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Original Article

Comparative Efficacy of Intralesional Tranexamic Acid and Platelets Rich Plasma (Prp) In The Treatment of Melasma

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ABSTRACT

Objective: To study the efficacy of intralesional tranexamic acid compared to platelets rich plasma (PRP) in treatment of melasma.

Study Design: Randomized Controlled Trial (ClinicalTrials.gov Identifier: NCT05884151).

Place and Duration of Study: Department of Dermatology, CMH (Combined Military Hospital) Abbottabad, from Nov 2022 to April 2023.

Methodology: Sample size of 60 patients, aged 20 to 40 years, was calculated by using OpenEpi online calculator. Informed consent was taken and patients were randomly allocated to two groups: Group A, where 30 patients were injected with intradermal tranexamic acid (4 mg/ml) and Group B, where 30 patients were treated with PRP (1 ml) intra-dermally, every fourth week, for up to 12 weeks between both groups. The modified Melasma Area and Severity Index (mMASI) was used to evaluate all patients. The final evaluation was performed on the 24th week of follow-up. For data analysis Statistical Package for the Social Sciences (SPSS) version 27.00 was used. To determine statistical significance, a paired t-samples test was used where *p*-value was <0.05.

Results: Of the 60 patients randomly assigned to two groups, Group A had mean age of 30.23+5.24 years while Group B had mean age of 29.50+5.83 years. The majority of patients were females 47(78.30%). Overall, 31(51.70%) patients had malar pattern of melasma (*p*-value=0.030) while 46(76.70%) patients had mixed melasma (*p*-value=0.015). While comparing pre-treatment efficacy, mMASI score in Group A was 12.55+8.15 while in Group B, it was 12.23+8.00, whereas post-treatment mMASI score in Group A was 7.05+5.98 and in Group B was 7.83+5.41 (*p*-value < 0.001).

Conclusions: Tranexamic acid was found to be highly effective and safer than PRP with patient compliance being better due to no pain.

Keywords: Melasma, mMASI (modified Melasma Area and Severity Index), Platelets Rich Plasma (PRP), Tranexamic Acid.

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INTRODUCTION

Melasma is a skin condition that is caused by hyper-melanosis, most frequently appearing on sun-exposed tissues such as cheekbones, chin, upper lip, and forehead among women, throughout their reproductive years.[1]. It occurs at a frequency of 1-50.00% worldwide while in Pakistan, one study reported 45.00% frequency of melasma among pregnant females[2]. Melasma can be challenging to treat because of its relapsing nature and its indeterminate aetiology [3], although certain factors play a part in its pathophysiological process, such as genetic predisposition and female hormones, both endogenous and exogenous[4]. Additionally, thyroid disorders, drugs, sun exposure and cosmetics can all be melasma triggers[5]. To date, several clinical treatments for managing melasma have been explored, including topical agents[6], oral medications[7], microinjections, mesotherapy[8], and lasers. Tranexamic acid (TXA) is a plasminogen activation inhibitor that has been utilized in the treatment of melasma in a variety of formulations and has been reported to lessen melasma, without causing major adverse effects, by lowering epidermal melanin content as well as dermal vascularity and mast cell numbers[9]. Platelet rich plasma has also been shown to cure melasma and post-inflammatory hyperpigmentation[10]. However, to the best of our knowledge, there is a lack of literature comparing the efficacy of both treatments. Thus, the rationale behind this study was to compare the efficacy between intralesional tranexamic acid compared to platelets rich plasma (PRP) in treatment of melasma.

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METHODOLOGY

A randomized controlled trial study was done in Department of Dermatology, CMH, Abbottabad from November 2022 to April 2023, after Ethics Committee

approval (Reg# CMHAtd-ETH-51-Derma-22) and RCT registration (Reg# ClinicalTrials.gov Identifier: NCT05884151). The sample size was determined using OpenEpi online sample size mean difference calculator, with a significance level of 95%, power of study 80%, the ratio of sample size B: A of 1 and assumed mMASI score in Group A (TXA) Mean + SD = 4.639 ± 3.863, in Group B (PRP) Mean + SD = 10.673 ± 4.642, where calculated sample size was 16 with 8 in each group, however sample size was increased to 60, with 30 in each group, to increase the validity of the study11. Informed written consent was taken from all participants who were enrolled using non-probability consecutive sampling technique. The confidentiality and anonymity of data taken during the examination was ensured at every level.

Inclusion Criteria: Patients belonging to either gender, between 20 to 40 years of age, suffering from melasma, who presented to Dermatology Out-patient Department (OPD) and agreed to return for follow-up were included.

Exclusion Criteria: Women who were pregnant or breastfeeding, patients with bleeding disorders, prior history of allergy for TXA, active herpes simplex, face warts or active dermatoses, concurrent use of anti-coagulants and patients with unrealistic expectations were not included.

Patients were randomly assigned into two equal groups, where Group A, with 30 patients, was treated with intradermal tranexamic acid injection (4 mg/ml). For preparation, an insulin syringe was used with a volume of 1ml containing 0.04 ml of TXA and the reminder being normal saline to ensure 4 mg preparation in each insulin syringe. Group B, with 30 patients, was prescribed with PRP (1 ml) intra-dermally. PRP was obtained manually by a two-step procedure using a centrifuge machine where first spin was performed at 1500 RPM for 10 minutes and second spin was performed at 4000 RPM for 10 minutes, obtaining a two-part plasma of which upper two-thirds was platelet poor plasma and was discarded while lower one-third was platelets rich plasma and collected. Before injection, 0.1 ml calcium chloride was added for each 1 ml of PRP to activate the platelets and 1 ml PRP was injected by using insulin syringe in each cm2 of melasma. Both groups were treated every fourth week for up to 12 weeks in total. All patients had clinical examination using the mMASI (modified Melasma Area and Severity Index) scale and on follow-up, final evaluation was carried out at 24th week mark. Demographic characteristics, (age, gender, weight) were analyzed as frequency and percentages by using SPSS version 27.00. To determine statistical significance, paired t-sample test was applied for pre-and post-treatment effectiveness evaluation, taking a *p*-value<0.05 as significant.

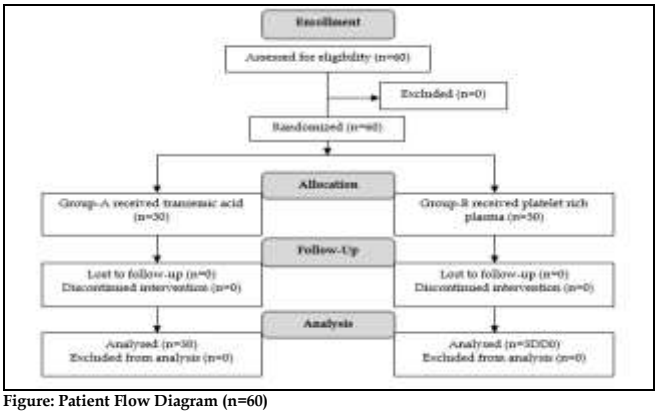

Figure: Patient Flow Diagram (n=60)

RESULTS

A total of 60 patients, with an age range of 20 to 40 years, were enrolled in two groups, 30 patients in Group A, with mean age of 30.23+5.24 years, and 30 patients in Group B with mean age of 29.50+5.83 years. The majority of patients were females (n=47, 78.30%) in both study groups, with p-value of 0.754. The pattern of melasma reported among most of the patients was malar pattern in Group A (n=18, 60%) while in Group B it was 13 patients (43.30%) with *p*-value of 0.030. Fitzpatrick skin Type III and Skin Type IV were noted, respectively, in Group A (n=13, 43.30%) and in Group B (n=15, 50.00%) with p-value of 0.406. There was a statistically significant relation between pattern and type of melasma in both groups as *p*-value was less than 0.05 as enlisted in Table-I.

Table-I: Baseline Clinical Findings in Both Treatment Groups (n=60)

Variables		Group-A (n=30) TXA n (%)	Group-B (n=30) PRP n (%)	Total n (%)	*p*-value
Gender	Male	7(23.30%)	6(20.00%)	13(21.70%)	0.754
	Female	23(76.70%)	24(80.00%)	47(78.30%)	
Pattern of Melasma	Centro-Facial	7(23.30%)	16(53.30%)	23(38.30%)	0.030
	Malar	18(60.00%)	13(43.30%)	31(51.70%)	
	Mandibular	5(16.70%)	1(3.30%)	6(10.00%)	
Type of Melasma	Mixed	27(90.00%)	19(63.30%)	46(76.70%)	0.015
	Epidermal	3(10.00%)	11(36.70%)	14(23.30%)	
Fitzpatrick Skin Type	Type-III	13(43.30%)	9(30.00%)	22(36.70%)	0.406
	Type-IV	10(33.40%)	15(50.00%)	25(41.70%)	
	Type-V	7(23.30%)	6(20.00%)	13(21.70%)	

In Group A, TXA had showed greater reduction in mean mMASI score than Group B using PRP. Group A also showed larger magnitude of paired t test

statistics of -10.406, indicating potentially larger and greater treatment efficacy and effect. Both treatments were able to significantly reduce melasma severity with $p < 0.001$ as shown in Table-II.

Table-II: Comparison of Treatment Efficacy at Week 24 of Treatment Between Both Groups (n=60)

Modified MASI score	Group-A TXA (n = 30)	Group-B PRP (n = 30)
Pre-treatment (Mean+SD)	12.55+8.15	12.23+8.01
Post-Treatment (Mean+SD)	7.05+5.98	7.83+5.41
Paired Sample t-test Statistic	-10.406	-7.804
p-value	< 0.001	< 0.001

As shown in Table-III, there was a statistical difference between groups in terms of side effects as only one patient (n=1, 3.33%) in Group A reported itching.

Table-III: Frequency of Side Effects Reported at End of Treatment Between Both Groups (n=60)

Side Effects	Group-A TXA (n = 30)	Group-B PRP (n = 30)	p-value
Erythema	0	16	< 0.001
Itching	1	2	1.000
Hyper-pigmentation	0	4	< 0.038
Pain	0	14	< 0.001
Oedema	0	0	-

DISCUSSION

In the past, several therapeutic techniques for melasma have been employed, including topical, oral, and interventional treatments[12]. The findings of this study showed that intralesional tranexamic acid had higher efficacy than PRP while treating melasma, similar to another study where tranexamic acid was noted to be much safer and more compliant among patients due to its lesser side effects[13]. Melasma was mostly reported among females with mean age of 29.67+5.35 years, which was similar to another study reported mean age to be 29.90±7.18 years[14]. In our study, most reported pattern was malar, contrary to another study which reported most common clinical pattern to be centro-facial[15] with similar finding also reported by another study[16]. In Group A of our study, tranexamic acid was administered via intradermal injection (4mg/ml) which showed higher efficacy with significant difference of post treatment mMASI mean score between tranexamic acid (Mean+SD; 7.05+5.98) and PRP (Mean+SD; 7.83+5.41), with *p*-value of 0.00 but these findings are contrary to another study which concluded that both methods of treatment were equally effective because *p*-value > 0.05 showed no significant difference between them[11]. However, another author reported statistically significant difference at the end of third and fourth session by using same treatment option and subjective patient assessment with MASI scale[17]. Furthermore, in another study, statistically significant difference was observed between micro-needling and intra-dermal tranexamic acid in the treatment of melasma with *p*-value < 0.001 but patients treated with micro needling using tranexamic acid showed more satisfactory response as compared to the intra-dermal route, thus, this different route of drug administration offers further avenues of exploration in terms of treatment efficacy[18].

LIMITATION OF STUDY

Despite its randomized controlled design, this single-center study with a modest sample size (n=60) limits generalizability to diverse populations beyond the Department of Dermatology at CMH Abbottabad. The short 24-week follow-up period may not capture long-term efficacy, recurrence rates, or sustained safety of intralesional tranexamic acid versus PRP for melasma. Potential biases from unblinded administration and assessment and reliance solely on mMASI scoring without patient-reported outcomes or histopathology further constrain the robustness of conclusions on superiority and compliance. Multicenter trials with extended follow-up and blinding are recommended.

CONCLUSION

Tranexamic acid is highly effective and safer than PRP with better compliance among patients because of no pain.

Conflict of Interest: None.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

SA & BM: Data acquisition, data analysis, critical review, approval of the final version to be published.

MAS & MH: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

DS & HF: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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