

Cost Excursion Study of Various Insulin Preparations Available in India

MAYUR B PHULPAGARE¹, SMITA A TIWARI², RAJESH S HIRAY³

ABSTRACT

Introduction: Poor drug compliance affects clinical outcome and increases healthcare costs in various disease setting. Several type II diabetes mellitus patients, not controlled on oral hypoglycaemics eventually require insulin therapy. Antidiabetic treatment is to be taken lifelong and in such a setting insulin price variation imposes a huge economic burden on poor diabetic patients. Moderating drug cost is associated with improved adherence to the medication regimen.

Aim: To study the variation in cost amongst various brands of insulin analogues.

Materials and Methods: This was an observational, cross-sectional study. Data regarding the 116 formulations and cost of 18 types of insulin preparations was collected from sources like Current Index of Medical Specialties (CIMS), National Pharmaceutical Pricing Authority (NPPA), Government of India official website (<https://nppaimis.nic.in/nppaprice/pharmasahidaamweb.aspx>)

and compared with its lowest counterpart. The cost ratio and percentage cost variation was analysed and expressed as percentages.

Results: This study showed a noticeable variation in the prices of insulin analogues. The highest percentage of cost variation was found for Insulin (Highly Purified) Zinc-40 IU (135.17%), followed by Insulin (Analogue) Glargine-100 IU (109.31%). The lowest percentage were for: Insulin (Human-Isophane Recombinant)-40 IU (1.40%), and Insulin (Analogue) Aspart- 100 IU (6.26%).

Conclusion: A noticeable variation in cost prices was observed especially in commonly used intermediate acting insulin that help basal glycaemic control. Similarly, the lowest variation was observed with recombinant counterparts as an effect of pre-existing high prices of each. Need for vital medication like insulin at affordable costs has incited national and global efforts to make it cheaper and accessible to maximum beneficiaries.

Keywords: Cost variation, Diabetes mellitus, Drug price, Insulin analogues, National pharmaceutical pricing authority, Pharmacoeconomics

INTRODUCTION

Pharmacoeconomics is defined as “the description and analysis of the cost of drug therapy to health care system and society”. It identifies measures and compares the cost and consequences of pharmaceutical products and services [1]. Cost analysis is a type of pharmacoeconomic evaluation in which comparison of costs of two or more alternative medication is made without regard to outcome [2,3]. Individual drugs have great cost variation in the market which may directly influence the patient compliance [4-6].

Compliance is defined as the extent to which a patient follows a regimen prescribed by a healthcare professional. Compliance in a patient is a composite outcome of various patient and drug related factors like age, financial status, market availability of medication, dosing frequency, adverse effects, etc., [7]. Poor or non compliance not only affects the clinical outcome but also increases healthcare costs [8]. Interventions and regulations of drug prices can improve the accessibility and affordability for everyone [9]. This implies the need for cost analysis of available drug formulations, which may promote the practice of selecting affordable alternatives while prescribing [10]. The consideration of the cost of treatment for ailments is an important aspect of health economics [11]. In the Indian scenario, a majority of the healthcare costs are borne by the patients and India is one of those countries that have the highest Out-Of-Pocket (OOP) expenses on healthcare. A significant portion of this health expenditure is on medicines [12].

Diabetes mellitus is associated with significant human and economic burdens. Diabetes is the leading cause of adult onset blindness, end stage renal disease, and non traumatic amputation and is a major contributor to cardiovascular disease [13]. The treatment of diabetes involves a combination of various interventions, with the primary aim to achieve the best glycaemic control with minimal side effects [14]. Insulin is an essential medication in the management of type I diabetes and in certain cases in type II diabetes too [15,16].

A Diabetes Outcome Progression Trial (ADOPT) showed that the incidence of monotherapy failure at five years in patients with type II DM was 34% for glyburide and 21% for metformin [17]. Patients with diabetes have per capita medical expenses 2.3 times higher than their non diabetic counterparts [18].

Insulin is available from various sources (animal, recombinant human, analogues), have variable strengths (40, 100 IU/mL) and different delivery vehicles (phials, cartridges, pens). Insulin preparations (e.g., insulin lispro, insulin aspart, insulin glargine and insulin degludec) are the most recent advancement in insulin therapy, attenuating many of the common barriers to traditional insulin use. The use of new insulin products, that lessen the clinical barriers to insulin use, have also demonstrated potential to reduce the overall healthcare economic burden associated with diabetes management [19].

Cost effective management of diabetes with insulin therapy has been shown to improve glycaemic control in poorly controlled type 2 DM patients, without adversely affecting the quality of life [20]. Despite having a century old experience with the discovery of insulin, it unfortunately is still not available and/or affordable for millions of diabetic patients world-over.

Generally, in India most of the diabetic patients seek private medical consultation and treatment for their medical condition that adds to their financial burden in the form of out of pocket payments for health care. Taking in view this aspect, it is therefore essential to estimate the availability and cost variation of insulin and its analogues [21].

The NPPA was established in 1997 for ensuring availability and affordability of the drugs [22]. Drug Price Control Order (DPCO) issued by NPPA fixes the ceiling price of a scheduled formulation of any brand or generic drug of a pharmaceutical company having more than or equal to one percent share in the market. Currently, only three insulin preparations are covered under DPCO [22].

As antidiabetic treatment is required lifelong, it contributes to the economic burden on patients [23]. A decreased drug cost is associated with improved adherence to the medication regimen [24]. This study was aimed at investigating and comparing the costs of various brands of the insulin preparations to observe the cost variations among them.

MATERIALS AND METHODS

This observational cross-sectional study was carried out after approval from Institutional Ethics Committee (BJGMC/IEC/Pharmac/ND-DEPT 1219258-258). Data was collected from 15 January 2020 to 15 February from various sources namely CIMS, NPPA official website of Government of India and website for "medguideindia" [25-27]. The further data refining and analysis were done over additional two months, till April 2020.

In the current study, insulin preparations manufactured by more than one company were considered. The study included price of insulin preparation dispensed in vials only. The newer insulin preparation manufactured by a single company and insulin preparations with no cost information available were excluded. Insulin preparations available in newer drug delivery systems were not considered for this study.

Prices of insulin preparations of different strength available in India were noted from:

- CIMS [25]
- NPPA, Gol official website [26]
- Website for "medguideindia" [27]

Unit prices (per 10 mL) were expressed in Indian Rupee (INR) of drug formulations and compared with DPCO price list 2013 (Price Revision w.e.f. 1.4.2019) [22]. The cost ratio and percentage cost variation were noted for each brand. The prices of 18 insulin preparations, available in 116 different products were analysed as:

- Cost of a particular insulin preparation (cost per 10 mL), in the same strength and dosage forms being manufactured by different companies was obtained to identify the price (in INRs) of various brands of insulin preparation- i.e., Minimum price (INR), and maximum price (INR) (of a particular insulin preparation manufactured by various pharmaceutical companies in the same strength).
- The cost ratio, the ratio of the highest cost brand to lowest cost brand of the same insulin preparation was calculated. This calculation gives an assessment for the ratio of cost variation of the most expensive brand from the cheapest insulin preparation. This tells, how many times costliest brand costs more than the cheapest one in each insulin preparation group [28].

STATISTICAL ANALYSIS

The data collected was entered in Microsoft Excel 2018. Cost ratio and percentage cost variation were calculated. The data was presented in the form of tables as percentages.

RESULTS

The cost of a total of 116 insulin preparation formulations was analysed. The insulin formulations for which more than five preparations are available in the Indian market are as that shown in [Table/Fig-1].

A noticeable variation in the prices of insulin preparations was observed in the current study. As per study protocol when the maximum and minimum rates were compared for the respective insulin preparations, the highest percentage of cost variation was noticed for Insulin (Highly Purified) Zinc-40 IU (135.17%). The second preparation with high cost variation was Insulin (analogue) Glargine-100 IU (109.31%), which was closely followed by Insulin (Highly Purified)-40 IU (105.98%).

There were four insulin preparations that had low cost variation i.e. less than 10%. The lowest cost variation was seen with Insulin (Human - Isophane Recombinant)- 40 IU i.e., 1.40%. Insulin (Analogue) Aspart-100 IU had a cost variation of 6.26%. Other preparations like {Insulin (Human Recombinant)- 40 IU had a cost variation of 7.51% and that

Sr. No.	Insulin preparations	No. of brands available in the Indian market
1	Insulin (Human)-40 IU	16
2	Insulin (Human)-30%/40 IU Insulin (Human-Isophane)-70%/40 IU	14
3	Insulin (Human-Isophane)-40 IU	12
4	Insulin (Human)-100 IU	10
5	Insulin (Human)-50%/40 IU Insulin (Human-Isophane)-50%/40 IU	10
6	Insulin (Highly Purified)-40 IU	7
7	Insulin (Highly Purified) Isophane (NPH)-40 IU	6
8	Insulin (Human)-30%/100 IU Insulin (Human-Isophane)-70%/100 IU	6

[Table/Fig-1]: Number of insulin preparations.

of Insulin (Human)-40 IU was 9.92%, which was less than 10% or rather low cost variation. Cost variation of preparations like Insulin (Human)-30%/Insulin (Human-Isophane)-70%-40 IU was 13.23% and Insulin (Human)- 100 IU was 25.64% which were low but more than 10% and limited to 25% only [Table/Fig-2].

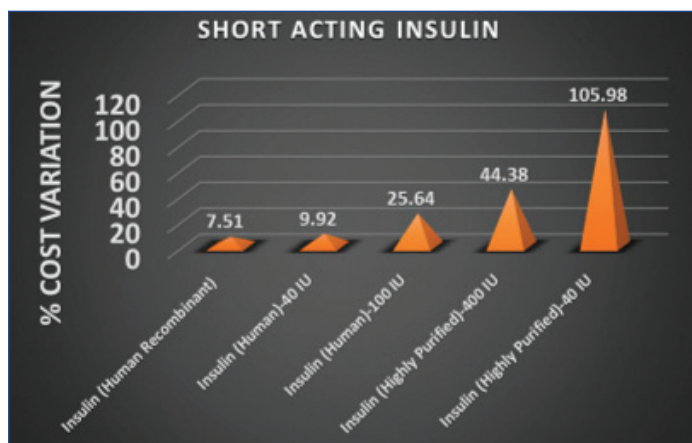
Sr. No.	Insulin preparations	Max price (INR)	Min price (INR)	Cost ratio	Cost variation (%)
Rapid acting insulin					
1	Insulin (Analogue) Aspart-100 IU	1952	1837	1.06	6.26
Short acting insulin					
2	Insulin (Highly Purified)-40 IU	185.38	90	2.06*	105.98
3	Insulin (Highly Purified)-400 IU	113.37	78.52	1.44	44.38
4	Insulin (Human)-40 IU	154.66	140.7	1.1	9.92
5	Insulin (Human)-100 IU	490	390	1.25	25.64
6	Insulin (Human Recombinant)-40 IU	154.2	143.43	1.07	7.51
Intermediate acting insulin					
7	Insulin (Highly Purified) Zinc-40 IU	218	92.7	2.35*	135.17
8	Insulin (Highly Purified) Isophane (NPH)-40 IU	129.34	73.69	1.75	75.52
9	Insulin (Human-Isophane)-40 IU	192.09	140.07	1.37	37.14
10	Insulin (Human-Isophane)-100 IU	490	334.45	1.46	46.51
11	Insulin (Human-Isophane Recombinant)- 40 IU	147.7	145.66	1.01	1.40
Long acting insulin					
12	Insulin (Analogue) Glargine-100 IU	2983.1	1425.2	2.09*	109.31
Premixed insulin					
13	Insulin (Highly Purified)-30%/40 IU Insulin (Highly Purified) Isophane (NPH)-70%/40 IU	119	74.01	1.6	60.79
14	Insulin (Highly Purified)- 30%/40 IU Insulin (Highly Purified) Lente-70%/40 IU	129.34	95	1.36	36.15
15	Insulin (Human)-30%/40 IU Insulin (Human-Isophane)-70%/40 IU	158.6	140.07	1.13	13.23
16	Insulin (Human)-30%/100 IU Insulin (Human-Isophane)-70%/100 IU	490	263.9	1.85	85.68
17	Insulin (Human-Isophane)-50%/100 IU Insulin (Human)-50%/100 IU	429.37	334.45	1.28	28.38
18	Insulin (Human)-50%/40 IU Insulin (Human- Isophane)- 50%/40 IU	182.81	140.07	1.30	30.15

[Table/Fig-2]: Variation in cost of insulin preparations.

Dosage form as injection and strength of 10 mL; *Preparations with cost ratio >2 i.e., double the minimum price

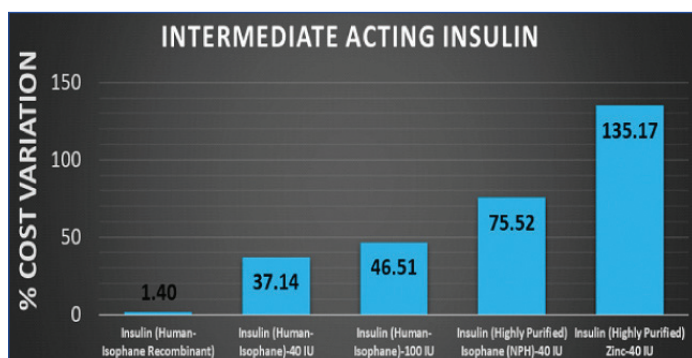
It was observed that Insulin (highly purified) Zinc-40 IU had a cost ratio of 2.35 i.e., the costliest brand (Rs. 218) of this preparation was 2.35 times costlier than the cheapest brand (Rs. 92.7) of the same formulation available in the Indian market. The other two insulin preparations that had such cost ratio of two and more were Insulin (analogue) Glargine-100 IU (2.09) and Insulin (highly purified)-40 IU (2.06).

There are three other insulin preparations that had cost ratio of more than 1.5. Premix Insulin (human)-30%/Insulin (human-Isophane)-70%-100 IU had a cost ratio of 1.85, Insulin (highly purified) Isophane (NPH)-40 IU and Insulin (highly purified)-30%/Insulin (highly purified) Isophane (NPH)- 70%-40 IU also had a cost ratio of more than 1.5. In the short acting insulin preparation group, Insulin (highly purified)-40 IU had a highest cost variation of 105.98%, where the cheapest brand of this preparation costed Rs. 90 and the costliest one was available for Rs.185.38. Similarly, the lowest cost variation was observed with Insulin (human recombinant) -40 IU which was around 7.51% [Table/Fig-3].



[Table/Fig-3]: Percentage cost variation in short acting insulin preparation group.

It was observed that in intermediate acting insulin preparation group, Insulin (Highly Purified) Zinc-40 IU had highest cost variation of 135.17%, where the cheapest brand of this preparation costed Rs. 92.7 and the costliest one was available for Rs. 218. Similarly lowest cost variation was noted with Insulin (Human-Isophane Recombinant)- 40 IU which was 1.40% [Table/Fig-4].



[Table/Fig-4]: Percentage cost variation in intermediate acting insulin preparation group.

According to DPCO 2013 (w.e.f. 01.04.2019), Premix Insulin 30:70 Injection (Regular:NPH) (40 IU), Insulin (Soluble) (40 IU), Intermediate Acting (NPH) Insulin (40 IU) prices were under price control by NPPA, Government of India. Yet, intermediate acting (NPH) Insulin (40 IU) had cost variation of 30.41% with DPCO ceiling price [Table/Fig-5].

DISCUSSION

This study was carried out with the objectives of computing the costs and percentage price variation among insulin preparations across the different brands available in the Indian market. The study findings reveal that among the different insulin preparation, three formulation have price variation of more than 100%, only five <15%.

Sr. No.	Insulin preparations	Dosage form	Strength	Ceiling price (INR)	Highest retail price	CV with DPCO rate (%)
1	Insulin (Soluble) 40 IU/mL	Injection	1 mL	14.73	18.54	5
2	Intermediate Acting (NPH) Insulin	Injection	1 mL	14.73	21.8	30.41
3	Premix Insulin 30:70 Injection (Regular: NPH) 40 IU/mL	Injection	1 mL	14.73	15.87	7.67

[Table/Fig-5]: Insulin preparations under DPCO 2013 (w.e.f. 1.4.2019).

Highest price variation was seen with Insulin (Highly Purified) Zinc-40 IU, Insulin (analogue) Glargine-100 IU. Newer drug delivery system are available as disposable pens, flexpens, prefilled pens, kwikpens, cartridges and flextouch. Such novel drug delivery systems are lucrative and user friendly, but offer an additional financial burden. Such modalities of therapy may not be pocket-friendly for patients with lower socioeconomic status.

Cost variation issues are not only limited to insulin preparations but also are seen regarding available preparations of antiasthmatics [29], antidepressants [12], antihypertensives [30], dyslipidaemic drugs [31]. Similar cost variation study done by Mehani R and Sharma P, for various antidiabetic drugs available in Indian market showed maximum variation with sulfonylureas which is the most commonly used oral hypoglycaemic and minimum was observed with meglitinide analogues [32].

According to DPCO 2013 (w.e.f. 1.4.2019) Only Premix Insulin 30:70 Injection (Regular:NPH) (40 IU), Insulin (Soluble) (40 IU), Intermediate Acting (NPH) Insulin (40 IU) prices are under price control by NPPA, Government of India. These are also included in national list of essential medicine, 2015 as well as in World Health Organisation (WHO) essential medicine list for adults, 2019 (40 IU,100 IU in 10 ml vial), (except Premix Insulin 30:70 Injection (Regular:NPH)) [33]. Therefore, prices of all insulin analogues available in the market are not controlled by DPCO of India [22].

Medicine pricing plays a significant role in a developing country like India. This situation is further complicated by the number of branded formulations for different drugs. The price of medicine in India is regulated by DPCO issued by Government of India through the official gazette. This in turn is implemented by NPPA. This helps in regulation of prices of various essential drugs mentioned in the National Essential Drug List.

There is a great price variation between different brands of the same drug and some drugs still cost more than the prescribed limits by DPCO [34,35]. The price variation can be due to different factors like cost of the ingredients, methods used in preparation of drug, procurement mechanism in public and private pharmacies. In the government sector, procurement is made directly from pharmaceutical manufacturers recognised by the government or from government established manufacturing facilities, whereas in the private sector there is multi-layered procurement mechanism leading to increase in price of medicine brought by consumer (patient) [36]. According to Singal GL et al., a substantial margin of 25-30% can be gained in the sales of branded medicine in private retail pharmacy. This profit margin rises to a whopping range around 200% to more than 1000% in case of branded generics [37]. Interestingly, a cost ratio of two or more and percentage of price variation more than 100 are worrisome and assume significance. Such prevalent factors contribute to unaffordable healthcare [38].

The penalty for selling drugs at prices over and above the ceiling price or that notified by the government, is relatively mild. The manufacturers only need to deposit the overcharged amount

in addition to the interest from the date of such an event. Thus, Government policy towards the pharmaceutical companies is not too stringent, as it may adversely affect the production of drugs under DPCO regulation, as it is a well known fact that less profits hamper the pharmaceutical industry growth [39]. Therefore, rational and pharmacoeconomical prescribing practices by physicians is an alternative for providing cost-effective therapy [40].

It has been observed that there is lack of appreciation among the physicians for the cost difference between the inexpensive and expensive drugs [41]. This can result in increased overall health care costs. Such factors can be improvised by imbibing the concepts of pharmacoeconomic at the undergraduate and postgraduate curriculum in practical sessions [42].

According to WHO Bulletin 2015, an estimated 8% of the Indian population had been pushed below the poverty line by high OOP payments for healthcare [43]. Most of the insulin analogues are prescribed on an outpatient basis. Studies have shown that increase in “out of pocket spending” from patients and this may affect drug compliance and add to the cost of the drug making it difficult to reach a broad fraction of the population [44].

As appropriately commented by Rataboli PV and Dang A in their study, Government should include lifesaving and essential drugs (barring innovator products) under the DPCO [45]. The Government of India on 25th November 2008 had started the Jan Aushadhi Campaign. Numerous ‘Jan Aushadhi Medical Stores’ were opened in India as an initiative for providing affordable drugs without compromising on quality. This scheme was later renamed as “Pradhan Mantri Bhartiya Janaushadhi Pariyojana” (PMBJP) [46]. Increasing market competition, particularly from Indian companies through by opening up the option of lower priced quality assured biosimilars can provide a ray of hope to improve insulin access and affordability [47].

At the global level the WHO announced the start of a pilot programme to prequalify human insulin on 13 November 2019. Prequalification of Medicines Programme devised by WHO accelerates and increases access to critical medical products that are quality assured, affordable and adapted for markets in low and middle income countries [48].

Limitation(s)

The study did not compare cost of all the insulin preparation available in newer drug delivery system as such preparations that are not covered under DPCO. The costs computed also purely reflect drug cost and is not a complete estimate of health care expenditure in diabetic patients.

CONCLUSION(S)

The DPCO implemented by NPPA helps in regulation of prices of drugs mentioned in the national essential drug list. Despite of the regulation, there is a huge price variation is present between different brands of the same drug although capped by DPCO. A noticeable variation in the prices of insulin preparations was observed in the current study. The highest percentage of cost variation and cost ratio was noticed for Insulin (Highly Purified) Zinc-40 IU followed by Insulin (Analogue) Glargine-100 IU. The lowest cost variation was seen with Insulin (Human- Isophane Recombinant) 40 IU as the cheapest brand had a higher cost than the conventional insulin counterpart and for similar reasons lowest cost variation was observed with Insulin (Human Recombinant)-40. Initiatives are taken at national and global levels to make such a vital medication affordable and accessible to patients of all economic background all over the world.

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PARTICULARS OF CONTRIBUTORS:

1. Junior Resident Doctor-3, Department of Pharmacology, B. J. Government Medical College and Sassoon Government Hospital, Pune, Maharashtra, India.
2. Associate Professor, Department of Pharmacology, B. J. Government Medical College and Sassoon Government Hospital, Pune, Maharashtra, India.
3. Professor and Head, Department of Pharmacology, B. J. Government Medical College and Sassoon Government Hospital, Pune, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Smita A Tiwari,
Associate Professor, Department of Pharmacology, B. J. Government Medical College and Sassoon Government Hospital, Pune-411001, Maharashtra, India.
E-mail: drsmitamd@gmail.com

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