

Market

The cure within

*The life saving nature of blood was always known, but it's therapeutic nature had seldom been explored, until plasma fractionation. **Suja Nair** surveys the scenario*

It's a well known fact that fractionated protein products are a very important class of therapeutics. They are sometimes the only available option in the prevention, management, and treatment of life-threatening conditions caused by trauma, congenital deficiencies, immunologic disorders, or infections. Human plasma is the source of over 700 proteins of considerable therapeutic value such as albumin, clotting factors, immunoglobulins, fibrinogen and others. The process of extracting and purifying these proteins is known as plasma fractionation. The first practical large-scale method of blood fractionation was developed by Edwin J Cohn during World War II. Thus, plasma fractionation is also known as the Cohn method.



Explaining the importance of plasma fractionation, Dr Ranjeet Ajmani, Chief Scientific Officer, Celestial Biologicals, adds, "Plasma is a very complex biological fluid, which has hundreds of biological active ingredients, including proteins. These proteins have tremendous therapeutic value. In plasma fractionation, proteins are separated either by Cohn method or chromatography. After separation of proteins, the proteins undergo viral inactivation protocols." Ajmani adds that at the moment, there is a huge gap between the demand and the supply as the market is not well developed because of availability and affordability of the products, partly due to poor diagnosis. As far as the imports of the products are concerned the products come from various countries like China, Hungary, Germany etc.

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Exploring the past

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- Dr Ranjeet Ajmani
Chief Scientific Officer
Celestial Biologicals

"The government should also encourage plasmapheresis programs to generate more plasma for fractionation. This would have a bearing on the cost of the product, bringing it down significantly and thereby making it available to a larger population"



- K V Subramaniam
President and CEO
Reliance Life Sciences

Unfortunately, in India we do not have a single blood fractionating centre, though some companies are recognising the need and putting efforts in developing them. India collects over seven million units of blood every year, however, more than 60 percent of the plasma from the collection goes waste because there is no facility available here to fractionate. As per the Union Ministry of Health, there is a need for a plant that has a capacity of processing 1,00,000 litres of plasma annually to meet the entire demand of plasma products. Dr Sanjaykumar Jadhav, Assistant Director, Maharashtra State Blood Transfusion Council (SBTC); Member Governing Board, National Blood Transfusion Council (NBTC), Government Of India; Member, Technical Resource Group, Voluntary Blood Donation Committee, NBTC, Government Of India, informs, "India has 2223 blood banks, but only 223 blood banks have component preparation facilities ie plasma separation. However, there are companies in private sector like Reliance, who fractionate plasma. Prathma blood centre of Celestial Biologicals, Ahmedabad get plasma fractionated from Korea." Reliance has a pilot plant for plasma proteins in central Mumbai complying with cGMP guidelines and operating under license from Indian Food and Drug Administration (FDA). The facility is also WHO-GMP certified. Earlier, the National Plasma Fractionation Centre (NPFC) established in 1988-1989 and located in the premises of the KEM Hospital, was the only plasma fractionation centre in India. It was set up to fulfil a long-felt need for safe plasma products in India and had the capacity to fractionate 10,000 litres of plasma annually. It was established as an autonomous unit governed by a trust—Research Foundation for National Blood Transfusion

Services—with the funds provided by the Swedish International Development Agency and with the assistance from the Brihanmumbai Municipal Corporation (BMC) and the Government of India. However, this plant was closed down in 2001 due to financial losses.

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The trendmakers

Celestial Biologicals, a subsidiary of Intas Biopharmaceuticals Limited (IBPL), is planning to set up a fractionation facility near Ahmedabad. The company is planning to invest Rs 100 to 120 crore over two years on the facility that will have an installed capacity to fractionate 1,50,000 litres of plasma in the initial phase. Later, it is planning to be scaled up to 5,00,000 litres.

Ajmani reveals, "The new fractionation centre we are setting up will be of national importance as it will help us (as a nation) to become self reliant. It will also lead to implementation of the national blood policy, advocating modern and right scientific practice in clinical science. Apart from the uplift of the overall transfusion medicine scene in India, it will lead to developing new plasma products from Indian plasma and also help to become a major hub in the SAARC region."

Apart from Celestial Biologicals, there are many others who have entered or are in the process of entering the plasma fractionation segment—Reliance Life Sciences is working on a plasma fractionation plant and is also into marketing plasma products; while Piramal Healthcare, a part of the Piramal Group, recently completed a definitive agreement with PlasmaSelect AG, Germany, to acquire PlasmaSelect's polygeline-based blood plasma products marketed under the brand name Haemacel in over 38 countries.

Sharing the company's future plans K V Subramaniam, President and CEO, Reliance Life Sciences, says, "Reliance is commissioning an The European Medicines Agency (EMA) and US FDA compliant commercial scale facility for plasma fractionation at Dhirubhai Ambani Life Sciences Center, Navi Mumbai."

What lies within

Plasma is composed of many different proteins which carry out various physiological functions. When any of these proteins become deficient in certain diseases, they need to be replaced. In the past, plasma was the only source of these proteins, however, its use could be associated with side-effects and also result in waste of proteins that are not necessary for a particular patient. But now, this can be avoided by plasma fractionation, through which important plasma proteins can be separated in a purified and concentrated form for effective treatment. Plasma is fractionated into albumin, gamma globulins, blood-typing sera, clotting factors for people with haemophilia and so on. Albumin continues to be the main product of the blood fractionation industry, as it is used in treating patients with burns, liver and kidney diseases, oedema, shock due to loss of body fluids, etc. Immunoglobulins are used in treating patients with antibody deficiencies, in Idiopathic thrombo-cytopenic purpura and for preventing or modifying viral infections eg hepatitis, measles etc. Factor IX complex concentrate is used to control bleeding of patients with deficiencies of coagulation factors IX, II, VII & X.

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Component therapy

Component therapy is a much safer method for administration instead of blood as whole, and also has the advantage of optimum utilisation of blood. Previously, even if a patient required only platelets he was given blood, which further resulted in complications. But with the help of blood fractionation, only the components required by patients are administered. By the way of component therapy, at least four products from the same blood can be administered to four different people. It is not feasible for the body to accept blood as whole just because it lacks a particular component, as it may be useless, and sometimes, dangerous.

There is a need for fractionation centres in India not only because it will help our country to become self-reliant, but will also help meet increasing demand for the same. But to achieve this, the Indian Government also should take initiatives to collaborate with various companies. Jadhav, says, "Upgradation of the KEM plasma plant is in process. Government of India is establishing four centres of excellence in Mumbai, Chennai, Delhi and Calcutta for which Rs 468 crore have already been budgeted. So that there will be no problem in future with regard to demand."

Speaking on the need for government initiatives for improving the present conditions Ajmani says, "The history of plasma fractionation across the globe has shown that wherever the government has supported plasma fractionation project, it has improved the quality of life of people who use these products. Since it is a very complex project, it requires to be comprehensively and thoroughly understood by the government as well as regulatory authorities."

Subramaniam suggests that the government should encourage all blood banks to separate collected blood into its components so that the surplus plasma generated can be used for fractionation and the country's need for blood products can be met without having to import the same. The government should also encourage plasmapheresis programs to generate more plasma for fractionation. This would have a bearing on the cost of the product, bringing it down significantly and thereby making it available to a larger population.

Looks like this is another sector where the industry and patient population is totally dependent on the government to extend a lifeline of critical support.

suja.nair@expressindia.com

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