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Letters to Editor

A word of caution

Sir,

All readers and practitioners of the art of PRP (platelet rich plasma), it is imperative that you be cautioned of the fact that the Indian FDA considers 'preparing Platelet Concentrate' amounts to 'manufacturing' of blood components (sic) and those who do contravene the provisions, as per the Drugs and Cosmetics Act 1940, read with rule 122EA of the Drugs and Cosmetics Rules, 1945 and are punishable under section 27 of the said Act.

Some of our Plastic surgery colleagues and some Dermatologists have been served with such notices recently.

According to the US FDA there are numerous PRP preparation systems on the market today with FDA clearance; however, nearly all of these systems have 510(k) clearance for producing platelet-rich preparations intended to be mixed with bone graft materials to enhance bone graft handling properties in orthopaedic practices. The use of PRP outside this setting, for example, an office injection, would be considered 'off label'. Clinicians are free to use a product off-label, as long as certain responsibilities are met. As per rules, when the intent is the practice of medicine, clinicians 'have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects.' This is from the US FDA site!

A first spin, also called soft spin, separates plasma, buffy coat (containing PRP), and cells at 130 g during 15 min two different phases are seen: A first clouded phase containing platelets, platelet-poor plasma (or PPP), and buffy coat, and a second phase containing red blood cells, representing, respectively 45% and 55%. A second spin or hard spin, further concentrates platelets giving highly concentrated platelets from whole blood. Thus it is concentration and not 'manufacture' of platelets.

We as responsible clinicians and members of national representative, bodies, need to make aware the Indian FDA to review its provisions and to set widely published guidelines to include PRP and Regenerative cell therapy.

Many orthopaedic surgeons are already practicing PRP therapy in India with some clinical papers being read at national conferences; and a chain of cosmetic clinics has even advertised in Delhi its use for 'Vampire Face lift' about 2 years ago. Some even tout stem cell and PRP therapies in the news dailies for hair growth, but the role is yet to be clearly esatblished.

There are 3 bodies, which by and large regulate abuse.

FDA, DCGI and ICMR. We expect all three regulatory bodies to issue amened and written guideline to all practitioners of PRP therapy.

These respected Institutions help rein in malpractice and quackery.

Some suggestions are as follows: In PRP, blood must be obtained by a phlebotomist

What is the volume of the blood to be collected? Each company has different recommendations.

It must be collected in tubes or kits approved by the DCGI be it glass or any other plastic material.

We need to know the legal definition of 'drug' as per FDA rules.

Is it legal to use 'foreign' certification as valid internationally? Some products are US FDA approved some are CE (European) approved.

The anti-coagulant is NOT Heparin The approved ones are ACD (or Acid Citrate Dextrose) or PCD (Phosphate-citrate-dextrose). This makes the medium acidic and delays the activation of platelets. This must be FDA approved.

The centrifuge too is NOT the common one used in the blood bank. Even this is special and must be approved.

PRP is now combined with PRF (platelet rich fibrin) that can be simultaneously obtained for wound care.

The addition of 'unregulated' growth factors is illegal.

Storing for future use is prohibited.

All unused tissue MUST be discarded appropriately, and not submitted to 'Commercial Industries'

Ethics committee: Members proficient in respective field of investigation or therapy may be included from time to time for specific research, and compensated for their inclusion and contribution.

PRP is a world-wide proven therapy for decades. It is efficient, safe, simple and an inexpensive modality to aid in tissue repair. It uses autologous blood, simple technology and is practical in many ways. It eschews complicated, time-consuming and industry-for-profit driven restrictions that a developing country such as ours can ill afford.

Regenerative cell therapy from autologous adipose tissue and bone marrow is the future. However one must be wary of 'Embryonic Cell Therapy'. It has an explosive potential.

This is purported to be a note of abundant caution.

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