



## International Journal of Research in Pharmacology & Pharmacotherapeutics



ISSN Print: 2278-2648

IJRPP |Vol.8 | Issue 2 | Apr - Jun - 2019

ISSN Online: 2278-2656

Journal Home page: [www.ijrpp.com](http://www.ijrpp.com)

Research article

Open Access

### Price variation analysis of various drugs used for thromboembolic disorders currently available in Indian pharmaceutical market

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#### ABSTRACT

##### Background

Major population in developing countries purchases medicine through out-of-pocket payment thus making them the largest family expenditure item after food. As a result, medicines are unaffordable for large sections of the global population and a major burden on government budgets. In developing country India, price of drugs play a major role in prescribing a drug for treatment.

##### Methods

An analytical study was done for comparing price variations among various drugs prescribed in thromboembolic disorders. Indian Drug Review (IDR) (January 2019) and CIMS (October December 2018) was referred to know the maximum and minimum price in INR of drugs in all available strength and dosage forms being manufactured by different companies in India and percentage price variation was calculated.

##### Results

Wide variation in the price of several brands of same anticoagulants, fibrinolytics, antiplatelets and their combinations were found in Indian pharmaceutical market. Highest percentage price variation was found for Aspirin 150 mg + Clopidogrel 75 mg Tablet (741.03%) combination. Percentage price variation is >100% for all the different combinations of aspirin + clopidogrel. In single drug, highest percentage price variation was found for Aspirin 100 mg Tablet (435.13%) followed by Aspirin 75 mg Tablet (403.78%), Clopidogrel 75 mg Tablet (275%), Aspirin 50 mg Tablet (221.96 %). In single drug, lowest percentage price variation was found for Eftifibatide 20mg/10 ml injection (1.15%) followed by Tirofiban 5mg/100 ml injection (2.63%), Warfarin 5 mg Tablet (3.23%).

##### Conclusion

Steps should be taken by the government towards reduction in price variation among the various brands so as to them affordable and aim to improve the health status of community. This will definitely reduce the economic burden on government. The purpose of "Health for all" can only be achieved by efforts from all stakeholders.

**Keywords:** Price variation, Thromboembolic disorders, Indian pharmaceutical market

## INTRODUCTION

Medicines account for 20–60% of health expenditure in developing and transitional countries. Up to 90% of the population in developing countries purchases medicines through out-of-pocket payments, making medicines the largest family expenditure item after food. As a result, medicines are unaffordable for large sections of the global population and are a major burden on government budgets. [1]

In developing country like India, price of drug play a major role in prescribing a drug for treatment. Apart from safety and efficacy, price is also a major factor for drug to be included in formulary and national essential medicines of India. Rational prescribing also means right drug, right dose, right formulation, and right duration at a right price that an individual can afford.

There has been a lack of appreciation among clinicians about the difference between inexpensive and expensive drugs. Due to their ignorance about the drug price, they also have tendency to overestimate the price of inexpensive drugs while underestimating the price of expensive ones. This lack of concern ultimately results in increased overall healthcare expenditures. [2] In India, two third of the health spending is out of pocket. In India, 28% of the rural population and 20% of the urban population do not seek treatment of medical ailments due to financial constraints. [3] Hemostasis means limiting blood loss as a consequence to bleeding which include three basic mechanisms like vascular spasm, platelet plug formation reinforced by fibrin threads and blood coagulation. If clotting happens abnormally early in intact blood vessels, the result is thrombosis. If thrombosis occurs in veins, it can lead to pulmonary embolism or deep vein thrombosis. If thrombosis occurs in arteries, it may lead to various coronary artery diseases like cerebrovascular stroke, cardiovascular stroke and myocardial infarction. [4]

Anticoagulants, fibrinolytics, and antiplatelets are main stay drugs in treating thromboembolic disorders. Their use is considered as secondary prophylaxis, in a patient that has had a thromboembolic event or primary prophylaxis in the patient at risk of cardiovascular diseases.

Cardiovascular diseases (CVDs), especially coronary heart disease (CHD), have assumed epidemic proportions worldwide. Globally, CVD has

led to 17.5 million deaths in 2012. More than 75% of these deaths have occurred in developing countries. In contrast to developed countries, where mortality from CHD is rapidly declining, it is increasing in developing countries. In India, more than 10.5 million deaths occur annually, and it was reported that CVD led to 20.3% of these deaths in men and 16.9% of all deaths in women. [5] According to 2010-2013 Registrar General of India (RGI) data proportionate mortality from CVD increased to 23% of total and 32% of adult deaths in years 2010-2013. The mortality varies from <10% in rural locations in less developed states to >35% in more developed urban locations. [5] Pharmaceutical industry manufactures many branded formulation of the same drug with large difference in selling price. In India, most of the drugs are available in brands and these are also prescribed by clinician mostly by brand name. This may affect the patient's finance adversely if a pricey brand is prescribed, especially in cardiovascular diseases which need treatment for prolonged duration. [6]

Limited studies are available in Indian scenario, so we decided to do such analytic study which mainly focuses on price variation of different anticoagulants, antiplatelets and fibrinolytics and their fixed dose combinations with following aims and objectives:

1. To evaluate the price of oral anticoagulants, fibrinolytics, antiplatelets and their fixed dose combinations of different generic and brand drugs of one compound.
2. To evaluate the variation in price of different brands for the same active drug by calculating percentage variation of price.
3. Comparison of ceiling price of drugs which are given by National Pharmaceutical Pricing Authority (NPPA) in accordance with Drug Price Control Orders (DPCO).

## MATERIAL AND METHODS

### Type of Study

Analytical study.

### Inclusion criteria

Anticoagulants, Fibrinolytics, and Antiplatelet drug formulations with same strength, dose. (Single drug & Fixed dose Combinations)

### Exclusion criteria

The drugs manufactured by single company were excluded. Combination of Anticoagulants, Fibrinolytics, and Antiplatelet drugs with other than these groups of drugs were also excluded. The drugs were excluded whose prices were not given in source.

### Sources for price of drugs

“Indian Drug Review (IDR)” (January 2019 edition Volume XXV Issue 1) and CIMS (October December 2018) was referred to know the maximum and minimum price in INR of anticoagulants, fibrinolytics, and antiplatelet drugs in all the available strength and dosage forms being manufactured by different companies in India. On basis of this we can know how many times the pricelist brand prices more than the cheapest brands in each drug.

To compare prices of brand drug with generic drug, prices of generics which were given on <http://janaushadhi.gov.in/ProductList.aspx> (Accessed on 01.05.2019) used as source.

- Price ratio = Maximum price/Minimum price
- Percentage price variation was calculated by
- Price Variation (%) =  $[\text{Maximum Price} - \text{Minimum Price} / \text{Minimum Price}] \times 100$
- Data were analyzed using percentage and proportions.

### RESULTS

The prices of anticoagulants, fibrinolytics, and antiplatelets produced by several pharmaceutical companies were analyzed. Tables 1-3 show percentage price variation of anticoagulants, antiplatelets, and fibrinolytics.

**Table 1: Percentage price variation of Anticoagulants**

| Drug            | Dose & Formulation (Quantity) | No. of Manufacturing Companies | Minimum Price | Maximum Price | Price Ratio | Price Variation (%) |
|-----------------|-------------------------------|--------------------------------|---------------|---------------|-------------|---------------------|
| 1 Acenocoumarol | 1 mg Tablet (10)              | 3                              | 27.5          | 60.4          | 2.19        | 119.63              |
|                 | 2 mg Tablet (10)              | 3                              | 39            | 103.9         | 2.66        | 166.41              |
|                 | 3 mg Tablet (10)              | 2                              | 85            | 132.7         | 1.56        | 56.11               |
|                 | 4 mg Tablet (10)              | 3                              | 57            | 141.5         | 2.48        | 148.24              |
| 2 Enoxaparin    | 20 mg / 0.2 ml Inj (0.2 ml)   | 4                              | 288           | 433.79        | 1.50        | 50.62               |
|                 | 40 mg / 0.4 ml Inj (0.4 ml)   | 10                             | 385           | 490           | 1.27        | 27.27               |
|                 | 60 mg / 0.6 ml Inj (0.6 ml)   | 13                             | 475           | 601.08        | 1.26        | 26.54               |
|                 | 80 mg / 0.8 ml Inj (0.8 ml)   | 2                              | 805.71        | 1176.61       | 1.46        | 46.03               |
| 3 Heparin       | 25000 IU / 5 ml Inj (5 ml)    | 3                              | 69            | 205.6         | 2.97        | 197.97              |
| 4 Warfarin      | 5mg Tablet (10)               | 2                              | 24.08         | 24.86         | 1.03        | 3.23                |

**Table 2: Percentage price variation of Antiplatelets**

| Drug      | Dose & Formulation (Quantity) | No. of Manufacturing Companies | Minimum Price | Maximum Price | Price Ratio | Price Variation (%) |
|-----------|-------------------------------|--------------------------------|---------------|---------------|-------------|---------------------|
| 1 Aspirin | 50 mg Tablet (10)             | 2                              | 2.64          | 8.5           | 3.21        | 221.96              |
|           | 75 mg Tablet (10)             | 7                              | 2.64          | 13.3          | 5.03        | 403.78              |
|           | 100 mg Tablet (10)            | 3                              | 1.85          | 9.9           | 5.35        | 435.13              |

|   |   |    |         |         |      |        |
|---|---|----|---------|---------|------|--------|
|   | 150 mg Tablet (10)                              | 3  | 4.21    | 12      | 2.85 | 185.03 |
|   | 325 mg Tablet (10)                              | 2  | 8.17    | 14.8    | 1.81 | 81.15  |
| 2 | Cilostazole 50 mg Tablet (10)                   | 4  | 63      | 124.5   | 1.97 | 97.61  |
|   | 100 mg Tablet (10)                              | 4  | 109     | 239.5   | 2.19 | 119.72 |
| 3 | Clopidogrel 75 mg Tablet (10)                   | 31 | 36      | 135     | 3.75 | 275    |
|   | 150 mg Tablet (10)                              | 3  | 73.82   | 224     | 3.03 | 203.44 |
|   | 300 mg Tablet (10)                              | 2  | 91.05   | 197.5   | 2.16 | 116.91 |
| 4 | Dipyridamol 100 mg Tablet (10)                  | 3  | 10.84   | 17.2    | 1.58 | 58.67  |
| 5 | Eptifibatide 20 mg / 10 ml Inj (10 ml)          | 3  | 2471.51 | 2500    | 1.01 | 1.15   |
| 6 | Ticlopidine 250 mg Tablet (10)                  | 3  | 75.5    | 97.45   | 1.29 | 29.07  |
| 7 | Tirofiban 5 mg/100 ml Inj (100 ml)              | 2  | 4200    | 4310.77 | 1.02 | 2.63   |
| 8 | Prasugrel 5 mg Tablet (10)                      | 2  | 54      | 95.28   | 1.76 | 76.44  |
|   | 10 mg Tablet (10)                               | 3  | 94.82   | 169     | 1.78 | 78.23  |
|   | 5 mg FC Tablet (10)                             | 2  | 90      | 120.8   | 1.34 | 34.22  |
|   | 10 mg FC Tablet (10)                            | 2  | 145.1   | 216     | 1.48 | 48.86  |
| 9 | Aspirin + Clopidogrel 75 mg + 75 mg Tablet (10) | 17 | 23.75   | 75.01   | 3.15 | 215.83 |
|   | 150 mg + 75 mg Tablet (10)                      | 12 | 26.2    | 157.8   | 6.02 | 502.29 |
|   | 75 mg + 75 mg Capsule (10)                      | 9  | 28      | 62.5    | 2.23 | 123.21 |
|   | 150 mg + 75 mg Tablet (10)                      | 6  | 19.69   | 165.6   | 8.41 | 741.03 |

Table 3: Percentage price variation of Fibrinolytics

| Drug | Dose & Formulation (Quantity)      | No. of Manufacturing Companies | Minimum Price | Maximum Price | Price Ratio | Price Variation (%) |
|------|------------------------------------|--------------------------------|---------------|---------------|-------------|---------------------|
| 1    | Streptokinase 1500000 IU Inj (1ml) | 3                              | 1818.24       | 3450          | 1.89        | 89.74               |
| 2    | Urokinase 500000 Inj (1)           | 2                              | 3350          | 3640          | 1.08        | 8.65                |

Wide variation in the prices of several brands of same anticoagulants, fibrinolytics, and antiplatelets was found in Indian pharmaceutical market. Most of the brands we have analyzed were single drug. Only one combination is included in our analysis that is aspirin + clopidogrel as it is widely used. Among all drugs used for thromboembolic disorders, highest percentage price variation was found for Aspirin 150 mg + Clopidogrel 75 mg Tablet (741.03 %) combination. Percentage price variation is >100% for all the different combinations of aspirin + clopidogrel [Table 2]. In single drug, highest percentage price

variation was found for Aspirin 100 mg Tablet (435.13 %) followed by Aspirin 75 mg Tablet (403.78 %), Clopidogrel 75 mg Tablet (275 %), Aspirin 50 mg Tablet (221.96 %), Clopidogrel 150 mg Tablet (203.44 %), Heparin 5000 IU/ ml Injection (197.97 %), Aspirin 150 mg Tablet (185.03 %), Acenocoumarol 2 mg (166.42 %). [Table 1-3] In single drug, lowest percentage price variation was found for Eftifibatide 20 mg/10 ml injection (1.15 %) followed by Tirofiban 5 mg/100 ml injection (2.63 %), Warfarin 5 mg Tablet (3.23 %), Urokinase 500000 IU injection (8.65 %) and Enoxaparin 60 mg

/ 0.6 ml injection (26.54 %). [Table 1-3] On comparison of drug price which are under control of DPCO, it was found that prices of many brand drugs

were higher than those which were recommended ceiling price in NPPA-2018. [Table 4]

**Table 4: comparison of drug price which are under control of DPCO**

| SR No | Drug          | Dose & Formulation (Quantity) | Ceiling price in (Rupees) in NPPA-2018 | Maximum Price in market (Rupees) |
|-------|---------------|-------------------------------|--|----------------------------------|
| 1     | Aspirin       | 75 mg Tablet (10)             | 2.9                                    | 13.3                             |
|       |               | 100 mg Tablet (10)            | 1.6                                    | 9.9                              |
|       |               | 150 mg Tablet (10)            | 3.8                                    | 12                               |
|       |               | 325 mg Tablet (10)            | 5.2                                    | 14.8                             |
| 2     | Clopidogrel   | 75 mg Tablet (10)             | 65.2                                   | 135                              |
| 3     | Enoxaparin    | 40 mg / 0.4 ml Inj (0.4 ml)   | 381.6                                  | 490                              |
|       |               | 60 mg / 0.6 ml Inj (0.6 ml)   | 572.46                                 | 601.08                           |
| 4     | Heparin       | 25000 IU / 5 ml Inj (5 ml)    | 189.95                                 | 205.6                            |
| 5     | Streptokinase | 750000 IU Inj (1 ml)          | 1181.85                                | 1961                             |
|       |               | 1500000 IU Inj (1 ml)         | 1680.08                                | 3450                             |
| 6     | Warfarin      | 5mg Tablet (10)               | 22.2                                   | 24.86                            |

Wide differences were found in prices of brand drugs with the generic drug of the same product. Prices of brand drugs were compared with generic prices given on website

<http://janaushadhi.gov.in/ProductList.aspx>. Prices of brand drug of a same product were much higher than its generic version. [Table 5]

**Table 5: Comparison of prices of brand drugs with generic drugs (Jana Aushadhi)**

| Drug | Dose & Formulation (Quantity) | Minimum Price (Brand)       | Maximum Price (Brand) | Price (Generic) |       |
|------|-------------------------------|-----------------------------|-----------------------|-----------------|-------|
| 1    | Acenocoumarol                 | 2 mg Tablet (10)            | 39                    | 103.9           | 10.83 |
| 2    | Aspirin                       | 75 mg Tablet (10)           | 2.64                  | 13.3            | 1.42  |
|      |                               | 150 mg Tablet (10)          | 4.21                  | 12              | 1.92  |
|      |                               | 325 mg Tablet (10)          | 8.17                  | 14.8            | 3.82  |
| 3    | Cilostazole                   | 50 mg Tablet (10)           | 63                    | 124.5           | 54    |
| 4    | Clopidogrel                   | 75 mg Tablet (10)           | 36                    | 135             | 15    |
| 5    | Enoxaparin                    | 40 mg / 0.4 ml Inj (0.4 ml) | 385                   | 490             | 148   |
|      |                               | 60 mg / 0.6 ml Inj (0.6 ml) | 475                   | 601.08          | 180   |
| 6    | Streptokinase                 | 1500000 IU Inj (1 ml)       | 1818.24               | 3450            | 812   |
| 7    | Aspirin + Clopidogrel         | 75 mg + 75 mg Tablet (10)   | 23.75                 | 75.01           | 18    |

## DISCUSSION AND CONCLUSION

In our study, highest percentage price variation was found for Aspirin 150 mg + Clopidogrel 75 mg Tablet (741.03 %) combination. In single drug, highest percentage price variation was found for Aspirin 100 mg Tablet (435.13 %), Aspirin 75 mg Tablet (403.78 %) and Clopidogrel 75 mg Tablet

(275 %). This type of high variation in prices of various anticoagulants, antiplatelets and fibrinolytics was also found in other study by Deepak KR et al. [7]

Not only in the drugs used thromboembolic disorders but such high price variation was also found in other group of drugs like Antidiabetics,[8] Antihypertensives, [9] Anxiolytics, [10] Hypolipidemics [11] and NSAIDs [12] in Indian

pharmaceutical market. All these studies confirm that in India the system for pricing the drugs should be regularized.

The rising prices of drugs are a considerable hole on the pockets of the entire population, but it affects the socio economically poor the most. It is estimated that each year 20 million Indians fall below the poverty line because of indebtedness due to expenditure on healthcare. The economic constraints related to the ability to afford medicines, constitute a major reason for lack of access to essential medicines. In India both total health expenditure as percentage of gross domestic product (GDP) and public spending as percentage of total health expenditure are low when compared to developed countries. Availability of medicines in public sector is lacking in most developing countries including India, and is consistently lower than in the private sector. When medicines are unavailable in the public sector, patients are forced to buy medicines from the higher-priced private sector, or shun treatment altogether. [13]

Developing countries including India require medications at affordable prices for the benefit of masses. Most of the pharmaceuticals try to compensate the investments within a very short period without considering the financial status of the patients' population.

The drug prices available in Indian Drug Review (IDR) (issued January 2019) are compared as it is a readily available source of drug information and is updated regularly. Anticoagulants, fibrinolytics, and antiplatelet drugs are selected as they affect the morbidity and mortality in patients with cardiovascular diseases and their treatment requires continuous prescription drug use. Anticoagulants, fibrinolytics, and antiplatelet drugs are cornerstone therapy for patients with atherosclerotic vascular disease, including those with CAD, cerebrovascular disease, and peripheral arterial disease.

The price of pharmaceuticals, as a percentage of total health care spending, has been rising worldwide. This has resulted in strained national budgets and a high proportion of people without access to essential medications. Though India has become a global hub of generic drug manufacturing, the expected benefits of cheaper drugs are not translating into savings for ordinary people. This is in part due to the rise of branded generics, which are marketed at a price point close to the innovator brands. Unbranded generic

medicines are not finding their way into prescriptions due to issues of confidence and perception, though they are proven to be much cheaper and comparable in efficacy to branded medicines. Also, unbranded generic medicines are much cheaper when compared to the most selling brands and they can bring down the treatment prices in primary care and family practice. [14]

The researches in various countries have shown that generic drugs are as good as the branded original in the bio-equivalence and efficacy. However the acceptance on the use and prescription of generic drugs is low because of less confidence by the regulatory authorities and physicians in ensuring the quality, safety and efficacy of generic drugs. Also there are heavy and successful promotional activities for brand drugs by companies which lead to less prescription of generic medicines. Pharmacists are also less interested in dispensing generic medicines due to low profit margins. [15]

The drug prices in India are controlled using what is called the Drugs Prices Control Order (DPCO). The DPCO is an order issued by the government under Section 3 of the Essential Commodities Act, 1955 empowering it to fix and regulate the prices of essential bulk drugs and their formulations. NPPA (National Pharmaceutical Pricing Authority), Controls and regulates the prices of Pharmaceutical drugs in India, it has limited authority to fix, review and justify pharmaceutical prices under the Drug Prices Control Order (DPCO), 1995. In order to fix and revise the prices of controlled drugs, the NPPA monitors the prices of decontrolled drugs in order to keep them at a reasonable level. NPPA to regulate prices of India's NLEM, and authorizing the NPPA to regulate price increases of non-essential medicines. The DPCO uses market-based mechanisms to set price ceiling. [16]

The price of drugs is revised every year according to wholesale price index. The manufacturers may increase the maximum retail price of scheduled formulations once in a year, in the month of April on the basis of the wholesale price index with reference to the previous calendar year, and no prior approval from the government is required. [7]

There is a need for concerted action from regulatory authorities, doctors, pharmacists and general public at large to address this issue of price variation of drugs used for thromboembolic disorders. At the hospital

level authorities and concerned committees have to frame policies on these aspects.

The price of drugs is revised every year according to the wholesale price index. The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required.

Currently, very few medicines are under drug prices control order. Hence, it is desired that the Government should bring all lifesaving and essential medicines under price control. Many of the above groups of drugs are not included in essential drug list (EDL) which should be taken into consideration while revising the list. Due consideration must be placed on the pricing of drugs in the EDL to increase their accessibility to common people. DPCO appears to be an effective tool to keep in rein the drug prices which should be implemented for all drugs included in EDL. Government should also promote the use of generic medicines and also make it assessable by all in enough quantity. [17]

Many doctors are not very conscious about price variation. So the treating physician must keep this factor in mind while prescribing appropriate brand drugs considering the financial background of the patient. Treating physicians should also prescribe more generic medicines which are same in efficacy as brand drug and available in low prices. It is felt that physicians could provide better services and reduce prices of drugs if information about drug prices was readily available. Studies have shown that providing a manual of comparative drug prices annotated with prescribing advice to physicians reduced their patients' drug expense. [18]

Doctors also should make there P drug list which include high efficacy drugs at low price. Pharmacists should also avoid dispensing brand drugs and instead

dispense generic drugs so that will reduce price of treatment.

Pharmacoeconomics - The branch of pharmacology related with description and analysis of the prices of drug therapy to health care systems and society. Pharmacoeconomics and 'P' drug concept should be included in undergraduate curriculum as practical lesson. Students could be taught to use CIMS or MIMS for selecting the cheapest available formulation of a particular drug. [19]

Increase in awareness in general population about generic medicines and also enhance its availability will reduce price of health care.

Our study has some limitation as limited numbers of brand drugs were given in CIMS & IDR. There were many other brand drugs available on online websites and in the market. Also many generics were available in the market with different prices made by different companies, but for just an overview we have considered the prices given on official government websites. So similar study can be done which also take other brand drugs and generic drugs available on websites so we will get better idea of price variation. So from this study, we come to conclusion to that there is wide variation in prices of various drug used for thromboembolic disorder. Reduction in price variation and making drugs affordable to community will improve the health status of community and reduce economic burden on government. The purpose of "Health for all" can only be achieved by efforts from regulatory authority, doctors, pharmacists, drug manufacturers and general population.

#### Source of funding

None

#### Conflict of interest

None

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