

Original Article

## Split-face Comparative Study to Assess Therapeutic Efficacy of Intradermal Tranexamic Acid and Platelet-rich Plasma in Melasma

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### ABSTRACT

**Objectives:** Melasma is an acquired hyperpigmentary disorder for which various treatment modalities are available. Intradermal tranexamic acid (TXA) and platelet-rich plasma (PRP) are the 2 emerging options. We aimed to compare the therapeutic efficacy of intradermal TXA 10 mg/mL and PRP in melasma.

**Materials and Methods:** A split-face prospective study was conducted on 50 female patients with facial melasma. Six sessions of injections with intradermal TXA 10 mg/mL on the right side and PRP on the left side of the face were given at 2-week intervals. Reduction in modified melasma area and severity index (mMASI) score was assessed at each visit. Patient satisfaction score was calculated at the end of the sixth session using the Likert scale. Mean differences, standard deviation and *P* values were calculated for the reduction of melasma severity scores.

**Results:** A total of 47 patients completed the study, out of which 82% of those patients had malar type of melasma and the rest had involvement of the chin and forehead also. The mean mMASI score of patients treated with TXA decreased from  $3.7 \pm 2.1$  at baseline to  $1.4 \pm 1.13$  at 12 weeks which was statistically significant from the side treated with PRP where mMASI decreased from  $3.6 \pm 2.21$  to  $2.0 \pm 1.18$  ( $P < 0.05$ ). Dermoscopic changes showed partial resolution of telangiectasias and background erythema with TXA and reduction in the number of arcuate, annular and blotch patterns of pigmentation with TXA and PRP. No significant adverse effects were seen in any patient during the study period.

**Conclusion:** Both TXA and PRP are promising treatment modalities; however, outcomes with intradermal TXA (10 mg/mL) were better than with PRP which yielded an overall 'feel good' response.

**Keywords:** Melasma, Platelet-rich plasma, Split-face study, Tranexamic acid, Therapeutic efficacy

### INTRODUCTION

Melasma is an acquired hyperpigmentary disorder characterised by bilateral brown to grey brown macules or patches on the face, predominantly seen in women of child-bearing age with Fitzpatrick skin types 3–6.<sup>[1]</sup> Triggering factors include genetic predisposition, ultraviolet (UV) radiation, pregnancy, hormonal activity and certain drugs. Melasma is the most common hyperpigmentary disorder amongst Indians and its prevalence varies from 1.5% to 33.3%.<sup>[2,3]</sup> The condition is psychologically distressing for the patient because of frequent facial involvement, resistance to conventional treatment modalities, chronic progression and high relapse rates leading to a huge impact on the quality of life of the patient.

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The severity of melasma is assessed using the modified melasma area and severity index (mMASI) which depends upon the area and darkness of melasma.<sup>[4,5]</sup> Treatment of melasma is challenging with a myriad of therapeutic modalities available, including topical depigmenting agents, systemic drugs such as tranexamic acid, chemical peeling agents and use of Q-switched Neodymium doped Yttrium Aluminium Garnet (Nd-YAG) laser. Intradermal tranexamic acid (TXA) and platelet-rich plasma (PRP) are the two emerging treatment modalities which have different mechanisms of action yet both have shown promising results in melasma.

An increased level of melanocyte-stimulating hormone is attributed to the increased plasmin activity in keratinocytes after exposure to UV radiation. TXA, a synthetic derivative of lysine, inhibits this UV-induced plasmin activity and reduces the levels of vascular endothelial growth factor (VEGF), thereby reducing pigmentation.<sup>[6]</sup> Various modes of administration include intradermal, topical and oral, in varying dosages and concentrations with encouraging results in melasma.<sup>[7]</sup>

PRP is platelet-rich autologous plasma obtained by centrifugation of blood.<sup>[8]</sup> Studies have shown that alpha granules in platelets are rich in growth factors, such as transforming growth factor beta 1 (TGF-β1) which inhibits melanin synthesis and platelet-derived growth factor (PDGF) that increases angiogenesis, collagen synthesis and extracellular matrix formation, resulting in reduced pigmentation and improved skin quality in terms of wrinkle reduction, improved elasticity and skin hydration.<sup>[8]</sup>

Dermoscopy aids in the diagnosis of melasma, helps differentiate it from other facial pigmentary disorders or ascertains treatment-associated adverse effects (steroid-damaged face or hydroquinone-induced exogenous ochronosis). Uniform, well-defined brown pigmentation may represent epidermal pigmentation, while an irregular, mixed appearance of blue-grey hue with or without grey dots or annular/arcuate structures may represent dermal pigment deposition. Differentiating epidermal from dermal/mixed melasma has therapeutic and prognostic significance. Vascularity of melasma can be better appreciated with the help of a dermoscope which further aids in its management and assessing the treatment response.<sup>[9]</sup>

### Objective

- Primary objective - To compare the therapeutic efficacy of intradermal TXA 10 mg/mL and PRP in melasma
- Secondary objective - To compare the side effect profile of the two treatment modalities used.

## MATERIALS AND METHODS

This was a split-face prospective interventional study conducted on 50 female patients of facial melasma in a

tertiary care hospital from June 2023 to December 2023 after taking clearance from the Institutional Ethical Review Committee [Trg.9(310)2023/7599]. Clinically diagnosed patients with dermal or mixed types of melasma were randomly selected from the Outpatient Department after taking informed consent. Three cases were lost to follow-up; thus, 47 cases completed the study.

Pregnant or breastfeeding females, those on oral contraceptive pills, anticonvulsants, anti-coagulants or on any concurrent therapy for melasma were excluded from the study. Patients with bleeding or keloidal tendencies were excluded.

### Patient evaluation

Clinical patterns of melasma such as centrofacial, mandibular and malar were noted. The mMASI score was calculated on each side and dermoscopic examination was done using DermLite 5 dermatoscope in contact polarised mode at tenfold magnification and using UV light to determine the type of melasma (dermal or mixed). Clinical and dermoscopic pictures were taken with an iPhone 13 by the same physician in the same place with fixed illumination and distance. All patients were investigated for complete blood count, bleeding, coagulation profile and thyroid function tests. After evaluation, patients were injected with 10 mg/mL of intradermal TXA using an insulin syringe on the right side and intradermal PRP on the left side every 2 weeks for a total of 6 sessions. Patients were then followed up at 2 weeks after the last session.

### Method of preparation of TXA

For preparation of 10 mg/mL of TXA, 4 U of 100 mg/mL of TXA was drawn in a 40 U/mL, 30-gauge insulin syringe and diluted with 36 U of normal saline.

### Method of preparation of PRP

Five millilitres of venous blood were drawn from the antecubital vein and placed in tubes containing sodium citrate 3.2% as an anticoagulant under aseptic conditions. The first spin was done at 3000 rpm for 7 min, followed by transfer of the upper layer with buffy coat to empty sterile tubes, followed by second spin done at 4000 rpm for 5 min. Homogenisation of platelet pellets was done by thoroughly mixing into the lower 1/3<sup>rd</sup> volume of plasma, discarding the upper 2/3<sup>rd</sup>. PRP was then aspirated for injection.

### Procedure

After gentle cleansing with normal saline, a topical anaesthetic cream was applied under occlusion for 1 h duration on the area to be treated. Under aseptic conditions, TXA 10 mg/mL was injected on the right side and PRP on the

left side with the help of an insulin syringe at 1 cm<sup>2</sup> intervals. Ice packs were placed over the treated area post-procedure, followed by topical application of 2% mupirocin cream and sunscreen. All patients were advised on the avoidance of sun exposure and sunscreen application with SPF 50 in the morning and every 4 h thereafter till evening. This procedure was repeated every 2 weeks for 6 sessions. At every visit, mMASI score was calculated, dermoscopy was done and clinical and dermoscopic pictures were taken. Patient satisfaction score was calculated at the end of 12 weeks using the Likert scale. The primary outcomes were changes in the mMASI and dermoscopic pattern before and after treatment. Mean differences (MDs) with standard deviation (SD) and P value were calculated for the reduction of melasma severity scores from baseline to each subsequent session or follow-up.

### Statistical analysis

Qualitative outcome parameters were described using percentage response rates, whereas quantitative outcome measures were described using mean and SD. The difference in proportion was compared using the Normal tests of proportion and the significance of association in different groups was tested using Chi-square test of significance. IBM Statistical Package for the Social Sciences software was used for data analysis.

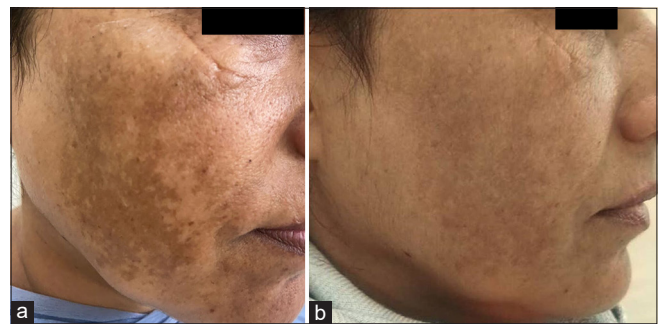
## RESULTS

Out of 50 patients with dermal/mixed type of melasma, 3 were lost to follow-up; thus, 47 patients completed the study. Most patients were in the age group of 30–45-year age group (85.1%). Most patients (82%) had malar type of melasma, while the rest had involvement of the chin and forehead also. Almost all patients had a gradual onset and progressive course. Mean duration of disease was more than 5 years in 26/47 (55%) and <5 years in 21/47 (45%). Photoaggravation was present in 36/47 (77%), and hormonal cause of melasma was implicated in 21% patients [Table 1].

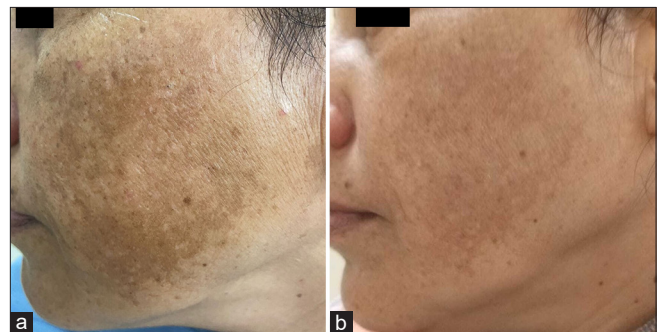
The baseline mMASI before treatment in both the groups was in the range 2.2–6.4. Baseline mean mMASI in TXA group was 3.1 and 3.0 in the PRP group [Figures 1 and 2]. Dermoscopic patterns at baseline are given in Table 2. Reduction in mMASI score at each visit is shown in Table 3. The mean mMASI score of patients treated with TXA decreased from 3.7 ± 2.1 at baseline to 1.4 ± 1.13 at 12 weeks (i.e. 69.5% mean reduction in mMASI score) while the mean mMASI score of patients treated with PRP decreased from 3.6 ± 2.21 at baseline to 2.0 ± 1.18 at 12 weeks (i.e. 43.1% mean reduction in mMASI score) [Figures 3 and 4]. The mMASI scores started decreasing from 6 weeks onwards, i.e. after 4 sessions of intradermal therapy on each side. Significant reduction in mMASI score was seen on the side treated with

**Table 1:** Demographic profile of the study participants.

| Variables                       | Number of patients (N) | Percentage (%) |
|---------------------------------|------------------------|----------------|
| Age (years)                     |                        |                |
| 15–30                           | 2                      | 4.3            |
| 30–45                           | 40                     | 85.1           |
| 45–60                           | 5                      | 10.6           |
| Gender                          |                        |                |
| Male                            | -                      | -              |
| Female                          | 47                     | 100            |
| Duration of disease             |                        |                |
| <5 years                        | 21                     | 45             |
| >5 years                        | 26                     | 55             |
| Type of melasma                 |                        |                |
| Dermal                          | 40                     | 85             |
| Mixed                           | 7                      | 15             |
| Distribution pattern of melasma |                        |                |
| Centrofacial                    | 8                      | 18             |
| Malar                           | 39                     | 82             |



**Figure 1:** (a) At baseline: Bilateral malar type of melasma with mMASI score of 5.4 on the right side, (b) Showing improvement at the 6<sup>th</sup> sitting (i.e., after 10 weeks) with mMASI score of 1.8. mMASI: Modified melasma area and severity index.



**Figure 2:** (a) At baseline: Malar type of melasma showing tan brown macules to patches with irregular and ill-defined borders with mMASI score of 4.8 on the left side, (b) Showing improvement at 6<sup>th</sup> sitting (i.e. after 10 weeks) with mMASI score of 0.9. mMASI: Modified melasma area and severity index.

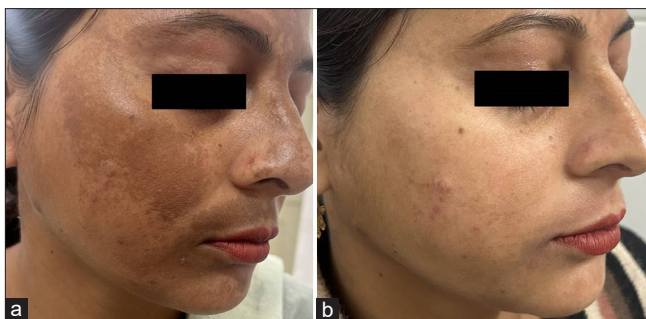
**Table 2:** Dermoscopic patterns at baseline and after treatment.

| Pattern                     | Before treatment        |                        | After treatment         |                        |
|-----------------------------|-------------------------|------------------------|-------------------------|------------------------|
|                             | Right side <i>n</i> (%) | Left side <i>n</i> (%) | Right side <i>n</i> (%) | Left side <i>n</i> (%) |
| Exaggerated pseudoreticular | 47 (100)                | 47 (100)               | 32 (68)                 | 39 (82.9)              |
| Telangiectasia              | 18 (38.3)               | 17 (36.2)              | 7 (14.9)                | 12 (25.5)              |
| Background erythema         | 23 (48.9)               | 23 (48.9)              | 12 (25.5)               | 14 (29.7)              |
| Arcuate                     | 32 (68.1)               | 33 (70.2)              | 14 (29.7)               | 18 (38.3)              |
| Dotted pigmentation         | 28 (59.5)               | 28 (59.5)              | 11 (23.4)               | 16 (34)                |
| Annular                     | 24 (51)                 | 26 (55.3)              | 10 (21.2)               | 15 (31.9)              |
| Blotches                    | 41 (87.2)               | 38 (80.8)              | 13 (27.6)               | 18 (38.3)              |

**Table 3:** Mean mMASI score at baseline and timeline for TXA and PRP.

| Timeline  | <i>n</i> =47 | Mean mMASI | ± standard deviation | <i>P</i> -value (between two groups) | <i>P</i> -value (compared from baseline) |
|---|--------------|------------|----------------------|--------------------------------------|--|
| Baseline (1 <sup>st</sup> session)              | Right (TXA)  | 3.7        | 2.1                  | 0.823                                | -  |
|   | Left (PRP)   | 3.6        | 2.21                 |                                      | -  |
| 4 <sup>th</sup> week (3 <sup>rd</sup> session)  | Right        | 3.5        | 1.89                 | 0.614                                | 0.62                                     |
|   | Left         | 3.3        | 1.94                 |                                      | 0.48                                     |
| 6 <sup>th</sup> week (4 <sup>th</sup> session)  | Right        | 2.9        | 1.34                 | 0.724                                | 0.03                                     |
|   | Left         | 2.8        | 1.4                  |                                      | 0.04                                     |
| 8 <sup>th</sup> week (5 <sup>th</sup> session)  | Right        | 1.8        | 1.15                 | 0.020*                               | <0.0001                                  |
|   | Left         | 2.4        | 1.3                  |                                      | 0.001                                    |
| 10 <sup>th</sup> week (6 <sup>th</sup> session) | Right        | 1.7        | 1.21                 | 0.024*                               | <0.0001                                  |
|   | Left         | 2.3        | 1.33                 |                                      | 0.0008                                   |
| 12 <sup>th</sup> week (Follow-up)               | Right        | 1.4        | 1.13                 | 0.014*                               | <0.0001                                  |
|   | Left         | 2          | 1.18                 |                                      | <0.0001                                  |

PRP: Platelet-rich plasma; TXA: Tranexamic acid, mMASI: Modified melasma area and severity index, *P* value < 0.05- statistically significant



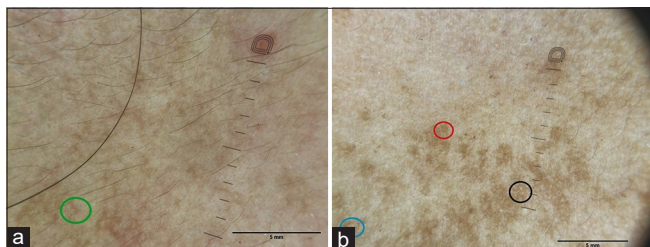
**Figure 3:** (a) At baseline: Bilateral malar type of melasma with mMASI score of 6.4 on the right side, (b) Showing improvement at the 4<sup>th</sup> sitting (i.e. after 6 weeks) with mMASI score of 2.6. mMASI: Modified melasma area and severity index.



**Figure 4:** (a) At baseline: Malar type of melasma showing tan brown macules to patches with irregular and ill-defined borders with mMASI score of 6.2 on the left side, (b) Showing improvement at 4<sup>th</sup> sitting (i.e. after 6 weeks) with mMASI score of 2.0. mMASI: Modified melasma area and severity index.

TXA after 8 weeks [Table 3]. Dermoscopic changes on the side treated with PRP showed a reduction in pigmentation of blotches at 8 weeks and of arcuate and annular patterns of pigmentation from 8 to 10 weeks onwards. Telangiectasias and erythema improved at the end of treatment with PRP

[Figure 5]. Dermoscopic changes post-treatment with TXA showed partial resolution of telangiectasias and background erythema at 6 weeks. Reduction in arcuate and annular patterns of pigmentation and blotches started reducing



**Figure 5:** (a) Reduction in blotches, arcuate (green circle) and annular forms seen post-treatment with intradermal PRP after 6 sessions. (b) Dermoscopic image of a patient with melasma showing diffuse light to dark brown exaggerated pseudoreticular pigment network (black circle) with sparing of follicular openings and presence of blotches (red circle) and annular structures (blue circle).

at 8 weeks. Dotted pigmentation was the last to resolve [Figure 6].

The side effects experienced by the patients on the side treated with TXA side included pain in 52.5% and erythema in 45%, while pain was reported in 7.5% and erythema in 32.5% on the side treated with PRP.

Subjective assessment at the end of the treatment depicted that the maximum number of patients were somewhat satisfied. The difference in satisfaction level was not significant between the two modalities of treatment. Patients who were not at all satisfied were those who developed severe erythema and pain after each session. It was also noted that patients reported an overall ‘feel good’ face on the side with PRP apart from the resolution of melasma [Table 4].

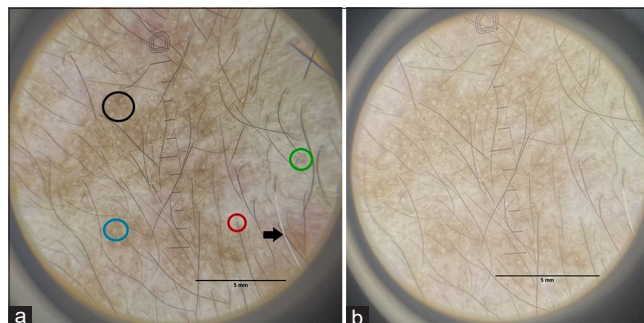
## DISCUSSION

Melasma tends to have a huge impact on the quality of life of the patients due to cosmetic disfigurement and chronic course. There are a myriad of treatment modalities available with different degrees of benefits and untoward effects. Use of TXA and PRP has shown promising results.<sup>[10]</sup>

This split-face study included 47 patients with dermal or mixed pattern melasma. This type of melasma requires more aggressive therapy.<sup>[11]</sup> Intradermal TXA was given with an insulin syringe in the concentration of 10 mg/mL on the right side and PRP was given intradermally on the left side.

TXA inhibits melanin synthesis through inhibition of the plasminogen/plasmin system.<sup>[12]</sup> Plasmin participates in inflammatory cytokine production and release of basic fibroblast growth factor, which is a potent melanocyte growth factor causing melanin synthesis.<sup>[12]</sup> TXA can also inhibit melanogenesis by interfering with the catalytic reaction of tyrosinase.<sup>[13]</sup>

TGF- $\beta$ 1 in PRP inhibits melanin synthesis by delaying activation of extracellular signal-regulated kinase.<sup>[14]</sup>



**Figure 6:** (a) Dermoscopic image of a patient with melasma on the right side showing diffuse light-to-dark brown exaggerated pseudoreticular pigment network (black circle) with sparing of follicular openings (red circle) and presence of annular (blue circle) and arcuate structures (green circle) with background erythema (black arrow). (b) Reduction in arcuate, annular forms and background erythema seen post-treatment with intradermal tranexamic acid after 6 sessions.

**Table 4:** Likert scale for patient satisfaction score.

| Satisfaction level   | Score | Right n (%) | Left n (%) |
|----------------------|-------|-------------|------------|
| Very much satisfied  | 5     | 8 (17)      | 6 (12.7)   |
| Somewhat satisfied   | 4     | 22 (46.8)   | 17 (36.1)  |
| Undecided            | 3     | 3 (6.4)     | 3 (6.4)    |
| Not really satisfied | 2     | 12 (25.5)   | 17 (36.1)  |
| Not at all satisfied | 1     | 2 (4.2)     | 4 (8.5)    |

Concomitantly, PDGF in PRP also leads to increased skin volume (angiogenesis, collagen synthesis and extracellular matrix formation including hyaluronic acid) and reduced skin pigmentation.<sup>[15]</sup>

Numerous studies have evaluated the efficacy of TXA for the treatment of melasma using different methods of administration, including topical, use with microneedling, intradermally or orally.<sup>[16]</sup> TXA was studied by infiltration as shown in a 100-patient study conducted by Sharma *et al.* in 2017, in which the therapeutic efficacy of orally administered 250 mg TXA twice/day versus local infiltrations of 4 mg/mL TXA administered at 4-week intervals (0, 4, 8 and 12 weeks) was assessed. The study argues that intradermal TXA is as effective as orally administered TXA. It would appear that topical TXA is much safer and with fewer systemic adverse effects than oral TXA.<sup>[17]</sup>

In this study, the mean mMASI score started decreasing after 4 sessions on each side with difference being statistically significant on the TXA side after 8 weeks onwards. Mean mMASI decreased from 3.7 at baseline to 1.4 on the right side and from 3.6 to 2.0 on the left side after 12-week treatment. An opposite observation was seen in a study by Abd Elraouf *et al.* where the percentage score reduction in mMASI was higher on the side treated with PRP as compared to TXA

(4 mg/mL) administered as intradermal injections; once every 4 weeks for a total of 3 sessions and another study by Karthikeyan *et al.* which also observed significantly superior efficacy of intradermal PRP over intradermal TXA (4 mg/mL).<sup>[18,19]</sup> The plausible explanation for such contrasting results could be because of the use of higher concentration of TXA (10 mg/mL) administered more frequently (2 weeks apart) for a total of 6 sessions which led to better response yet with a comparable side effect profile.

A split-faced RCT compared different concentrations of intradermal TXA, 4 mg/mL and 10 mg/mL, to topical 4% hydroquinone (HQ) cream in 41 patients and demonstrated statistically significant reduction in MASI score in all 3 groups. Better response was seen with 4% HQ cream as compared to intradermal TXA 4 mg/mL; however, no significant difference was observed in the reduction of MASI scores between 4% HQ cream and intradermal TXA 10 mg/mL.<sup>[20]</sup> In other trials comparing monthly intradermal PRP to 4 mg/mL TXA injections for 3–5 months, statistically significant improvement was seen in mMASI scores from baseline but with insignificant difference in response between the two treatment modalities, yet favouring the PRP group.<sup>[10,21]</sup>

In this study, the outcome with intradermal TXA was better than with PRP when used at 2-week intervals for a total of 6 sessions, indicating a higher response rate and lesser side effects with intradermal TXA injection when used at a concentration of 10 mg/mL in the treatment of melasma. None of the patients reported post-inflammatory hyperpigmentation after the procedure although some studies do report this side effect secondary to intradermal PRP therapy. This may be explained by the fact that the upper layer [platelets and white blood cells (WBCs)] and only the superficial buffy coat layer (rich in WBCs) were taken after the first spin to minimise the number of red blood cells (RBCs) being transferred to the second spin tube. Haemosiderin deposition secondary to RBC accumulation in the skin may cause post-inflammatory hyperpigmentation after intradermal therapy. Furthermore, some erythrocytes are inevitably present in the volume that is transferred from the first spin which adsorbs platelets and WBCs on its surface interfering with the suspension of platelets in the plasma.<sup>[22]</sup>

Dermoscopy can be used for the diagnosis of melasma and for assessing the response to treatment. Lesions of melasma show diffuse reticular pigmentation in various shades of brown with sparing of follicular openings. Dermal melasma shows diffuse dark brown to greyish pseudoreticular pigmentation.<sup>[18]</sup> Annular, honeycomb and arcuate structures may be seen. Regarding dermoscopic assessment on both treated sides, reduction in blotches, arcuate or annular forms started at 6–8 weeks. Erythema and telangiectasia improved earlier on the side treated with TXA. A similar pattern of

improvement was observed by Rout *et al.* in the treatment of melasma with PRP.<sup>[11]</sup>

Unlike the previous studies, the advantages of this study were that it was a split-face comparative study, so each subject acts as his or her own control, thus minimising the risk of confounding. Furthermore, this is the first study comparing the therapeutic efficacy of intradermal PRP with a higher concentration of TXA, i.e. 10 mg/mL instead of 4 mg/mL.

Patient satisfaction score as per the Likert scale was noted at 12 weeks. More number of patients showed satisfaction with TXA, although some observed 'feel good' factor with PRP. There was no statistically significant difference in satisfaction level between the two sides. This can be due to the abundance of growth factors in PRP that facilitates a number of mechanisms resulting in facial rejuvenation.<sup>[18]</sup>

### Limitations

Lack of randomisation for the side being treated with either of the two treatment modalities in a split-face study. Both the treatment modalities were invasive. Transient erythema, pain and burning were more commonly reported on the side treated with TXA with spontaneous resolution. This study could not determine the relapse rate as there was no long-term follow-up.

### CONCLUSION

Both TXA and PRP appear as promising treatment modalities for dermal or mixed pattern melasma with minimal side effects. Intradermal TXA results in statistically significant improvement in melasma as compared to intradermal PRP. Dermoscopy, apart from diagnosing and monitoring the treatment response, can also aid in guiding the treatment modality depending on the predominance of pigmentary or vascular components.

**Ethical approval:** The research/study was approved by the Institutional Review Board at GMC and Rajindra Hospital, Patiala, number Trg.9(310)2023/7599, dated March 20, 2023.

**Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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