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Original Research Article

Role of leukocyte free platelet rich plasma in planter fasciitis: a prospective study

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ABSTRACT

Background: Planter fasciitis, is by definition, inflammation of planter fascia. Most of the cases are well treated conservatively and a few responds to surgery only. Objectives of present study were evaluating the efficacy of a single injection of leukocyte free platelet rich plasma in plantar fasciitis and to derive a correlation between the clinical and radiological outcome.
Methods: The present study consisted of 120 patients of bilateral (PF), (240 feet). These patients were divided into two groups PRP group of 60 patients and Placebo group of 60 patients. The study was conducted on patients attending Orthopaedics outpatient department Post Graduate Institute of Medial Education and Research (PGIMER) from July 2011 to June 2012. A primary efficacy criterion was changes from baseline in pain using (VAS). Functional results, level of satisfaction and outcome were measured by – AOFAS Foot Scale. Correlation of clinical with radiological outcome were performed.
Results: There was a significant decrease in the visual analogue scale (pain score) in the PRP. Group while in placebo group it was increased significantly at the end of 6 month. Functional outcome scores were improved significantly from their baseline values in PRP group while in placebo group the mean functional score were deteriorated at 6 months follow up. There was no improvement seen in functional status with normal saline injection. In PRP group the mean heal pad thickness was reduced significantly at 6 months follow up while in placebo group was not changed significantly at 6 months follow up. Correlation between radiological parameters and VAS was found to be positive while it was found negative with other functional outcome scores like AOFAS.
Conclusions: Platelet-rich plasma (PRP), which is a natural concentrate of autologous growth factors,plays a role in the regeneration process in treatment of (PF).

Keywords: Planter, Platelet, Plasma, PRP

INTRODUCTION

Plantar fasciitis is the common chronic condition of the foot, for which professional care is sought.[1]

Anatomic and biomechanical factors like foot arch problems, obesity, tight achillis tendon, shoes with poor arch support combined with overuse can contribute to its genesis.[2] The treatment of plantar fasciitis includes rest, NSAID, night splints, foot orthosis, stretching protocol and surgical procedures. Steroid injections have been popular with the physicians, but steroid injections have their own pitfalls, as these are effective for only a short period and to a small degree.[3]

One innovation which is revolutionising the treatment protocol is use of Platelet Rich Plasma (autologous growth factors) in treatment of plantar fasciitis.[4-7] In addition platelet rich plasma (PRP) possesses antimicrobial properties that may contribute to the

prevention of infections. When platelets become activated, growth factors are released and initiate body's natural healing process.[8,9]

There are a number of studies describing the use of different platelet-rich products with the purpose of accelerating tissue repair as in lateral epicondylitis.[10-12] The healing properties of the PRP has been attributed to the presence of various growth factors in the PRP which include platelet-derived growth factor (PDGF), Vascular endothelial growth factor (VEGF), Transforming growth factor – β1 (TGF- β1), Fibroblast growth factor (FGF), Epidermal growth factor (EGF), Hepatocyte growth factor (HGF), Insulin like growth factor-1 (IGF-1).[13]

METHODS

The patients were diagnosed clinically and measuring heal pad thickness radiologically with X-Rays, (USG) and MRI.[14-16]

Inclusion criteria

- Patients age >18 years.
- Plantar fasciitis pain for a minimum duration of 3 months with a VAS of at least 60 on a scale of 100.
- Cases confirmed on radiological investigations.
- Patient who had failed earlier treatments after 3 months including RICE (Rest, Ice, Compresses, Elevation), NSAIDS, Orthotics, Physiotherapy or corticosteroid injections were candidates for PRP.

Exclusion criteria

- Patients with plantar fascia pain due to spondylitis, calcaneal stress fracture, infection, osteomyelitis, psoriatic arthritis, reactive arthritis, sinus tarsi syndrome, tarsal tunnel syndrome, tendon injuries and tendonitis.
- Pregnancy.
- Patients having systemic disorders like rheumatoid arthritis or hepatitis.
- (Relative contraindication) Pertaining to platelet concentrate use like a history of thrombocytopenia, use of anticoagulant therapy, active infection, tumor, metastatic disease.

Patient randomization

A total of 120 patients were divided into two groups:

- PRP group of 60 patients
- Placebo group of 60 patients

Procedure

- PRP was prepared in department of transfusion medicine in following steps:
- 100 ml of venous blood was drawn into a blood collection bag containing CPDA as anti-coagulant. The blood was transferred to centrifuge tubes.
- Centrifugation was carried out for 15 min at 1,300 RPM to separate the packed cells from the plasma.
- The plasma was separated from the packed cells.
- The plasma was transferred into another blood bag. Plasma was run through a leukocyte filter Immugard – 4L, manufactured by Terumo-Penpol Inc. to obtain the product of leukocyte free platelet rich plasma.
- The product of 2 to 3 ml PRP was dispensed in 5ml syringes along with 2 ml of calcium chloride

Interventional procedure

An initial infiltration of Lignocaine and epinephrine was given into the overlying skin followed by injection of 4 ml of Platelet Rich Plasma in Study group and 4 ml of Normal Saline (Placebo) in the control group. Patients were followed at the outpatient department of orthopaedics at one and half month, 3 months and 6 months.

Statistical analysis

The analysis of data was done with the help of an experienced statistician by using the IBM SPSS (Statistical Package for Social Sciences) version 20 software.

The data which showed a normal distribution were analyzed further by parametric tests and those which didn't show a normal distribution were analyzed using non-parametric tests. Paired sample 't' test and independent sample 't' test was used for the comparison of the means by analysis of variance in case parametric data

Intra and inter group comparisons were made for the three outcome evaluation scores. The baseline values were compared with those at individual follow ups. A comparison between the differences of the scores at follow up with the baseline was also made. These comparisons were done by the 'T' tests. All the statistical tests used were two sided and p value of <0.05 was considered significant in all the analyses.

Correlation between functional and radiological outcome was analysed by Pearson correlation method.

RESULTS

Baseline demographic values of the two groups are shown in Table 1.

The statistical details of the two groups in respect to base line demographic data is given in Table 2.

Table 1: Comparison of baseline values between two group PRP and group placebo.

Demographic factors	Group	Mean		Std. Deviation	p value
Age (years)	PRP	42.0		9.66	0.138
	Placebo	46.8		10.37	
Sex (% of females)	PRP	60%		Not significant	0.749
	Placebo	55%		Not significant	
BMI	PRP	24.92		2.2	0.248
	Placebo	24.10		2.19	
Heel pain duration (months)	PRP	13.8		6.93	0.914
	Placebo	14.05		5.56	
Pre-injection X-ray heel pad thickness	PRP	R	18.43	1.32	0.890
		L	18.47	1.27	0.854
	Placebo	R	18.40	1.30	
		L	18.42	1.31	
Pre-injection USG-plantar fascia thickness	PRP	R	5.84	1.18	0.820
		L	5.87	1.1	0.791
	Placebo	R	5.89	0.87	
		L	5.85	0.90	
Pre injection MRI plantar fascia-thickness	PRP	R	5.94	1.15	0.342
		L	5.91	1.1	0.472
	Placebo	R	5.75	1.009	
		L	5.80	0.91	
Pre injection HPCI	PRP	1.147		0.073	
	Placebo	1.141		0.038	0.586
Pre-injection VAS	PRP	7.10		0.64	0.330
	Placebo	6.90		0.64	
Pre-injection AOFAS	PRP	70.70		5.68	0.748
	Placebo	70.05		6.96	
Pre-injection WHOQOL	PRP	62.30		7.40	0.400
	Placebo	64.40		8.17	
Pre-injection PCS	PRP	27.35		3.69	0.492
	Placebo	28.22		4.19	
Pre-injection MCS	PRP	36.22		6.38	0.871
	Placebo	36.52		5.35	

Table 2: Comparison of baseline values between two groups: the statistical details of the two groups in respect to age, height, weight and BMI.

Demographic factors	Group	Mean	Range	Standard deviation	p value
Age (years)	PRP	42.0	26-64	9.66	0.138
	Placebo	46.8	28-59	10.37	
Weight (kg)	PRP	68.3	55-80	1.2	0.991
	Placebo	67.6	52-78	1.6	
Height (m)	PRP	1.64	1.5-1.81	0.61	0.288
	Placebo	1.62	1.5-1.78	0.54	
BMI (kg/m^2)	PRP	24.92	19.61 -28.84	2.2	0.248
	Placebo	24.10	19.60-27.31	2.19	

a= P<0.05 is considered as statistically significant

Pair wise comparison was done of the VAS value at each time frame and is given in Figure 1.

It was noted that there was a significant change in VAS from pre-injection to 1st and 2nd follow up and was statistically significant (p=0.000). There was also significant change from 1st follow up to 2nd follow up (p=0.000) and from 2nd to 3rd follow up (p=0.106) VAS score has decreased. Pair wise comparison of VAS scores in Group Placebo was done at each time frame and It was noted that there was significant change in VAS from pre-injection to 1st, 2nd and 3rd follow up and was statistically

significant (P=0.000) there was also a significant change from 1st follow up to 2nd follow up (p=0.010).

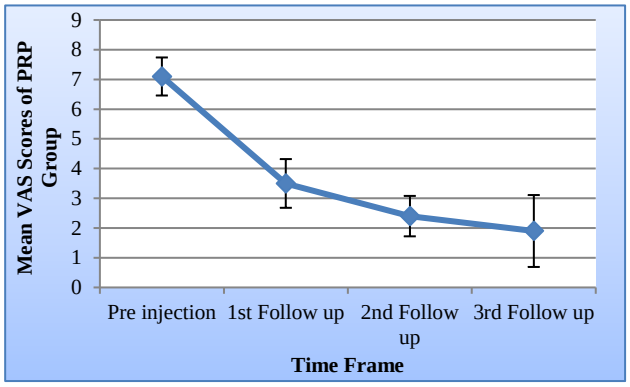

Figure 1: Linear graph showing mean VAS scores and trend of Group PRP at baseline and subsequent follow up.

There was also a significant change from 2nd follow up to 3rd follow up. The trend is as shown in the graph below (Figure 2).

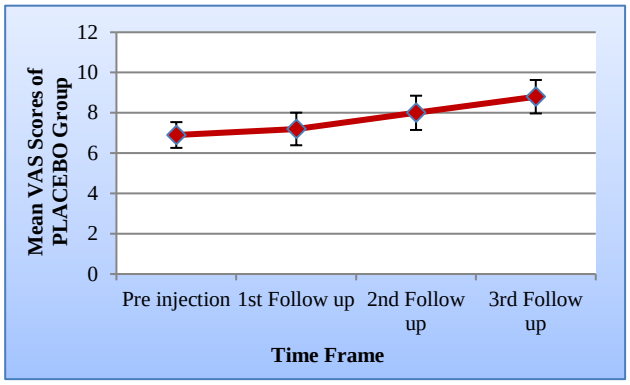

Figure 2: Mean VAS scores and trend of Group placebo at baseline and subsequent follow ups.

Pair wise comparison in PRP group was done of the AOFAS value at each time frame and It was noted that there was a significant change in AOFAS from pre injection to 1st, 2nd and 3rd follow up (p=0.000). The mean AOFAS scores increased from pre injection to 1st, 2nd and 3rd follow up.

Pair wise comparison in Placebo group was done of the AOFAS values at each time frame and It was noted that there was a significant change in AOFAS from pre injection to 1st, 2nd and 3rd follow up and was statistically significant (P=0.000). The mean AOFAS values decreased from pre injection to 1st, 2nd and 3rdfollow ups.

Same trend was noticed in mean WHOQOL scores in PRP group and placebo group as were with AOFAS values. The mean WHOQOL scores increased in Group PRP and decreased in Group PLACEBO following treatment. Short form-36 (SF-36) is a well-known, widely used and validated generic health outcome that consists of 8 – dimensions, higher scores are associated with better quality of life.

Pair wise comparison in PRP group was done of the PCS value at each time frame and It was noted that there was a significant change in PCS from pre-injection to 1st, 2nd and 3rd follow up and was statistically significant (p=0.000). The mean PCS scores increased from pre injection to 1st, 2nd and 3rd follow up.

In Placebo group, the mean PCS scores decreased from pre injection to 1st, 2nd and 3rd follow ups. The mean PCS scores increased in Group PRP and decreased in Group PLACEBO following treatment.

Pair wise comparison in PRP group was done of the MCS value at each time frame and it was noted that there was a significant change in MCS from pre injection to 1st, 2nd and 3rd follow up and was statistically significant (p=0.000). The mean MCS scores increased from pre injection to 1st, 2nd and 3rd follow up. In Placebo group, the mean MCS scores decreased from pre injection to 1st, 2nd and 3rd follow ups.

Radiological outcomes

X-ray heel pad thickness

PRP group

It was noted that there was a significant change in both foot in X-ray HPT from pre injection to post injection and was statistically significant (p value = 0.000; 0.00).

The mean X-ray HPT scores decreased from pre-injection to post-injection

Placebo group

The mean X-ray HPT scores decreased from pre-injection to post-injection and was statistically significant (p value = 0.081; 0.077).

USG plantar fascia thickness

PRP group

The mean USG PFT scores decreased from pre-injection to post-injection and was statistically significant (p value = 0.000; 0.000).

Placebo group

The mean USG PFT scores decreased from pre-injection to post-injection and was statistically significant (p value =0.066; 0.05).

The mean MRI PFT scores decreased from pre-injection to post-injection and was statistically significant (p value = 0.000; 0.000).

Placebo group

The mean MRI PFT scores decreased from pre-injection to post-injection and was statistically significant (p value = 0.071; 0.08)

Heel pad compressiblity index

PRP group

The mean HPCI scores decreased from pre-injection to post-injection and was statistically significant (p value = 0.04; 0.04).

Placebo group

The mean HPCI scores decreased from pre-injection to post-injection and was not statistically significant (p value =0.08; 0.07).

DISCUSSION

Planter fasciitis diagnosis is based on the typical history and the finding of localized tenderness in the medial calcaneal tubercle.[16] The conservative treatment includes changes in daily activities, orthosis, stretching, taping, and non-steroidal anti-inflammatory drugs (NSAID) therapy. The most preferred method of non-surgical plantar fasciitis treatment is local corticosteroid injection with or without the addition of a local anaesthetic agent. Resistant cases have been treated surgically as well.[17] Multiple steroid injections may lead to planter fascia rupture.[18] Identification of the role played by the growth factors like VEGF, EGF, HGF, PDGF, FGF and TGF-β1 in the healing response of the tissues and the fact that these are found abundantly in platelets provided the stimulus for research in devising methods of delivering platelets. Thus, came along the concept of Platelet Rich Plasma (PRP) and its use in orthopaedics.

Platelet-rich plasma PRP, which is a natural concentrate of autologous growth factors, its local injection is a new modality for the treatment of plantar fasciitis.[19-22]

In present study, the mean age of group PRP and placebo were 42±9.66 years 46.80±10.37 respectively. Most of the patients in our study were found between the age group of 30-50

In our study, PRP group had 40% male and 60% female whereas in placebo group there were 45% males,55% females.

The mean BMI in PRP group was 24.92±2.2 (ranged 19.62-28.84) whereas in placebo group mean BMI was 24.10±2.19 (ranged 19.60-27.31). In study by Ertugrul et al the mean BMI in PRP group was 32.77±5.02 where as in placebo (Steroid) group mean BMI was 29.6+4.07.[23] Thus in our study the mean BMI was less than the comparative study.

Most of the patients in present study, heel pain duration was 13.80±6.93 months and in placebo group the duration was 14.05±5.56. In a study by Peerbooms et al the duration of heel pain was 6 to 12 months.[11,22] Thus, present study was comparable with previous studies in respect to minimum heel pain duration.

Present study consisted of 120 patients (240 feet) with 60 cases and 60 controls. Barret et al conducted their study with nine patients with no control group.[13] All patients of group PRP and Placebo reported for follow-up. Peerbooms et al studied 120 patients which included 60 cases and 60 controls.[11,22] Present study was the first randomized control trial. We used a control group which received Normal Saline (NS), serving as physiological control.

Previously conducted studies have used leukocyte rich PRP containing leukocytes along with the platelets. In our study the PRP used was leukocyte free PRP.[24-26] The exact interaction of the leukocytes with the platelets in the PRP is still not fully known but there is evidence that leukocytes in PRP may lead to inflammatory reactions. Thus, the PRP that we used for injections may be considered superior to the ones used in previous studies.

We used the area of maximum tenderness, indicated by the patients as the guide for the PRP injection. Peerbooms et al, Ertugrul et al used ultrasound guided PRP injections in their study.[22,23]

In present study, functional outcome employed was evaluated by VAS, AOFAS, WHOQOL and SF-36 scores whereas radiological outcome was assessed by estimating X-ray HPT, USG PFT, MRI PFT. Barret et al used evaluation of USG-thickness (only Radiological outcome) of plantar fascia for measuring the outcome of their study.[13] No functional outcome was used. Peerbooms et al used VAS, AOFAS, WHOQOL and SF-36 scores (only Functional outcome).[22] No radiological outcome was used moreover results are still not reported in the literature. Ertugrul et al used modified Roles and Maudsley scores for patient's satisfaction and VAS for pain assessment (only functional outcome.[23] Thus, ours is the only study where both functional as well as radiological outcomes were performed to evaluate the efficacy of PRP in chronic cases of Plantar fasciitis.

In present study, we noted 50.70% improvement in the VAS score for pain in the PRP group at one and half month follow up, while the placebo group had 4.16% deterioration. The trend was same at 3 months i.e. 2nd follow up with the PRP group showing 66.99% improvement and the placebo group had 13.75% deterioration. At 6 months the improvement in PRP

group was 73.23% and 21.5% deterioration were noticed in placebo group.

The improvement in VAS scores at 6 months follow up for the case group in our study was better than that in the study by Lee et al (73.23% vs. 63%), Andrew et al (73.23% vs. 70.8% and Ertugrul 73.23% vs. 71.1 %) at the end of 6 months follow up.[13,21,23]

In present study we used AOFAS foot scores for the outcome evaluation. At 6 months follow up, there was 24.12% improvement in the AOFAS foot scores in the PRP group as compared to deterioration of 8.64% in the placebo group.

At 6 months follow up, a trend of sustained improvement in WHOQOL was seen in PRP group. The mean WHOQOL scores at the end of 6 months follow up had an improvement of 32.08% over the baseline value in group PRP. Group placebo patients had a deterioration in WHOQOL scores. 28.64% of deterioration was seen at the end of 6 months follow up.

The trend of sustained improvement in PCS scores was seen in PRP group. The mean PCS scores at the end of 6 months follow up had an improvement of 30.17% over the baseline value in group PRP. Group placebo patients had a deterioration in PCS scores 29.22% deterioration in scores was seen at the end of 6 months follow up.

Also, the trend of sustained improvement in MCS scores was seen in PRP group. The mean MCS scores at the end of 6 months follow up had an improvement of 16.70% over the baseline value in group PRP. Group placebo patients had a deterioration in MCS scores 5.83% deterioration in scores was seen at the end of 6 months follow up. Thus, PRP group patients had a sustained and greater improvement in WHOQOL, PCS and MCS scores while group placebo patients had deterioration in the above scores in follow up.

The scores used for the evaluation of the functional status of the foot in plantar fasciitis are different for each of the previously reported studies. As all the studies have used a different score to measure functional outcome, a direct comparison between them could not be performed. Thus, in the present study, the PRP group showed significant improvement in the functional outcome as compare to the placebo (control) group.

In the present study, the mean USG PFT (Pre-injection) in PRP group was 5.848±1.18 which was reduced to 3.73±1.16 with improvement in pain in 6months follow up (p=0.000). In placebo group the mean USG PFT (Pre-injection) was 5.892±0.871 which was reduced to 5.402±0.869 with improvement in pain in 6 months follow up (p=0.066).

In present study, in PRP group, the mean MRI PFT (Pre-injection) was 5.94±1.15 which was reduced to 3.78±1.12 with significant improvement in pain after 6 months follow up (p=0.000). In placebo group the mean MRI PFT (Pre-injection) was 5.75±1.00 which was reduced to 5.409 with not much significant improvement after 6 months (p=0.071).

Also, after 6 months follow up the mean X-ray HPT (Pre-injection) was 18.43±1.320 which was reduced to 16.53±1.033 with improvement in pain after 6 months follow up (p=0.000). In placebo group the mean X-ray HPT (Pre-injection) was 18.40±1.304 which was reduced to 18.25±1.361 with not so much significant improvement in pain after 6 months follow up (p=0.081). The present study used X-ray, USG and MRI for the evaluation of plantar fascia thickness while Barret et al and Andrew et al used only USG for the assessment of plantar fascia.[13,20] The present study is the only PRP study in chronic cases of plantar fasciitis which used vast radiological parameters to assess radiological outcomes as compared to the previous published studies.

The present study, the only PRP study in plantar fasciitis, derived the correlation of BMI with radiological and functional outcome as compare to the published literature. Correlation was derived by Pearson correlation method.

Correlation between BMI and X-ray heel pad thickness (radiological outcome) was derived and it was found correlation is positive (r=0.026) i.e. with the decreased in mean BMI values the mean x-ray heel pad thickness decreased.

Correlation between BMI and USG plantar fascia thickness (radiological outcome) was derived and it was found correlation is positive (r=0.096) i.e. with the decreased in mean BMI values the mean USG plantar fascia thickness decreased.

Correlation between BMI and MRI plantar fascia thickness (radiological outcome) was derived and it was found correlation is positive (r=0.0301) i.e. with the decreased in mean BMI values the mean MRI plantar fascia thickness decreased.

Correlation between BMI and HPCI (radiological outcome) was derived and it was found correlation is positive (r=0.054) i.e. with the decreased in mean BMI values the mean HPCI decreased.

Correlation between functional outcomes and radiological outcomes

Correlation between X-ray heel pad thickness (radiological outcome) and Visual Analogue Score (functional outcome) was found positive (r=0.1833) i.e. with the decrease in mean X-ray HPT scores the mean VAS scores decreased. Correlation between X-ray heel pad thickness (radiological outcome) and AOFAS (functional outcome) was found negative (r=-0.0854) i.e.

with the decrease in mean X-ray HPT scores the mean AOFAS scores increased.

Correlation between USG Plantar Fascia thickness (radiological outcome) and VAS (functional outcome) was found positive (r=0.0346) i.e. with the decrease in mean USG Plantar Fascia thickness scores the mean VAS scores decreased.

Correlation between USG Plantar Fascia thickness (radiological outcome) and AOFAS (functional outcome) was found negative (r=-0.0854) i.e. with the decrease in mean USG Plantar Fascia thickness scores the mean AOFAS scores increased.

Correlation between MRI Plantar Fascia thickness (radiological outcome) and VAS (functional outcome) was found positive (r=0.1618) i.e. with the decrease in mean MRI Plantar Fascia thickness scores the mean VAS scores decreased.

Correlation between MRI Plantar Fascia thickness (radiological outcome) and AOFAS (functional outcome) was found negative (r=-0.1414) i.e. with the decrease in mean MRI Plantar Fascia thickness scores the mean AOFAS scores increased.

Present study contributes to the pool of evidence supporting the use of PRP in plantar facilities. It supports the notion that PRP is better than the conventionally used injections of corticosteroids and local anaesthetics in plantar facilities. The gradual, progressive and sustained improvement that we found over the period of follow up in the patients who received PRP over those who received bupivacaine is the evidence of the efficacy of leukocyte free PRP. This improvement is expected to continue in the patients over time.[24,25]

The results of present study support the hypothesis of the effectiveness of leukocyte free PRP injection over placebo (normal saline) for relieving pain, stiffness and improving foot functions in cases of plantar fasciitis. None of our cases required surgery.[26-28] No complication occurred in present study.

Strength of the present study: It was a prospective randomized and double blinded study. The patient, clincian assessing the functional and radiological outcome were blinded for the procedure. This excluded errors because of bias.

It was controlled study thus the outcome of the PRP therapy could be assessed more effectively.

- This study included 120 patients (60 PRP group and 60 placebo group).
- We used functional outcome measures such as VAS score, AOFAS, WHOQOL, SF-36 which was not been previously employed in the studies reported in the literature.[24,25]
- We used radiological outcome scores X-ray, HPCI for the evaluation of heel pad thickness and USG and MRI for the evaluation of plantar fascia thickness which were not been employed in the studies reported in the literature.
- We were the first who derived a correlation of BMI with radiological and functional outcome as compared to the previous studies reported in the literature.
- Also, we were the first who had correlated BMI with functional outcomes and radiological outcomes as compared to the previous studies reported in the literature

Limitations of our study included shorter duration of follow up and single centre study. Further research with larger follow up and multicentre study is suggested.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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