



Publication : Mid Day
Date : January 26, 2015
Page : 1 of 1
Title : Drug that could save thousands is off the shelves

DRUG THAT COULD SAVE THOUSANDS IS OFF THE SHELVES

mid-day investigation

A nationwide supply crunch of human albumin, essential in the treatment of cancer, liver ailments, burns and more, has hit patients hard; pharmacists say the reduced price of the expensive drug has made importing it unviable. Vinod Kumar Menon reports on P10-13

₹3,849
Cost of a bottle (20% in 100 ml) of human albumin

₹5,200
The cost, before National Pharmaceutical Pricing Authority imposed price restrictions



Varsha Chandan, a liver cirrhosis patient for the past eight years, needs albumin two to three times a week. She had to be hospitalized recently as she missed her dose twice due to non-availability of the drug. PIC/SAYYED SAMHEER ABEEDI

10 | mid-day special story

monday, january 26, 2015, mumbai, web www.mid-day.com, twitter @mid_day

Desperate patients wait for drug

mid-day investigation

Human albumin has been off the shelves for months, leaving patients and their families desperate; experts say the supply crisis is not just in Mumbai but across India and the neighbouring countries

VINOD KUMAR MENON
vmenon@mid-day.com

SHEETAL SHETTY was in the Intensive Care Unit (ICU) of the Pwani-based Hirandani Hospital when she was admitted for a liver tumour. When the treating doctors told her younger brother Raj to procure human albumin — a protein found in blood plasma and which is produced by the liver — he had no idea how tough it would be. A nationwide supply crunch has put human albumin off the shelves since the past few months, resulting in black marketing and often deaths of patients unable to get hold of it.

Human albumin is used to treat patients suffering from liver ailments, cancer and even burns. Like Shetty, thousands of desperate relatives all over the country are contacting every possible source to lay their hands on something that is getting alarmingly inaccessible. Raj (40) says he had no idea. "I visited almost every medical shop in the city," he says. "I could not find it anywhere. I finally found a contact who could arrange for imported human albumin manufactured by the US-based company Baxter." Shetty said. Eventually, Sheetal (42) died on January 6 this year. But a testimony of how badly the drug is needed, the four bottles that remained unused were picked up by relatives of other patients within an hour.

Despite the urgency of the problem, the discussion surrounding it mostly seems to be a blame game between the stakeholders in the human albumin industry. To see how difficult it is to procure the protein, mid-day called several chemists and hospital pharmacists in the city and received the same response — not available. There is no record of the total

human albumin is often used to replace lost fluid and help restore blood volume in trauma, burns and surgery patients. PIC/SAYYED SAMHEER ABEEDI

human collection in India, as it is only one of the byproducts extracted from human plasma. Moreover, there is no system in place to lower profit margins, a Mumbai drug stockist who supplies human albumin in their stock for over three months. "On average, we get five or six enquiries a day from Mumbai as well as Rajasthan and Gujarat," he said. "But we are helpless. We depend on wholesale stockists who themselves do not receive regular supply."

Once easily available, the protein's short supply now could be an unforeseen effect of the government's move to control its price due to lower profit margins, a Mumbai drug stockist reveals. The shortage has been felt since the NPPA (National Pharmaceutical Pricing Authority) imposed price restrictions on the drug in September 2014. The drug was earlier being sold for ₹5,200, while the current price is ₹3,849 (20% concentration in 100 ml). This has made it unviable to import the drug.

In India, any human blood element like RBCs, platelets, plasma, or human albumin are treated as drugs, and they can be brought under price control as they are categorized as essential drugs. However in case of human albumin, which is mostly imported into India, the price cap meant it made no business sense for wholesalers and retailers. When pressed for answers, Dilip Mehta, president of the Pharmaceuticals Wholesalers Association, Mumbai, blamed moonsoon-related ailments like dengue and malaria for the present shortage of human albumin. "Human Albumin was always in short supply in the country, as it is one of the most prescribed drugs because of the safety of usage. And now, apart from patients of liver cirrhosis, burns and cancer, even patients suffering a dip in platelets due to moonsoon ailments are demanding human albumin," he said.

"Only two in every 10 patients manage to get the drug today, and the situation will remain the same for the next few months, until some urgent measures are taken at the manufacturer — and the central government level," Mehta added. "Presently only 20 percent of the demand in the estimated ₹200 crore market is met. Around 70 percent is either imported as product or imported



others said available blood was being wasted. In fact, this newspaper had carried a report about the state-run St George Hospital, where 44.5 litres of whole blood and another 97.284 litres of plasma were wasted due to expiration between January 2012 and August 2012. RTI reveals rampant wastage of donated blood, mid-day, November 9, 2013.

S T Patil, Joint Commissioner, FDA, confirmed this. "When we inspected St George's blood bank we found they were allowed wasting the excess blood and plasma," he said. "However, we have taken in writing from St George blood bank that hereafter all their excess blood and plasma will be supplied to other blood banks or hospitals."

Further questions were raised when an RTI activist found discrepancies in the blood collection data. Records obtained under RTI from GT Hospital in the year 2012, showed a total of 925 units of blood had been collected. But records at the Mumbai District Aids Control Society (MDACS) showed that GT hospital had collected only 976 units in the same period.

While the hospital's superintendent

₹3,849
Cost of each 100 ml vial of albumin (20% concentration)

25%
The percentage demand met by the current supply of albumin in the country

70%
The percentage of plasma or plasma protein-based products imported by India



Once the plasma centre and fractionation unit at Shatabdi hospital become functional, it will be able to meet albumin requirements at civic run hospitals across the state. PIC/SAYYED SAMHEER ABEEDI

various therapeutic equipments. However, most of it is processed and consumed in places such as the US, Europe, Japan, South Korea, India and many of its neighbours are completely dependent on supply from these countries, as they have not evolved their own capability to either source the plasma locally or to manufacture the therapeutic products. This is not only expensive, but is highly unviable in terms of long-term health security. This situation is also against the World Health Organisation's recommendations on avoiding cross border movement of human albumin.

Dr Nabajyoti Choudhary, secretary general of the Asian Association of Transfusion Medicine, New Delhi (a registered body of specialists from 12 Asian countries) said, "In India, we have three plasma fractionation companies, while Iran has one. The rest of the world has none. We are now looking to set up such set ups. The companies send the plasma abroad for fractionation and the extracted products like albumin, immunoglobulin etc are then marketed here, which makes the overheads expensive."

According to him, what the industry really needed was to be given a free rein, much like the daily industry. This would relieve manufacturers of the restrictions placed on pricing, import and export and other aspects of the drug.

"The government should give a free hand to manufacturers running fractionation centres in the country, then why is the government not doing anything to make it easily available?" said Vasudeo's son, Vinay Chandak.

fractionation blood into different components enhances its shelf life, since each component has a different shelf life. For example, 42 days for red blood cells, 5 days for platelets and 39 months for albumin

compensation of blood at the blood bank level, which resulted in a lack of quality plasma. This in turn is caused by "low investment in technology towards component preparation, quality standardisation and storage."

"This vicious cycle of underinvestment leading to shortage can be addressed by evolving a regional strategy. The issue is best addressed by blood banks, which are the only source of plasma, the basic raw material required for manufacturing of human albumin," Iyer added.

He explained that while blood banks separate plasma from whole blood, they are not equipped to separate albumin from the plasma, leading to 70 per cent of it being wasted. This could be an excellent source for the fractionation industry, as India alone collects around 7 million units of blood yearly and has the potential to generate plasma for fractionation in the range of around 2 to 2.5 million litres yearly.

Perhaps a resolution to the problem could be on the cards, as the NPPA and its soon-to-be dissolved, the National Pharmaceutical Pricing Authority, will soon convene to discuss the pricing and supply problem of human albumin. "We had a meeting with the manufacturers of the human albumin drug to discuss the issue," said A K Khurana, director, pricing and

administration, NPPA, New Delhi. In a couple of months (by March), the National Plasma Fractionation Centre (NPPFC) is also expected to begin operations at the new unit at Shatabdi Hospital in Goregaon, which can handle up to 20,000 litres of plasma for fractionation.

Further, the NPPA is currently working on a technological solution to the problem. According to him, the current standard format followed the world over for fractionation is to collect plasma from donors, which they involve a mammoth investment of around ₹100 crore, much more than ₹100 crore to set up a plasma fractionation unit. "We are currently attempting to develop an end-to-end modular plasma-fractionation platform to process plasma from donors. This will take care of regional needs and will be capable of maintaining a steady, cost-effective supply. This will be done either directly through blood banks or by developing a commercial unit standing with plasma companies. This initiative is supported by the government's department of Science and Technology, the Centre for Biotechnology in Vellore and other agencies," he said.

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While in the US and in Europe, consumption of human albumin adds up to about 400 kg/million persons, the consumption is far lower in India, at around 1kg/million persons

12 | mid-day special story

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'Without human albumin, my wife's health is at stake'

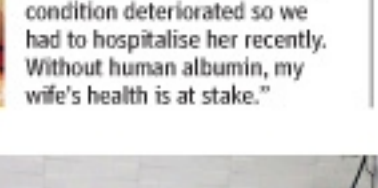
Case studies

VARSHA CHANDAN (53)
Residence - Ghatkopar (East)
Ailment - Liver cirrhosis
Since - 8 years



In order to understand the inside story to the albumin shortage, its important to have an overview of the system and economy surrounding its collection and processing. An estimated 10 million litres of plasma are fractionated every year globally. Fractionation means a separation of different protein and peptides and other pharmaceutical entities from human plasma used for

For the past four months, fluid has been accumulating in Varsha's liver, and she was prescribed human albumin by a liver specialist. She is supposed to take the drug two to three times a week, but it has been hard to find a steady source for it. Her husband, Praveen Chandan said, "We had to skip her dosage twice due to non-availability of the drug, and her condition deteriorated so we had to hospitalize her recently. Without human albumin, my wife's health is at stake."



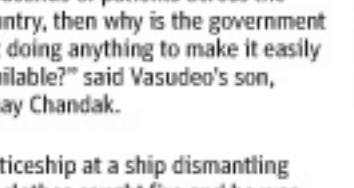
"During an apprenticeship at a ship dismantling unit, my nephew's clothes caught fire and he was burnt to Masina hospital in Byculla with 40 percent burn injuries, that badly affected his left hand. I went to almost all possible chemist outlets searching for human albumin but could not find it. Even the hospital pharmacy could not arrange for it initially," said Dinesh's uncle, Jagdish.

VASUDEO CHANDAK (74)
Residence - Malad (West)
Ailment - Liver cirrhosis
Since - 6 years



Vasudeo was advised to take the drug twice a week, but his family has had trouble finding enough of it, despite the fact that the manufacturing unit is in Mumbai itself. "If the government brought the drug under price control in the interest of thousands of patients across the country, then why is the government not doing anything to make it easily available?" said Vasudeo's son, Vinay Chandak.

DINESH CHANDAN (21)
Residence - Reay Road
Ailment - Accidental burns
Since - January 6, 2015



"In a discussion with mid-day, K V Subramaniam (in pic), president and CEO of Reliance Life Sciences talks about human albumin, its shortage and the possible reasons and solutions for the issue. MD, Why is there an uneven supply of plasma proteins in the Indian market today? SUBRAMANIAM: It is not a situation of uneven demand of uneven supply. The plasma proteins market in India is growing at about 14 per cent per year, and is currently estimated at 600,000 litres. Albumin supplies from industry majors into India has been happening depending on the supplies available in the US and Europe. IVIG supplies were largely coming from China, but this has come down with increase in consumption within China. The current albumin supplies are estimated at

DOCTORSPEAK
Dr Geeta Billa
Consulting Gastroenterologist/Hepatologist
"As a liver specialist I have to prescribe human albumin to most of my patients. I can only prescribe but cannot procure the same and have to depend on the hospital pharmacist, who has been unable to get the same from stockists/manufacturer since the past few months. On an average I come across 5 to 6 liver patients daily who are running from pillar to post to get human albumin."

Dr Ketan Vaghobkar
Consulting surgeon
Jupiter hospital
"In the surgical context the need for albumin is great, especially in patients who are undergoing supra major liver or intestinal surgery. This is more applicable in patients who are malnourished. The outcome of the surgery after administration of human albumin is much better than otherwise. When the product is not available, one has to resort to traditional plasma transfusion, which obviously increases the chances of disease transmission."

Dr. Suhas Abhyankar
Consulting plastic surgeon
Masina hospital
"In severe burn cases, there is heavy loss of body fluids and patients' protein levels go down rapidly. We have to depend on various blood components to treat the patient and one of them is human albumin, as it helps in healing and repairing of wounds apart from keeping blood pressure from fluctuating. At present we have 17 severe burn cases in the hospital, but our hospital's stock of human albumin was exhausted a few months ago. The drug's shortage has caused severe inconvenience to not only the relatives searching for the drug, but also to the treating doctors who face challenges in patient management."



2.5 million litres The potential plasma available for fractionation from the 7 million units of blood collected in India every year

'Price control has put pressure on Indian drug manufacturers'

600,000 vials of 20% conc. in 100 ml. There is currently a global shortage of albumin. This is because price points in India are far lower than developed country markets. MD, What effect has price control had on the drug's supply here? SUBRAMANIAM: With just raw material costs making up 55 to 60% of total costs, margins become very thin. As a result, the pressure is on an Indian manufacturer like Reliance Life Sciences to produce and sell. Reliance Life Sciences can also source plasma with additional plasma supplies and also create new capacities. Reliance has been working on importing plasma, but has to get it through ICMR and approvals from DCGI for which applications are pending.

MD, Why does plasma need to be imported when we can get the same in our country through blood donation camps? SUBRAMANIAM: The total volume of plasma required to attain self-sufficiency in plasma protein products in the country cannot be obtained through blood donation camps. We have sufficient in-house capacity, component separation and plasma supplies value chain. Hence one needs to import plasma from other countries.

Reeling under unmanageable overhead expenses, the BMC has decided to increase the price it will provide human albumin at. "The National Plasma Fractionation Centre at KDM Hospital has a stock of around 1,000 bottles of human albumin (as on last week) and our first preference is to cater to the requirements of government- and BMC-run hospitals. Our present MRP for albumin for indoor patients is ₹2,600 per bottle (20% conc. in 100 ml), and ₹3,849 for outside patients. We intend to increase the cost by another ₹200, as the overhead expenses, including procurement cost, are high," said Dr Subhasini Nagla,

director of Medical Education at the corporation and major city hospitals. While the government currently collects plasma and sends it to Koram for fractionation, Dr Nagla said that once the fractionation unit at Shatabdi hospital became functional, it should be able to meet albumin requirements at civic run hospitals across the state.

Action against overpricing
Springing into action after the NPPA put a price cap on albumin sales, the State FDA has already started taking action against stockists and dealers for overcharging customers. Confirming the move, S T Patil, Joint Commissioner (Drugs) of the Food and Drug Association said, "Acting on a complaint, we laid a trap at an outlet in Wadada, seized 38 bottles of human

albumin in the raid and cancelled the stockist's licence. We are now keeping strict vigil in and around chemist outlets at Parel and other parts of the city." Patil has appealed to the public to inform them about any hoarding activities or overpriced sale of human albumin in the market. Anonymous calls can be made to the FDA toll free number 1800-22-2325.

The plasma protein manufacturing facility at Reliance Life Sciences. To meet the growing demand the company is planning to import plasma, pending permission from ICMR and DCGI. PIC/SAYYED SAMHEER ABEEDI

