Acta Scientific Pharmacology

Volume 4 Issue 4 September 2023

Editorial

Regulatory and Ethical Concerns for the Research on Platelet Rich Plasma (PRP)

Yogendra Narayanrao Keche*

Department of Pharmacology, All India Institute of Medical Sciences, Raipur, India

***Corresponding Author:** Yogendra Narayanrao Keche, Department of Pharmacology, All India Institute of Medical Sciences, Raipur, India.

Received: September 04, 2023

Published: October 01, 2023

Technology Assessment (TA) need to be there for preparation of PRP

The applicable government regulatory organizations' final approval is required for the technology utilised for the preparation of PRP. The US Food and Drug Administration (FDA) does not regulate the injection of PRP because it is a technique. Through the 510(k) process, the FDA has approved a number of devices used to separate whole blood into PRP. Protein-rich plasma (PRP) and autologous chondrocyte/osteocyte implantation are not regulated by the Indian CDSCO and ICMR because they are classified as different cell-based applications [1,2].

Blood products Regulations by USFDA and FDA India

USFDA and the Centre for Biologics Evaluation and Research (CBER) of the India FDA is in the role of regulating the research and use of human cells, tissues, and products obtained from these different sources. The FDA's 21 CFR 1271 of the Code of Regulations outlines the regulatory process for these items. These restrictions exempt certain items from the FDA's standard regulatory process, which involves animal research and clinical trials, including blood products like PRP. The method that is employed for bringing PRP preparation systems to the market is the 510(k) application. The 510(k) application enables products that are "substantially equivalent" to those that are already on the market (such as the Fidia PRP Kit). For creating platelet-rich preparations intended to be blended with bone graft materials to enhance bone graft handling characteristics in orthopaedics procedures, nearly all of these systems and devices have obtained 510(k) clearance. Clinicians are permitted to administer a product outside of its label as long as certain criteria are met. Clinician should be well informed about the product, its firm scientific rationale and on sound medical evidence and shall maintain records of the product's use and effects as per CBER [3]. As no regulatory guidelines available in India for Platelet Rich Plasma, Clinicians using these product need to be well informed about this product, preparation of product, utility and indications, contraindications and safety concern about the PRP.

(FDA's 21 CFR 1271) Platelet Rich Plasma Preparation Method and Storage [4] for producing PRP, blood is drawn from a single uninterrupted venipuncture with the least amount of donor's tissue manipulation and damage. Within 4 hours of the phlebotomy or as per time frame stated in the blood collecting, processing, and storage system's instructions, the plasma and red blood cells must be separated by centrifugation. Centrifugation's time and speed will result in a product with at least specified platelets per microliter. The plasma must be kept at specified temperature as soon as the last container is filled. A gentle and continuous agitation of the product shall be maintained throughout the storage period, if stored at a temperature of 20 to 24 degree C [4]. Standard procedure and devices approved by DGCI/FDA for production of PRP need to be used.

While using Platelet Rich Plasma following contraindication and safety concern to be kept in mind by the Principal Investigators/Clinicians [5]

Platelet Rich Plasma: Contraindications

Absolute contraindications

Syndrome of platelet dysfunction, thrombocytopenia severe, cardiovascular instability, septicemia, local infection at the surgery site, patient not willing to taking on hazards.

Relative contraindications

Consistent use of NSAIDs within 48 hours of procedure, Within a month, corticosteroids injection at the treatment site, within two weeks, systemic usage of corticosteroids, using tobacco, recent sickness or fever, notably hematopoietic or bone cancer, Haemoglobin less than 10 g/dl, Platelet count < 105/ul.

Safety of platelet rich plasma

- Universal precautions to be taken at all times during the procedure and immediately following the procedure.
- **Infection:** PRP is effective against most bacterial classes—with the exception of Klebsiella, Enterococcus, and Pseudomonas—and is also having antimicrobial activity. Before administering an injection, use a standard skin disinfectant.
- Since this is a fully autologous graft, there is no risk of disease transmission unless the graft is contaminated.
- Risks to patient from the procedure: Infection, Bleeding, Nerve damage, Pain, Lack of result, death and limb loss are extremely uncommon.

Based on the previously discussed evidence, Ethical Issues were noted for use PRP

As a different cell-based uses rather than stem cell transplantation, protein rich plasma (PRP) and autologous chondrocyte/osteocyte implantation are not included by the 2017 National Guidelines for Stem Cell Research. ICMR guidelines 2017 and New Drugs and Clinical Trial Rule does not mention about approval and use of platelet rich plasma. CDSCO site also does not mention about PRP regulation.

Hence PRP therapy to be considered as "off label." Clinicians are free to use a product off-label provided physician is well versed with collection process, contraindication, relative contraindications and safety concerns of Platelet Rich Plasma. A phlebotomist is required to obtain blood. It must be gathered in kits or tubes that have DCGI approval. Patient written consent to be taken and patient should be made aware about alternative therapies available for treatment of his clinical condition even if it used off label by the clinician. All about the collection process, contraindication, relative contraindications and safety concerns of Platelet Rich Plasma need to written in consent form.

PRP is a promising treatment for some musculoskeletal diseases; however, evidence of its efficacy has been highly variable depending on the specific indication. Additional high-quality clinical trials with longer follow-up will be critical in shaping our perspective of this treatment option. There is no clear cut clinical approved indication or clinically sound base for the use of PRP as pe this review [6]. Hence it is advised to use Platelet rich plasma only in clinical trial mode by taking appropriate ethical and regulatory approvals.