



Research Article

A COMPARATIVE STUDY OF TRANEXAMIC ACID VERSUS PLATELET RICH PLASMA INJECTIONS IN MELASMA PATIENTS

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ARTICLE INFO

Article History:

Received 21st December, 2023

Received in revised form 12th January, 2024

Accepted 22nd February, 2024

Published online 28th February, 2024

Key words:

Melasma , tranexamic acid , platelet rich plasma

ABSTRACT

Melasma is an acquired hyperpigmentation disorder of the skin characterised by hyperpigmented macules over face. **Aims:** To compare the efficacy and safety of intradermal tranexamic acid injections versus autologous platelet rich plasma in patient with melasma. **Setting and Design:** A hospital based single blinded interventional prospective study. **Material and Methods:** The patients were randomly assigned into 2 groups consisting of 63 patients each. In group A (54 female and 9 male patients) were treated with intradermal tranexamic acid injections (4mg/ml) whereas in group B (55 females and 8 male patients) patients were treated with autologous platelet rich plasma injections .The procedure was repeated after a gap of 2 weeks and a total of 4 sessions were carried out. Assessment was done using the mMASI (modified melasma area and severity index) score. **Statistical Analysis:** Data was compiled, tabulated and analysed using the SPSS software version 25.0 **Results:** In group A the mMASI score reduced from 7.73±1.81 to 4.97±1.58 and in group B it reduced from 7.59±1.68 to 3.89±1.36. Side effects were minimal in both groups. **Conclusion:** Both intradermal tranexamic acid injections and autologous PRP were found to be safe and effective therapeutic options for melasma providing substantial improvement when used as standalone therapies. PRP was found to be better than intradermal tranexamic acid injections.

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INTRODUCTION

Melasma is an acquired hyper pigmentation disorder of the skin mainly present over the sun exposed area of the body.¹ Etiological factors include hormonal influences such as changes in estrogen levels, hypothyroidism , certain drugs , visible light and genetic predisposition.² Currently available therapies include topical therapy comprising of depigmenting creams such as hydroquinone, Kojic acid, Azelaic acid and tranexamic acid. Other modalities include chemical peels and laser therapy.³ Tranexamic acid is a plasmin inhibitor which acts by inhibiting plasminogen activator, also present in epidermal basal cell and keratinocyte responsible for melanin synthesis in the skin.⁴ PRP has rejuvenating effects and helps in wound healing and may have a role in treatment of hyperpigmentation.⁵

MATERIAL AND METHODS

Study design

It was a hospital based single blinded interventional prospective study(single blinding was done by placing the injections in an opaque envelope and the patients were not aware of the coding) which was conducted in the outpatient department of dermatology over 12 months from March 2021 to February 2022 after obtaining clearance from the institutional ethical committee.

Sample size

It was calculated using sealed envelope power calculator for the binary outcome superiority trial. On the basis of previous studies it was obtained considering 31% success in the Intradermal tranexamic acid group⁶ and 54% success in the autologous platelet rich plasma group⁷. The sample size thus obtained was 69 patients in each group.

Study subjects

A total of 138 patients attending the outpatient department during the study period between the age group of age 20-50 years, Fitzpatrick skin type II - V having moderate to severe melasma and stable for last 3 months were included in the study.

Patients with history of hypertrophic scars and keloids, presence of active dermatitis , pregnant or lactating females and patients having pre-existing bleeding or coagulation disorder were excluded. The patient were explained regarding the side effects like slight pain, mild erythema and burning sensation. Informed written consent was taken from each patient.

Study intervention

The patients were randomly assigned into two groups using the coin toss method (heads was assigned group A and tails

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was assigned group B) of 69 patients each. Group A patients were treated with Intradermal tranexamic acid injections and group B was treated with autologous platelet rich plasma. In both groups patient was advised to wash the face with soap and water and pat dry. Cleansing was done by spirit swab. Topical anaesthetic agent in the form of lidocaine and prilocaine was applied for 45 minutes.

In group A Intradermal tranexamic acid at a concentration of 4 mg / ml was taken in an insulin syringe diluting it with distilled water and injected intradermally in the lesion at a gap of 0.5 cm. In group B anticoagulant citrate dextrose A (0.5 ml) and 10 ml blood were drawn into a tube. The tube was then shaken slowly for 15 seconds to allow the liquids to mix properly and then centrifuged at 2500 revolutions per minute for 15 minutes at room temperature. The resultant buffy coat and plasma were extracted in 1 ml insulin syringes and injected into the lesion at a gap of 0.5 cm.

Follow up

The patients were followed up after 2 weeks and total of 4 sessions were done. Assessment was done using mMASI score. (fig.1 : Modified Melasma Area Severity index)

Statistical Analysis

After collecting information, data was compiled, tabulated and analysed using the SPSS software version 25.0. The parameters of mean, standard deviation, ratio, frequency and percentage were used for analysing descriptive statistics. Chi square test and t test were applied. P<0.05 was considered statistically significant. The statistical power of the sample was 80% and type 1 error was 0.05.

RESULTS

Out of 138 patients 12 patients were lost to follow up (due to long duration of study and difficulty in commuting from remote areas) and only 63 patients in both groups were studied (Fig. 2). Demographic and clinical data of patients in both the groups has been mentioned in tables 1 and 2. Mean age was 32.35±7 in group A and 31.02±6.71 in group B. Most patients were females in both the groups and were Fitzpatrick's skin type 4 or 5. Most patients were of mixed type under Woods lamp examination in both the groups.

Table 1 Demographic data of Patients in both groups

	GROUP A	GROUP B	P VALUE
Age (range)	21-47 YRS	20-46 YRS	
Mean age	32.35±7.3 S.D.	31.02±6.71 S.D.	0.2891
Sex			0.794
Male	14.29 %	12.70 %	
Female	85.71 %	87.30 %	

Table 2 Clinical evaluation of patients in both groups

	GROUP A(%)	GROUP B(%)	TOTAL	P VALUE
Fitzpatrick's skin type				
Type 4	41.27	34.92	38.1	
Type 5	42.86	50.79	46.83	0.667
Type of melasma (under woods lamp):				
Dermal	22.22	20.63	21.43	
Epidermal	23.81	22.22	23.02	
MIXED	53.97	57.14	55.56	0.937
USAGE OF OCP / DRUGS	16.67	29.09	22.94	0.122
Previous Intervention (Peels Etc)	6.35	14.29	10.32	0.143

Evaluation of treatment response

Treatment response of patients in both groups has been summarised in Fig.3 .There was a statistically significant reduction in mMASI score in both the groups. It reduced from 7.73±1.81 SD (fig. 4 a), b), c)) to 4.97±1.58 SD (Fig. 5 a) , b) , c))in group A after 4 sessions of Intradermal Tranexamic acid injections. Whereas in group B the mMASI score reduced from 7.59±1.68 SD(Fig.6a), b) , c)) to 3.89±1.36 SD(Fig. 7a) , b) , c)) after 4 sessions of autologous Platelet Rich Plasma injections. A statistically better improvement of mMASI score was observed in patients with group B than those of group A at the end of 4 sessions. Side effects were mild post procedure erythema or burning sensation in both the groups (Fig. 8, Fig. 9).

DISCUSSION

We studied the efficacy of intradermal tranexamic acid injections versus autologous PRP in patient with melasma.

Our findings revealed a reduction in mMASI score from 7.73±1.81 SD to 4.97±1.58 SD in group A. These findings were in agreement with Hadidi *et al* who did a study on 40 patients of melasma and divided them into 3 groups and showed a significant reduction in mMASI score at 12 weeks. The percentage reduction in mMASI score was 48% for group A, 50% for group B and 44% for group C (where group A was given oral tranexamic acid 250mg bd, group B intradermal tranexamic acid 10mg/ml and group C 4mg/ml intradermal tranexamic acid injections).⁴

In our study the mMASI score showed a reduction from 7.59±1.68 SD to 3.89±1.36 SD in group B . This was in congruence with Sirithanabadeekul *et al* which was a pilot study done on 10 patients with melasma and reported that mean melanin levels were significantly reduced and there was mean mMASI score improvement of 1.03±0.44 between baseline and week 10 in patients treated with PRP therapy.⁸ Our study showed that the improvement was better in group B in comparison to group A. Similar results were observed by

Mumtaz *et al* who did a study on 64 patients and reported a 51% reduction in mMASI score in the tranexamic acid group and a 71% reduction in the PRP therapy group after 24 weeks.⁹ Side effects noted were only minimal post procedure erythema and pain or burning sensation. Ebrahim *et al* conducted a split face study on patient with melasma and

treated them with intradermal tranexamic injections versus microneedling and reported that side effects were minimal and well tolerated apart from mild erythema and oedema that occurred in 25(44.6%) and mild irritation reported only in 11 patients (19.6%).¹⁰

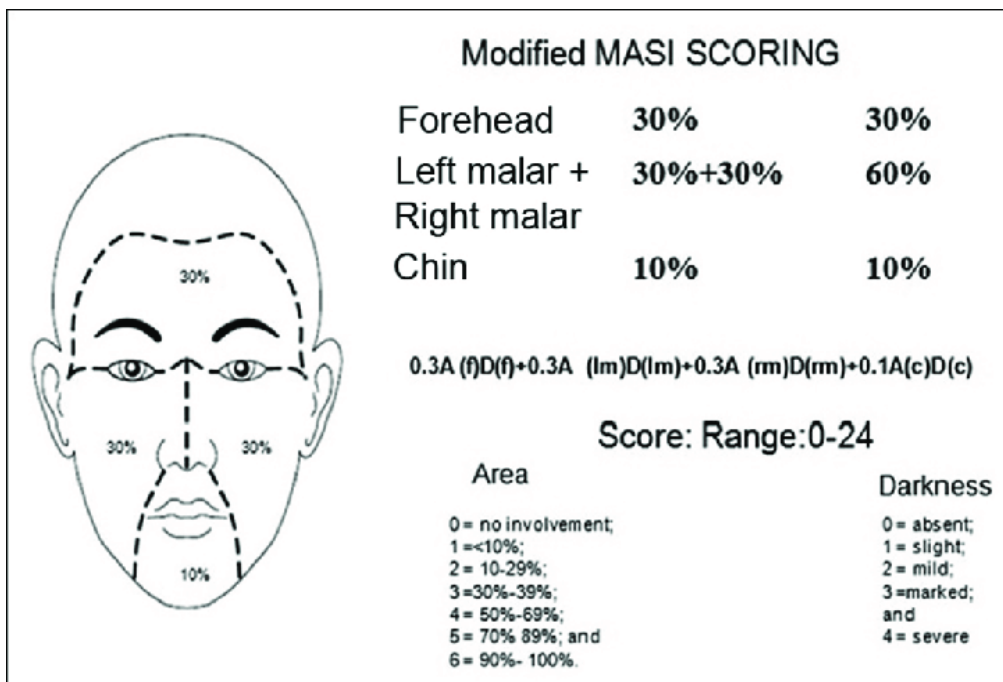


Figure 1 Modified Melasma Area Severity Index

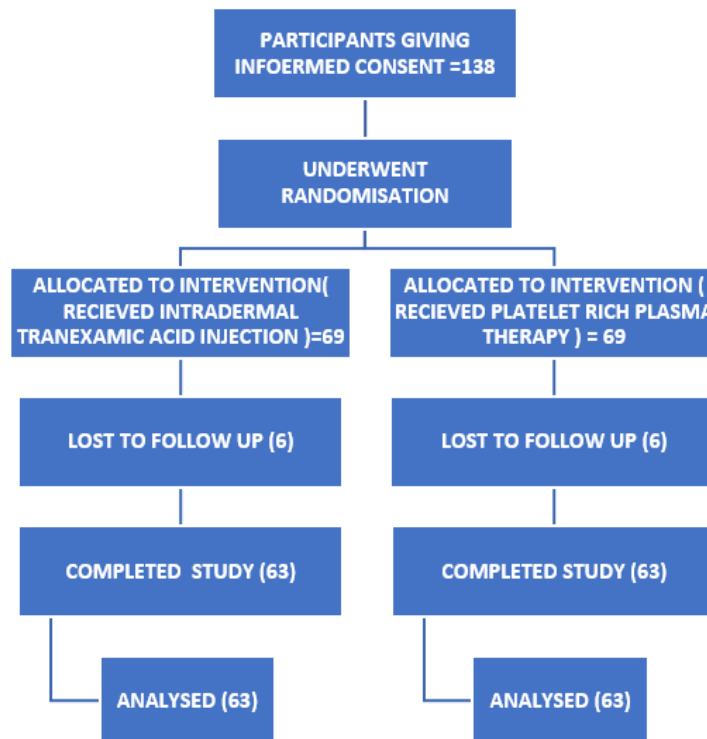


Figure 2 Flowchart of participants throughout the trial

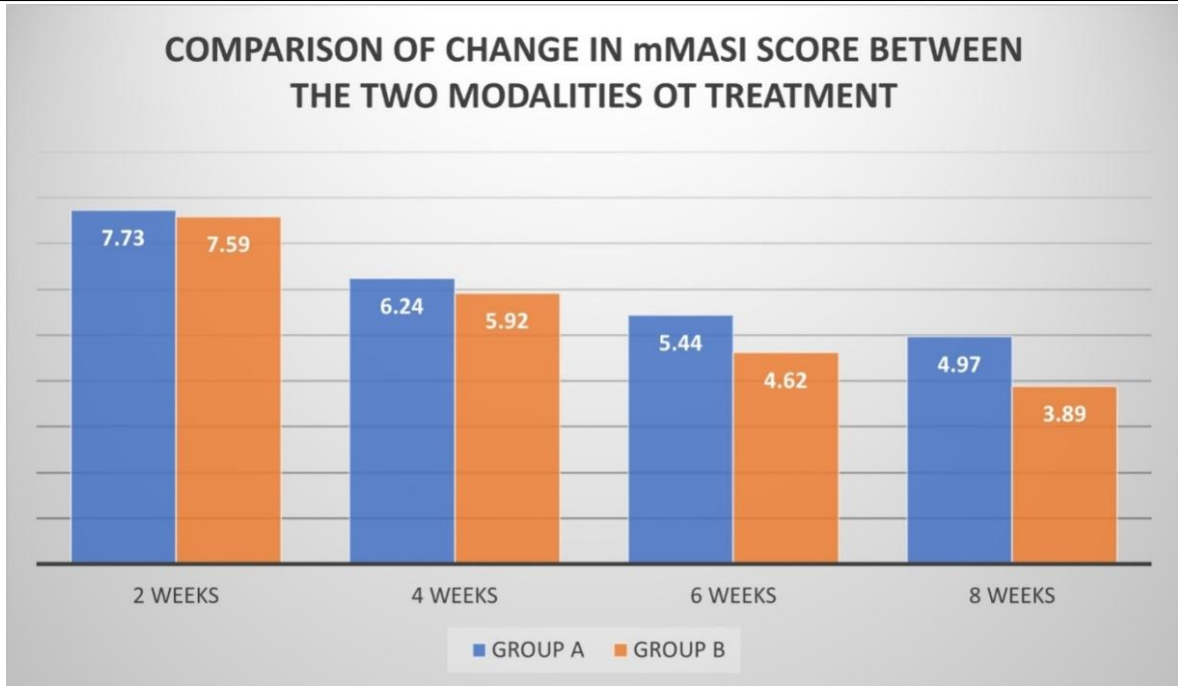


Figure 3 Graph Showing Comparison of Initial and Final mMASI score In Both Groups



Figure 4 a), b), c) : Patient in Group A at baseline



Figure 5 a), b), c) : Patient in Group A after 4 sessions of Intradermal Tranexamic acid injections



Figure 6 a), b), c) : Patient in Group B at baseline



Figure 7 a), b), c): Patient in Group B after 4 sessions of Autologous PRP injections.
Patient in Group A after 4 sessions of Intradermal Tranexamic acid injections

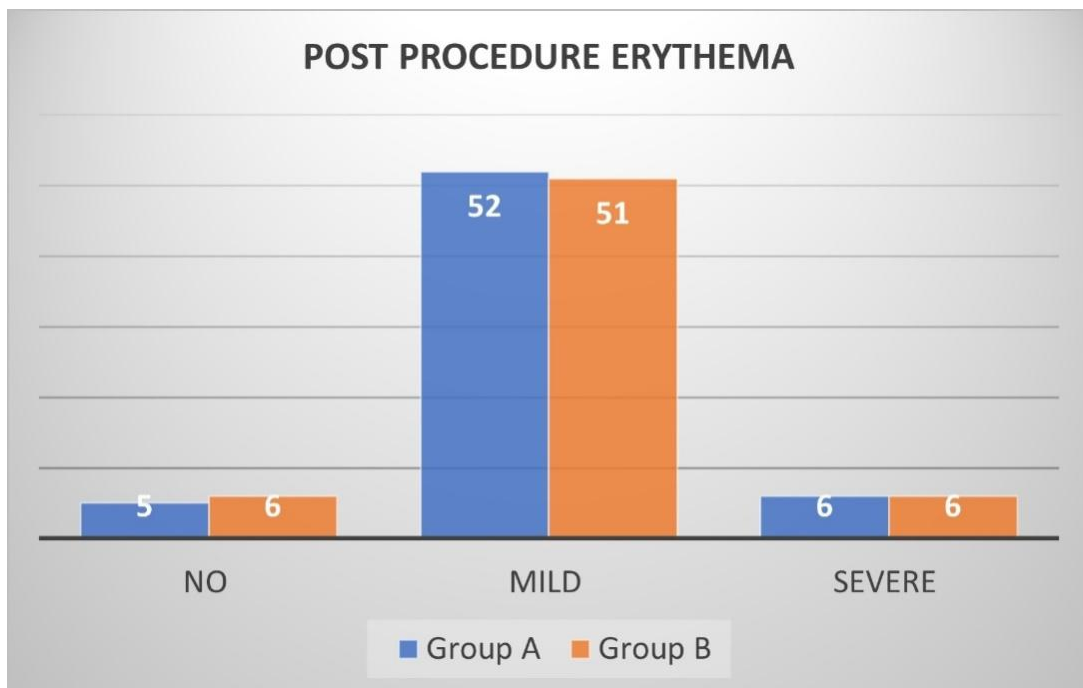


Figure 8 Post procedure erythema

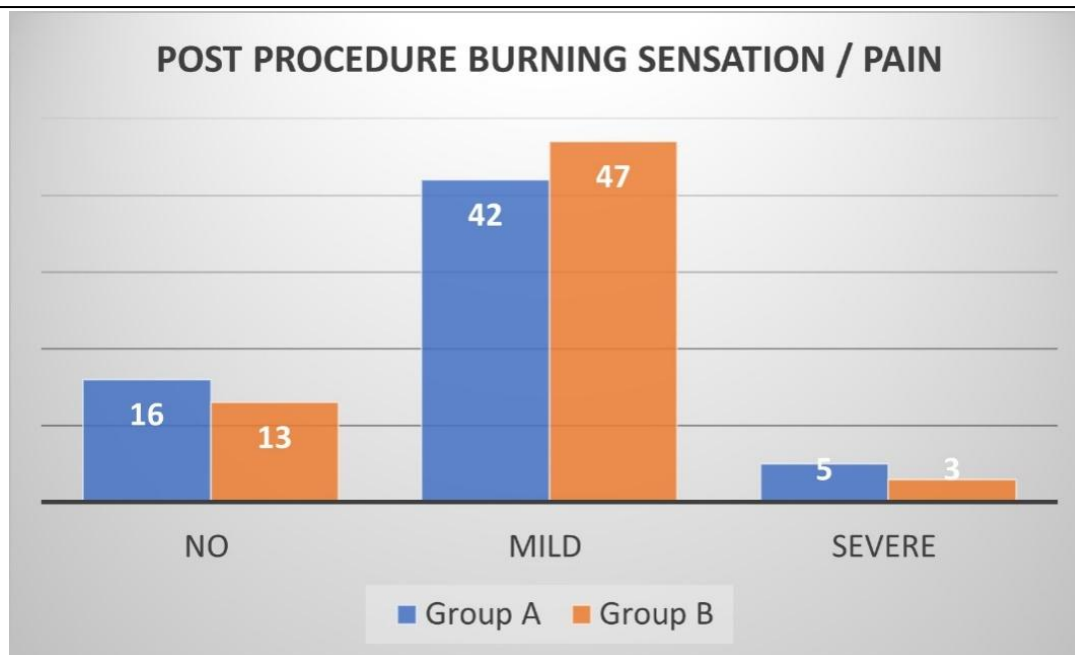


Figure 9 Post procedure burning sensation/ pain.

CONCLUSION

The study was completed by 126 patients and in group A mMASI score reduced significantly from 7.73 ± 1.81 at baseline to 4.97 ± 1.58 at end point whereas in group B it reduced from 7.59 ± 1.68 at baseline to 3.89 ± 1.36 at the end point, thereby proving that both intradermal tranexamic acid injections and autologous platelet rich plasma injections were both found to be effective and safe therapeutic options for melasma as standalone therapies. Autologous platelet rich plasma injections were found to be slightly better than intradermal tranexamic acid injections in our study and results were statistically significant. There were a few limitations to the study as long term follow up of patients was not done and there was loss to follow up due to transportation constraints and we could not look for recurrence. Also we only used mMASI score to measure melasma degree and other photography based modalities such as Mexameter were not used. Also the study was limited by a smaller sample size and further large scale studies with longer duration are recommended.

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How to cite this article:

Akshara Kharabanda, Yatendra Chahar, Karamvir Singh and Shruti Gupta. (2024). A comparative study of tranexamic acid versus platelet rich plasma injections in melasma patients. *International Journal of Current Advanced Research*.13(2), pp.2878-2883.
