between 0-6. The evaluation score of D and H is from 0-4. MASI score is calculated from the product of the score A and the sum of D and H for each of the six areas:

$$0.15(A)(D+H) + 0.3(A)(D+H) + 0.05(A)(D+H)$$

The maximum MASI score for each side is 24, and the minimum is 0. MASI score was calculated before treatment and the 3rd, $6^{th,}$ and 9^{th} wk after treatments. Evaluation of melasma improvement grading by the Physicians Global Assessment (PGA) was done dynamically using photos taken at the beginning and then at the end of the 9th week of treatment (>75% Lightning (Excellent), 51%-75% (Good), 26%-50% (Fair), 0%-25% (Poor)). Secondary outcomes include patient satisfaction and treatment side effects. Patient satisfaction with the treatment method was classified and recorded as satisfaction, relative satisfaction, and dissatisfaction.

Statistical analysis

SPSS program (IBM Corp., Armonk, NY, USA, ver. 28) was used for statistical data analysis. The Shapiro-Wilk test was used to determine the normal distribution of quantitative data. The independent sample *t*-test was used to compare quantitative data, and the chi-square test was used to compare qualitative data. In all analyses, a *P*-value less than 0.05 was considered significant.

Ethical statement

This Study was approved by ethical committee of Ahvaz Jundishapur University of Medical sciences (IR.AJUMS.HGOLESTAN.REC.1401.100). In addition, it was registered in Iranian Registry of Clinical Trials (IRCT20221025056287N1).

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RESULTS

Twenty-three patients were included in this study. All participants in this study were female. The mean age was 30.26 ± 2.66. The minimum age was 25, and the maximum was 45 yr. The age range of 30 to 35 yr had the highest frequency. The majority of patients had skin type 4 (43.48%). Moreover, 39.13% had type 3, and 17.39% had type 2. Ten patients (43.50%) had a family history of melasma. Regarding melasma types, 13 patients (56.52%) had an epidermal type, and ten patients (43.48%) had a mixed type. Regarding the involvement area, 60.87% had involvement in the malar area and 39.13% in the centrofacial area. The MASI score during the study period based on treatment groups is shown in Table 1. At the 6th and 9th wk after treatment, mean MASI scores were significantly lower in PRP than TXA group (P=0.02 and <0.01, respectively).

Melasma improvement grading (PGA) for each treatment group is shown in Table 2. There was no significant difference between groups (P=0.98). The level of patient satisfaction according to the type of treatment is shown in Table 3 that was no significant difference between groups (P= 0.44). Except for the burning and mild pain during the procedure, no side effects were seen in patients in each group. The MASI score during the study period in PRP and TXA treatment groups based on the type of melasma are shown in Tables 4 and 5, respectively. In the PRP and TXA treatment groups, the mean MASI score during the study period did not significantly differ based on the type of melasma (P>0.05).

Table 1: The MASI score during the study period

The MASI score	Mean (Sd)		
Time/Groups	**PRP**	**TXA**	***P*-value***
Before treatment	6.46 (1.18)	6.02 (1.06)	0.22
3th wk after treatment	6.16 (1.15)	5.80 (1.02)	0.29
6th wk after treatment	4.47 (1.03)	5.48 (1.37)	0.02
9th wk after treatment	3.72 (0.89)	4.59 (1.07)	<0.01

*: Independent sample *t*-test.

Table 2: Melasma physicians' global assessment (PGA) for each treatment group

	Number (%)		
Grading/Groups	**PRP**	**TXA**	***P*-value***
Excellent	4 (17.4)	5 (21.7)	
Good	10 (43.5)	9 (39.1)	
Fair	5 (21.7)	5 (21.7)	0.98
Poor	4 (17.4)	4 (17.4)	
Total	23 (100)	23 (100)	

*: Chi-square test.

Table 3: The level of patient satisfaction according to the type of treatment

	Number (%)		
Satisfaction /Groups	**PRP**	**TXA**	***P*-value***
Satisfaction	10 (43.5)	6 (26.1)	
Relative satisfaction	7 (30.4)	10 (43.5)	0.44
Dissatisfaction	6 (26.1)	7 (30.4)	
Total	23 (100)	23 (100)	

*: Chi-square test.

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Table 4: The MASI score during the study period in the PRP treatment group based on the type of melasma

The MASI score	Mean (Sd)		
Time/Groups	Epidermal	Mixed	*P*-value*
Before treatment	5.93 (1.15)	6.14 (0.84)	0.20
3th wk after treatment	5.73 (1.09)	6.73 (1.01)	0.60
6th wk after treatment	4.50 (0.75)	4.45 (1.35)	0.91
9th wk after treatment	3.99 (0.72)	3.38 (1.01)	0.10

*: Independent sample *t*-test.

Table 5: The MASI score during the study period in the TXA treatment group based on the type of melasma

The MASI score	Mean (Sd)		
Time/Groups	Epidermal	Mixed	*P*-value*
Before treatment	6.19 (1.20)	5.80 (0.85)	0.39
3th wk after treatment	5.90 (1.16)	5.67 (0.85)	0.60
6th wk after treatment	5.92 (1.68)	4.91 (0.42)	0.07
9th wk after treatment	4.77 (1.09)	4.35 (1.05)	0.35

*: Independent sample *t*-test.

DISCUSSION

This study evaluates the effectiveness and adverse effects of microneedling with PRP compared to microneedling with TXA in treating melasma. PRP and TXA treatments demonstrated efficacy, with significantly lower MASI scores in the PRP group at the 6th and 9th wk. However, the two groups had no significant difference in melasma improvement grading or patient satisfaction. Side effects were minimal, limited to transient burning and mild pain during the procedure.

Our study, closely mirroring the methodologies of Gharib et al. [12], demonstrated the efficacy of microneedling with Platelet-Rich Plasma (PRP) in treating melasma. The findings, including a significant reduction in Melasma Area and Severity Index (MASI) scores after the third and fourth sessions, align with the outcomes of Gharib et al. [12]. Importantly, the absence of significant differences in side effects reinforces the safety profile of microneedling with both PRP and Tranexamic Acid (TXA). Zhao et al. [13] in a meta-analysis, involving 395 patients, further supports the positive impact of PRP in melasma treatment, showcasing a significant reduction in MASI scores post-treatment. The emphasis on the efficacy of combining microneedling with PRP over intradermal PRP injections corresponds with our study's suggestion of microneedling with PRP as a superior approach. While similar in design, Hofny et al. [5] in a clinical trial revealed no statistically significant difference in MASI score reduction between microneedling with PRP and intradermal PRP injections. This nuanced perspective underscores the complexity of treatment outcomes and highlights the need for continued exploration of microneedling nuances in combination with PRP. Pazyar et al. [14] clinical trial focused on tranexamic acid's efficacy in melasma treatment, affirming its safety and effectiveness that aligns with our study. The comparative analysis of tranexamic acid concentrations and hydroquinone provides valuable insights into optimizing treatment approaches. Our study adds to the evolving understanding of melasma treatment by emphasizing the effectiveness of microneedling with PRP. While consistent trends support the superiority of this approach, the nuances in treatment protocols warrant ongoing investigation.

The collective evidence from diverse studies enriches our comprehension of melasma therapeutics, guiding clinicians toward tailored and effective interventions. Continued research, incorporating larger cohorts and longer-term assessments, is crucial to solidify these findings and refine treatment paradigms. The study's results support the efficacy of both microneedling with PRP and TXA in treating melasma. The lower MASI scores in the PRP group suggest a potential superiority in outcomes over the TXA group. However, the lack of significant differences in improvement grading and patient satisfaction between the groups warrants

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careful consideration. Other factors, such as patient preferences, cost, and long-term outcomes, should be weighed in clinical decision-making.

While the study provides valuable insights, it is essential to acknowledge its limitations. The sample size is relatively small, limiting the generalizability of the findings. The short follow-up period of nine weeks may not capture long-term outcomes and potential recurrence. Additionally, the single-center nature of the study could introduce biases related to local demographics and practices.

CONCLUSION

Microneedling with PRP and TXA appears safe and effective in treating melasma. The study suggests a potential advantage for PRP regarding MASI scores, although no significant differences were observed in improvement grading or patient satisfaction. Further research with larger sample sizes, more extended follow-up periods, and multi-center designs is warranted to validate these findings and provide a more comprehensive understanding of the comparative efficacy of these treatments in melasma management.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interests.

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