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IIT-B's new breakthrough to cut dialysis cost by 50%

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With the number of Indian diabetics to hit 101 million by 2030, there is a huge demand for dialysis and kidney treatments. According to data published by a hemodialyzer manufacturing company, around 42 percent of the world's kidney sufferers are present in the Asia Pacific region. 60 percent of the patients of chronic kidney diseases (CKD) in India are either diabetic or suffer from high blood pressure.

The dialysis market in India is expected to witness a robust growth in the coming years. The demand for dialysis is growing at a rate of 31 percent compared to 6 percent in the US and 8 percent in the rest of the world. The evolving dialysis market in offers remarkable growth opportunities due to factors such as increase in healthcare affordability, government initiatives, and presence of a large patient base.

According to an AIIMS study, around 90 percent of the 2, 30,000 people who develop kidney failure in India die due to high cost of treatments. Many local healthcare providers like Apollo and Fortis have increased their dialysis centers to meet the demand, however due to the high cost, these treatments are inaccessible to the poor.

Delivery of dialysis services is pathetically poor in this country making new research and cutting edge technologies for kidney treatments a 'crying need.' The dialyzers necessary for treatment are imported and this further enhances the cost of the treatments. A sizeable number of patients suffering from kidney failure are unable to undergo dialysis treatment regularly as the facilities are provided mainly in private hospitals and the cost of the treatment in these hospitals is much more than in government hospitals. For the 1.2 billion population of the country, India has less than 1,000 nephrologists. The process of dialysis alone has over a hundred processes and protocols that need continuous monitoring, thus making renal care supremely complex and expensive and, thereby, rendering the Indian market unrewarding.

"The Indian and global markets for dialysis are huge," added Prof. Bellare, "The Indian market alone for hemodialysis is estimated to be around $152 million. Many advantages offered by this hemodialyzer will make it attractive for patients suffering from kidney failure, and also those running and planning to set up dialysis centers. This may help to sharply increase the growth of global dialysis market as it can be made more affordable and thereby can reach a large section of the population at the base of the pyramid who suffer from this unfortunate condition."

The hollow-fiber membrane (HFM) developed by the team has completed laboratory tests and awaits pre-clinical trials. This work has led to five peer reviewed international publications, one Indian Patent, and one PCT. Both Indian and an international patents have been procured for the product. Prof. Bellare explained, "We are the first in India to develop an indigenous and low-cost pilot plant for production of these membranes."

The Discovery

There are two important achievements here. Firstly, IIT-B is the first globally to make a composite hollow fiber membranes (HFMs) with a novel composite material that is a special admixture of polysulfone with Vitamin-E. This imparts a dual functionality enhancement-simultaneous improvements in biocompatibility and in separation performance.

Secondly, the group is the first in India to develop an indigenous and low-cost pilot plant for the continuous production of hollow-fiber membranes to be used in hemodialysis and other applications at production rates of several kilometers per day. The team has obtained a national as well as international patent for this novel compound and the manufacturing process of the HFMs. The group working on this includes past PhD student Mr Ganpat Dahe, current PhD students Mr Rohit Teotia and Mr Surendra Verma, past MTech student Ms Shipra Batra and current MTech student Mr Sujit Das, together with several support staff and interns.

"There are many aspects to the delivery of dialysis care, and ours is a small but significant advance in the big picture," said Prof. Bellare, "But it is one that I hope can nucleate something impactful. In India, currently, most of the instruments and consumables are imported from abroad including the HFM dialyzer. There is news of multinationals coming and setting up plants here. However, import duty and taxes increase the overall cost of dialysis." An additional cost component is the time required for the patient and dialysis center, in terms of the duration and frequency of treatment, and for the need of super-specialists to handle any side-reactions that do occur from time to time in a section of patients. All this adds to the cost, which can be impacted by the innovation.

The heart of this treatment modality is the hemodialyzer, whose core component is the hollow fiber membrane (HFM) filter. "We have developed a pilot plant to fabricate HFM indigenously. The high efficiency of our fabrication process together with the material reduces the overall treatment time for dialysis patients. Additionally, the superior bio-compatibility of this HFM reduces side effects that occur due to poor bio-compatibility," he added.

The unique biomaterial makes the membrane more efficient and highly bio-compatible with blood, by which it decreases the overall treatment time and hence reduces the side effects that arise from lack of biocompatibility. The team has demonstrated the safety of the biomaterial through various case studies, elaborated in the paper published in the prestigious journal Biomaterials.

"Our study shows reduction in Reactive Oxygen Species (ROS) generation in case of our novel composite material due to incorporation of an additive which is a peroxyl radical scavenger. The membrane is also proved to reduce oxidative stress and confirms antioxidative property in cell lines. The membrane also shows lesser protein adsorption on its surface and hence reduces the platelet adhesion and activation of coagulation pathways. Two fold less hemolysis is observed in our membrane when compared to commercial membrane. No inflammatory responses were observed in our membrane, which

implies the superior compatibility of our biomaterial," explained Prof. Bellare.

The superior performance and bio-compatibility of the HFM has already been demonstrated through lab experiments and the team is currently ready with the prototype for an extensive animal trial. Following pre-clinical trials in animals the membrane can be tested for human trials. Prof. Bellare noted, "However, restrictions in animal experiments and lack of facilities for the same, together with regulatory barriers for human trials prevent us from moving as fast as we would like. The cost involved is also formidable for an educational and research institution like ours."

Some of the questions that Prof. Bellare answered. Excerpts

Can this technology be converted into an artificial bio-organ?

Our technology could lead to research into newer devices such as implantable/wearable artificial kidneys, including cell based ones, and other bio-artificial organs. Apart from that, our HFM technology can be used to speed up ongoing research and nucleate new research that eventually could make artificial as well as bio-artificial organs such as liver, pancreas, and lungs. Our pilot plant enables us to manufacture tailor made fibers from various novel polymers and blends including new experimental ones that would be more useful in bio-artificial organs.

How can this innovation spur research into medical and wearable devices research for kidney dialysis?
Hollow fiber membranes can be used in several biomedical applications. High performance helps in miniaturization. Low protein adsorption makes it washable and reusable. We have manufactured the tailor made fiber material and membrane module. This may help in developing wearable devices for kidney dialysis. In regular dialysis a patient has to go for 3 to 4 hours of treatment in the hospital or a dialysis center several times a week. In case of wearable devices one need not lie down on a bed for 3 to 4 hours, 3 times a week. He or she can wear the device and can carry on with their normal work life. Hospital charges will no longer be as big of an issue since it will be a point of care device. However, effective advice and periodic follow-up with skilled nephrologists would still be essential, and visits to dialysis centers for upkeep would likely still be needed.

What stage of development is the product currently in?
We have proven the superior performance and bio-compatibility of our HFM at the laboratory level. Certain selective tests have been done in animals. Currently we are ready with our prototype for an extensive animal trial. Now it needs preclinical proving in an animal model followed by a clinical trial.

How is the funding for the research managed?
We have benefited by funds we have competitively won as sponsored projects from Department of Science and Technology, and currently from the Department of Biotechnology (DBT), which is providing us funds for conducting laboratory experiments. Despite our recent efforts with a scheme run by a subsidiary of the DBT, we have not been successful in raising funds for proof of concept in animals, which would have speedily led to clinical trials in humans. If we can cultivate suitable private partnerships and Government sponsors, it may help us in conducting animal and clinical trials quickly, which would be followed by launch of a product in the dialyzer market, an event that could help so many afflicted by the disease. Even more important, it could spur completely new treatment devices like wearable, even implantable, bioartificial devices to manage not only kidney failure, but may other life threatening organs.