Platelet-rich plasma lacks evidence of clinically significant improvement in androgenetic alopecia

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Platelet-rich plasma (PRP) is widely used in dermatology. Its use is part of the global market for PRP that is expected to exceed $4 billion in the next 10 years.[1] Factors driving the market include PRP's theoretical scientific basis, demonstrated safety, ease of use, critical need for new therapies, hopes of patients, and predominantly persuasive advertising.[1] PRP is costly, usually requires multiple treatments, and is not covered by insurance in most cases.[1]

In the United States, PRP systems are approved through 510K clearance, which means that its performance is substantially equivalent to a device producing PRP to enhance bone graft handling properties. PRP itself is an exempt blood product.[1] PRP systems are medical devices within the European Directive 93/42. Use of human blood components are supposed to be performed only by hematologic centers that have obtained a designation, authorization, accreditation, or license for this purpose from the appropriate authority. However, authorities in many member states allow wide accessibility to PRP.[2]

As a result, PRP does not follow the US Food and Drug Administration's or European Union's traditional regulatory pathway that requires animal studies and clinical trials. Clinical trials have not demonstrated that the results of PRP injection are clinically meaningful. For example, in a systematic review of the use of PRP to treat androgenetic alopecia, the overall standard mean difference in hair density was 0.51 (95% confidence interval 0.23−0.80; $P < .0004$) when compared with placebo.[3] Whereas these results seem promising, the magnitude of the differences (a 17% shift in the population bell curves) suggests that, even among patients who improve, the potential benefits of PRP may not be clinically significant (Fig 1).

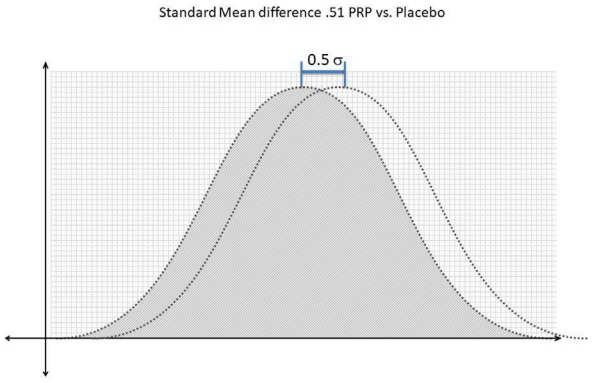

Fig 1. Graphic representation of the meaning of a standard mean difference of 0.51 comparing hair density in response to platelet-rich plasma (PRP; open bell curve) and control (solid bell curve). Whereas these results seem promising at the outset, the magnitude of the difference suggests that, even among patients who improve, the potential benefits of PRP may not be clinically meaningful.

A search of The Cochrane Database of controlled clinical trials, PubMed, and Embase yielded 9 saline or no treatment-controlled trials (Table I). The trials were of small size and poor quality. The trials indicated a modest increase in mean hair density compared with control subjects ranging from 2 to 59 terminal hairs per square centimeter. Whereas these results seem positive, the magnitude of the differences indicates that the potential benefits of PRP are not clinically meaningful. In addition, without individual patient-level data it is not possible to determine whether a few patients had large responses and most patients had little or no response, or that the majority of patients only had modest responses.

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Table I. Controlled Clinical Trials of PRP for Androgenetic Alopecia

Trial	Design	Outcome	Result (PRP vs control)	Comment
1	RCT, 3 blind, 3 injections in 3 months, 23 males	Trichogram 14 weeks after last injection	Terminal hair density increased from 149 to 189 vs 154 to 148 per cm^2	Normal terminal hair density 341 per cm^2
2	Half head RCT, 3 injections in 3 months, 12 men and 13 women	Phototrichogram at 6 mo	Terminal hair density increased from 160 to 166 vs 160 to 162 per cm^2	Normal terminal hair density 341 per cm^2
3	RCT vs saline, DB, single injection, 26 females	*t* test, hair mass, patient-centered	$t_{24} = 0.68$, $P = .5$; hair mass $t_{24} = 1.25$, $P = .22$; 13% vs 0% "substantial improvement"	*t* test inappropriate
4	Pseudo RCT vs saline (coin toss randomization), paired, 30 females, 4 weekly injections	Increase in hair density at 6 mo	Hair density from 74 to 150 vs 73 to 91 per cm^2	Normal terminal hair density 341 per cm^2
5	RCT vs saline, DB, 26 males, 4 injections every 2 wks	Trichoscan (hair density vs baseline), figure only, no tabulated data	Hair density from 140 to 160 vs 210 to 215 per cm^2, $P = .012$	Extrapolated from figure, no numbers provided, normal terminal hair density 341 per cm^2
6	CCT vs saline, 5 injections at 0, 2, 4, 6, and 9 wks, evaluated at 12 wks, 8 men and 5 women	Change in hair density at injected sites	112 to 127 vs 104 to 106 per cm^2	Left right comparison, normal terminal hair density 341 per cm^2
7	RCT vs saline, pilot study, 2 injections 1 mo apart, 17 men per protocol	Terminal and vellus hair density in 2.5 × 2.5 cm area before and after injection 1, 3, and 6 mo after injection	Terminal hair at 6 mo 87 to 85 vs 92 to 92 per cm^2, vellus hair 43 to 43 vs 42 to 40 per cm^2	Similar results at 1 and 3 mos
8	RCT vs saline, 6 injections at months 0, 2, 2, 6, 7, and 8, per protocol, 10 and 15 men completed control and PRP sessions	Hair density at 9 mos	275 to 285 vs 252 to 269 per cm^2	Statistical comparison of groups not performed
9	CCT vs saline, 3 injections monthly in 10 men	Hair density at 14 wks by TrichoScan	159 to 187 vs 171 to 168 per cm^2	Parietal area used as control for frontal PRP injection, vertex used as control for parietal PRP injection

CCT, Controlled clinical trial; *DB*, double-blind; *PRP*, platelet-rich plasma; *RCT*, randomized controlled trial.

Measuring the outcome of PRP treatment is difficult. Self-assessment, physician global assessment, global photography, and phototrichography are the commonly used.[3,4] None of these techniques may be fine enough to detect the subtle changes expected with this treatment.

KEY POINTS

- PRP is available through exemption and clearance that are not the same as approval, which would require animal studies and clinical trials.
- Clinical trials of PRP are of small size and poor quality and have not demonstrated clinically significant improvement.
- PRP is costly and mostly not covered by insurance.
- Informing patients when providing PRP "off-label" should include these facts.

Conflicts of interest

None disclosed.

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