Autologous Platelet-rich Plasma Injection for Androgenic Alopecia

This study was formally approved and initiated following clinical application review by the Medical Technology Committee of General Hospital of Western Theater Command, with the assigned project number **2023JSYY-28** and an initiation date of **August 14, 2023**. The original document is written in Chinese. The cover page with the Official Title of the study, and English summary of key design elements are provided as follows.

■批件号：2023 技术应用 28（2023JSYY-28）

西部战区总医院医疗技术临床应用审查批件

科室：输血医学科　　负责人：谭强

项目名称	自体富血小板血浆头皮注射治疗雄激素源性脱发	申报时间	2023-8-1
疾病预防控制科意见	无意见		
质量管理科意见	无意见		
卫生经济科意见	血细胞分离单采，310800005，1530 一次性使用单采血液成份分离器，C0903010100000002533，400 采自体血及保存，310800004，36 采自体血及保存(长期低温保存,每保存一月加收)，310800004，50 富血小板血浆治疗术，KND39801,260 元/次		
新增耗材情况			
伦理委员会意见	同意	医疗技术临床应用管理委员会意见	通过
综合评定意见	■已具备条件，可于近期开展 □须具备条件后开展 □不建议开展		

西部战区总医院
医疗技术管理委员会
（医疗管理科代章）
2023-8-14

Objective

Androgenetic alopecia (AGA) is a progressive condition with limited optimal therapeutic options. While platelet-rich plasma (PRP) therapy has been explored, the apheresis technique offers a distinct method of PRP preparation that yields higher platelet purity and more consistent cellular composition compared to conventional centrifugation methods. This study is specifically designed to evaluate the clinical effectiveness of this autologous apheresis PRP and identify key predictors.

Design

Given the exploratory nature of this investigation aimed at generating preliminary efficacy and safety data for a specific PRP preparation method, a single-arm design was chosen. This single-arm trial enrolled 201 male AGA patients receiving 3-5 sessions of autologous apheresis PRP injections. The primary endpoint, change in the BASP classification, was assessed by independent, blinded physicians. Patient-reported outcomes were assessed one month after treatment completion using a four-item questionnaire covering hair quality, hair thickness, hair loss reduction, and overall satisfaction. Associations between treatment response and key variables, including age, number of sessions, baseline severity, and PRP cellular composition were analyzed.

Methods

Participants

Eligible participants were required to meet all of the following criteria: (1) Male aged 18-55, who had history of hair loss more than 6 months and was diagnosed with AGA based on Chinese guideline for diagnosis and treatment of AGA. (2) General health: in good health with a body weight $\geqslant$ 50 kg, no history of hypertension, diabetes, platelet dysfunction, or any other contraindication to PRP apheresis. (3) Treatment naivety: no use of finasteride, minoxidil, or any other treatment for hair loss within

the 6 months preceding enrollment. Additionally, participants must have had no recent use of glucocorticoids (topical to treatment site for 1 month; systemic for 2 weeks) or nonsteroidal anti-inflammatory drugs (within 48 hours) prior to PRP apheresis. (4) Laboratory parameters: blood tests within 2 weeks before PRP apheresis meeting the following criteria: hemoglobin concentration>120 g/L, hematocrit 0.30-0.50, platelet counts>110×10^9/L. No clinically significant abnormalities in inflammation, coagulation, or electrolyte panels.

Exclusion criteria: (1) Concurrent Hair Loss Treatments: Concurrent use of finasteride, minoxidil, and other hair growth treatments during PRP treatments. (2) Incomplete treatment protocol: failure to complete a minimum of 3 consecutive PRP treatment sessions as per the study protocol, or failure to complete follow-up for any reason.

Interventions, Blinding, and Randomization

Before each PRP injection, photographs of the scalp were taken from four angles (frontal, vertex, and bilateral sides) for every participant. All participants received 3 or more consecutive injections of autologous PRP into the scalp, with an interval of 3 to 5 weeks between each treatment. To ensure objective assessment, all photographs were anonymized by removing any time or sequence identifiers. Subsequently, these photographs were randomly assigned to 2 or 3 independent, blinded physicians for the assessment of hair loss severity. The physicians were blinded to the treatment stage (before- or after-treatment), patient identity, and PRP cellular composition throughout the grading process.

Treatment Protocol

Autologous PRP was prepared using a closed-system blood cell separator (NGL XCF 3000, Nigale Biomedical, China) with disposable blood cell collection consumables, following the manufacturer's standardized protocol. Approximately 20–50 mL of PRP was harvested per session, of which 2 mL was used for quality control and the remainder was aseptically aliquoted into five sterile bags and stored at –80°C. Cellular components were quantified using an automated hematology analyzer (760CS, Mindray, China). Prior to injection, the treatment area was cleansed with sterile gauze. Topical anesthesia was achieved by applying compound lidocaine cream. Subsequently, the scalp was disinfected with 75% medical-grade alcohol. Frozen PRP aliquots were thawed to room temperature immediately before use. Using a 30-gauge sterile needle, rewarmed autologous PRP was administered via intradermal and subcutaneous injections at multiple points across the treatment area, with an injection volume of 0.05 mL per point at intervals of approximately 0.5 cm. Following the procedure, the scalp was cleansed and disinfected again. Participants were advised not to wash hair for the first 48 hours after treatment. In the event of minor bleeding or fibrin deposition at injection sites, gentle cleansing with sterile gauze was recommended.

Assessment Criteria

The severity of hair loss was graded using the Basic and Specific (BASP) classification criteria. Briefly, mild cases included patterns M1, M2, C1, V1, or F1; moderate cases included M3, C2, V2, V3, F2, or F3; severe cases were defined as C3

or any U-type pattern. Coexistence of basic and specific types resulted in an upgrade to the next severity level. Based on grading by blinded, independent physicians using standardized photographs, a positive response was defined as an improvement of at least one grade in either the Basic or Specific component of the BASP system from Baseline to the day of the last treatment. When the physician-assessed gradings were inconsistent, disagreements were resolved by a third blinded assessor, with the final outcome determined by a majority decision.

Patient-reported outcomes were assessed via telephone or outpatient visit one month after treatment completion using a four-item questionnaire covering hair quality, hair thickness, hair loss reduction, and overall satisfaction. Responses are recorded on a 3-point scale: -1 (deteriorated/dissatisfied), 0 (unchanged/neutral), +1 (improved/satisfied). The outcome will be reported as the proportion of participants reporting an improvement (score of +1) for each individual item. Adverse reactions during the treatment process were recorded.

Statistical Analysis

Statistical analysis was performed using SPSS 26.0 and Prism 9.0 software. Continuous variables were tested for normality (Shapiro-Wilk test) and were presented as mean ± SD or median (IQR), as appropriate. Categorical variables were expressed as n (%). Binary Logic Regression Analysis was used to analyze the relationship between the effectiveness of PRP injection treatments and age, treatment sessions, initial severity at diagnosis, and cellular components in PRP. A crosstabulation analysis was conducted to assess the association between treatment

sessions and clinical effectiveness. Chi-square test was used to analyze the impact of treatment sessions on effectiveness, and Mantel-Haenszel Chi-square test was used to assess for a linear trend. Receiver Operating Characteristic (ROC) curve analysis was conducted to assess the predictive utility of PRP RBC concentrations for treatment failure (defined as 'no improvement'). A two-sided p-value of < 0.05 was considered as statistical significance.

Ethical considerations

This study was approved by the Ethics Committee of the General Hospital of the Western Theater Command of the Chinese People's Liberation Army(2023xjsxxm-28). Written informed consent was obtained from all participants after a detailed explanation of the study procedures, potential risks, and benefits. Participant confidentiality would be strictly maintained by using coded identifiers for all data. The study adhered to the principles of the Declaration of Helsinki.