Biosimilar insulins: An unavoidable option in South-East Asia

Sir,

The editorial by Sanjay Kalra *et al.* focusing on various aspects of biosimilar insulin was quite an interesting reading. Diabetes management should be patient-centered,[1] and financial constraint is one of the major determinants of diabetes treatment in South Asian countries. Biosimilar insulin may reduce the cost of diabetes treatment and also may increase the access of patients to diabetes care.[2]

In the UK Prospective Diabetes Study trial,[3] it was seen that by 9 years of diabetes duration 75% individuals require multiple therapies which may include insulin, and thus, the cost of diabetes management progressively increases. India has higher than the world average (9.1% vs. 8.3% worldwide) of diabetes,[4] and the cost of diabetes drugs is 58% of total direct cost for households.[5] The poor strata of people spend more on diabetes drugs compared to richer (75.4% vs. 65.9%).[6] In India, as per one study,[7] 45.3% diabetes patients were started on insulin therapy within 6 months of diagnosis if the target glycated hemoglobin was not achieved. Hence, there arises the need for cheaper medications and insulin.

The global insulin market is expected to reach in excess of $32 billion by 2018,[8] with the sell of insulin glargine alone (Lantus®; Sanofi-Aventis, Paris, France) in 2013 was worth ~$7.5 billion.[9] In view of such a huge market, many companies are exploring the option of biosimilar insulin. Furthermore, a recent survey carried out in people with type 1 and type 2 diabetes suggested that the majority are willing to consider biosimilar insulins.[10] However, many in this study were also worried about the quality and effectivity of such insulin. As manufacturers of biosimilar products do not have access to the cell line and technique of reference product, the manufacturing process may change slightly, but this may have tremendous impact on the biological function of the product, including immunogenicity, potentially affecting the safety and efficacy profile. Hence, regulatory requirement for the biosimilar drugs is stringent.

Presently, there is no position statement for introduction of biosimilars from European Association for the Study of Diabetes and the American Diabetes Association. However, Diabetes UK[11] released a statement in 2013 emphasizing that the decision about which insulin is most appropriate should always be made jointly between patients and their healthcare providers. A similar strategy for South East Asian patients seems logical. Patients should have complete access to the various information about biosimilar insulin such as efficacy, safety, immunogenicity, and various trials in the respective country. This will help the diabetes patient to make a well-informed decision regarding choosing biosimilar insulin as a treatment option.

Diabetes patient also needs to be educated regarding substitution and interchangeability of biosimilar insulin.

Biosimilar product is considered interchangeable if it can be expected to produce the same clinical result as the reference product[12] in any given patient, whereas substitution occurs at the dispenser level.[13] Interchangeability requires crossover studies with robust data and the decision rests with regional medical authority such as Food and Drug Administration. However, substitution should be done under medical supervision as switching from one type of product to other type from one type of biological to another will make evaluation of adverse events, in particular, causality (e.g., hypersensitivity or other immune-mediated reactions), difficult. Physicians need to be careful and can prevent pharmacy switching by writing on prescription as "dispense as written."

Finally, a well-designed community health insurance scheme can improve access to medical care for poor people with diabetes as shown in one study.[14] South Asian countries need to adopt health insurance schemes to lessen the cost of diabetes care. Such scheme would bring the cost of insulin further down and help physicians make the diabetes treatment patient-centric.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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Access this article online

Quick Response Code:

Website: www.ijem.in

DOI: 10.4103/2230-8210.183462

Cite this article as: Kaduskar PU. Biosimilar insulins: An unavoidable option in South-East Asia. Indian J Endocr Metab 2016;20:574-5.