COST ANALYSIS STUDY OF ORAL ANTIPLATELET DRUGS AVAILABLE IN INDIAN MARKET

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ABSTRACT
Background: Cardiovascular disease is both highly prevalent and exceedingly costly to treat. Several novel antiplatelet agents have been found to be effective in reducing the morbidity and mortality associated with cardiovascular disease. There is a wide variation in the prices of oral antiplatelet drugs marketed in India. Thus, a study was planned to find out the variation in cost in the oral antiplatelet drugs available in India either as a single drug or in combination to evaluate the difference in cost of various brands of the same antiplatelet drugs by calculating percentage variation in cost. Methods: The cost of different brands of commonly used oral antiplatelet drugs was sorted out by referring latest “Current Index of Medical Specialties” October – December 2016, “Indian Drug Review” (IDR) 2016, Monthly Index of Medical Specialities December 2016. The cost of 10 dosage forms (Tablets / capsules) in INR of each brand, Cost Ratio and Percentage Cost Variation were calculated. Results: The percentage variation in cost for oral antiplatelet drugs marketed in India was found to be - Clopidogrel 75mg (692.75%), Dipyridamole 100mg (299.59%), Dipyridamole 25 mg (292.01%), Clopidogrel 150mg (263.26%), Aspirin 50mg (137.56%), Aspirin 150mg (125.71%), Aspirin 75mg (71.05%), Prasugrel 10mg (61.29%), Clopidogrel 300mg (57.89%), Ticlopidine 250mg (56%), Prasugrel 5mg (28.57%). The lowest percent cost variation found is ticagrelor 90mg (0%). In combination therapy the highest price variation (508.32%) was found for Aspirin (150mg) + Clopidogrel (75mg) followed by Aspirin (75mg) + Clopidogrel (75mg) (205.88%). Conclusion: Despite the implementation of price control, brand price variations still exist widely for commonly used drugs. Reassessment of pricing policy and implementation of quality norms is needed.

KEYWORDS: Antiplatelet drugs, Cost ratio, Price variation.

INTRODUCTION
Platelets have important and critical role in the coagulation and thromboembolic phenomenon. Platelets do not stick to healthy endothelium due to presence of prostacyclin (PGL2) but when there is damage to endothelium platelet aggregation occur to form the haemostatic plug. Inappropriate haemostasis accelerates atherosclerosis leading to pathological thrombosis. Pathological thrombosis leads to myocardial infarction, stroke and peripheral vascular thrombosis. The function of platelet is regulated by various endogenous substances which are either released within the platelets or from outside the platelet such as from the blood vessel wall. Currently available antiplatelet drugs interfere with one or more steps in the process of platelet activation process and produce a measurable reduction in the risk of thrombosis.

There are 2 situations in which antiplatelet therapy should be considered

- Secondary prophylaxis, in a patient that has had a thromboembolic event; and
- Primary prophylaxis, in the patient considered at risk.

In conditions associated with arterial thrombosis (atherosclerosis, cardiac disease), antiplatelet agents are the first line of drugs. In all others, antiplatelet drugs should be considered as adjunctive agents with anticoagulants.[1]

Cardiovascular diseases are major causes of mortality, accounting for around 50% of deaths. It has been predicted that these diseases will increase rapidly in India and this country will be host to more than half the cases of heart disease in the world within the next 15 years.[2] They were expected to be the fastest growing long-term disease expanding at 9.2% every year since 2000.[3] Antiplatelet drugs reduce the incidence of cardiovascular events by 20-25% in people with established CAD or at high risk of CAD. 2 Coronary heart
disease and stroke have increased in both urban and rural areas.

Pharmaco-economics plays an important role in practice of medicine in developing countries. Cost of drugs is an important factor influencing compliance with treatment of disease and also constitutes an essential part of rational drug prescription. Pharmaceutical Industry has 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 in brand name. This may affect the patient’s finance adversely if costly brand is prescribed specially in Cardiovascular diseases which need treatment for longer duration.8

Very few studies are available in Indian scenario, which compare the cost of drugs of different brands. Therefore, we decided to carry out the study which compares the cost of different brands of drugs used for the treatment of Cardiovascular diseases. The study here focuses on cost effectiveness analysis on different available brands of antiplatelet drugs in India.

METHODS

1. Cost of a particular antiplatelet drug (Cost per 10 tablets/ capsules) in the same strength and dosage forms being manufactured by different companies was obtained from latest “Current Index of Medical Specialties” October – December 2016, “Indian Drug Review” (IDR) 2016, Monthly Index of Medical Specialties December 2016. As they are readily available source of drug information and are updated regularly.

2. A number of brands available for a drug formulation.

3. Difference between the maximum and minimum cost of the same drug manufactured by different pharmaceutical companies was calculated.

4. Cost ratio between the maximum and minimum cost of the same drug manufactured by different pharmaceutical companies was calculated as follows:

5. Cost ratio = Maximum cost / Minimum cost

6. Percentage cost variation was calculated as follows:

7. % cost variation = \( \frac{\text{Max cost} - \text{Min cost} \times 100}{\text{Min cost}} \)

RESULTS

The prices of a total of 08 drugs (06 single and 02 combination preparations), available in 20 different formulations were analyzed. These 20 formulations are manufactured by different pharmaceutical companies.

Table 1: shows the price variation of a few commonly used antiplatelets used as a single drug therapy. Overall clopidogrel (75 mg) shows maximum price variation of 692.75%. Dipyridamole 100mg (299.59%), Dipyridamole 25 mg (292.01%), Clopidogrel 150mg (263.26%), Aspirin 50mg (137.56%), Aspirin 150mg (125.71%), Aspirin 75mg (71.05%).

Prasugrel10mg (61.29%), Clopidogrel 300mg (57.89%), Ticlopidine 250mg (56%), Prasugrel 5mg (28.57%). The lowest percent cost variation found is ticagrelor 90mg (0%). In combination therapy the highest price variation (508.32%) was found for Aspirin (150mg) + Clopidogrel (75mg) followed by Aspirin (75mg) + Clopidogrel (75mg) (205.88%).

Table 2: shows price variation in cost of combination therapies. In combination therapy the highest price variation (508.32%) was found for Aspirin (150mg) + Clopidogrel (75mg) followed by Aspirin (75mg) + Ticlopidine (75mg) (205.88%).

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulations</th>
<th>Doses</th>
<th>Manufacturing companies</th>
<th>Minimum cost (Rs)</th>
<th>Maximum cost(Rs)</th>
<th>Cost ratio</th>
<th>% cost variation</th>
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</thead>
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<td>4.3</td>
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<td></td>
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<td></td>
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<td>7</td>
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<td>0</td>
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<tr>
<td></td>
<td></td>
<td>150mg</td>
<td>6</td>
<td>3.5</td>
<td>7.9</td>
<td>2.25</td>
<td>125.71</td>
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<td>3.63</td>
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<td>500</td>
<td>1</td>
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Table 2: shows price variation in cost of combination therapy.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulations</th>
<th>Doses</th>
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<th>Maximum cost (Rs)</th>
<th>Cost ratio</th>
<th>% cost variation</th>
</tr>
</thead>
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<td>50mg + 75mg</td>
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<td>42.00</td>
<td>1</td>
<td>0</td>
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<tr>
<td></td>
<td></td>
<td>75mg + 75mg</td>
<td>24</td>
<td>25.50</td>
<td>78.00</td>
<td>3.05</td>
<td>205.88</td>
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<tr>
<td></td>
<td></td>
<td>150mg + 75mg</td>
<td>25</td>
<td>25.94</td>
<td>157.80</td>
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<td></td>
<td></td>
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<td>1</td>
<td>26.19</td>
<td>26.19</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
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<td>75mg + 10mg</td>
<td>1</td>
<td>180.00</td>
<td>180.00</td>
<td>1</td>
<td>0</td>
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</tbody>
</table>

DISCUSSION

Indian market is predominantly a branded generic market i.e., more than one company sells a particular drug under different brand names apart from the innovator company. Hence, the number of pharmaceutical products available in the market also is very high. This situation has led to greater price variation among drugs marketed.\[7\] Subsequently it can lead to poor patient compliance, especially in case of drugs like antiplatelets which need lifelong therapy. Poor patient compliance is a worldwide problem and can result in patients receiving inappropriate doses of medication.\[8\]

The drug prices available in CIIMS and IDR were compared as they are readily available source of drug information and are updated regularly. Antiplatelet drugs are selected as they affect the morbidity and mortality in patients with cardiovascular diseases and the treatment requires continuous prescription drug use. Antiplatelet agents are a cornerstone therapy for patients with atherosclerotic vascular disease, including those with coronary artery disease (CAD), cerebrovascular disease, and peripheral arterial disease (PAD).

Our study findings showed a very high fluctuation in the minimum and maximum price of antiplatelet agents which is being manufactured by several companies across the different brands. The cost ratio was also observed to be very high. The prices of most of the antiplatelet brands have percentage price variation above 100%, which is not acceptable situation for patients. Of 08 drugs studied, most of which are commonly prescribed, percentage price variation is very wide leading to unfair burden on the consumer.

As far as antiplatelet drugs are concerned, our study results are supporting the study done by Rashmi et al.\[9\] and Jean- Michel Gaspoz et al. Aspirin for secondary prevention of coronary disease is actually attractive from the costeffectiveness perspective. Clopidogrel, as currently priced, does not have an attractive cost-effectiveness perspective for patients who can tolerate aspirin, whether used alone or in combination with aspirin. This gap could be eliminated by reduction in the price of clopidogrel.\[10\]

Patients are paying out of their pockets for their medical bills and are not covered by insurance schemes unlike developed countries.\[11\] It is felt that physicians could provide better services and reduce costs of drugs if the 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.\[12\]

Drug price control order (DPCO) is an order issued by the government to fix prices of drug. Once medicine is brought under DPCO, it cannot be sold at a price higher than that fixed by the government. In India, in 1979, 80-85% of the drugs in the market were under price control. The number has slowly decreased and by 2002 only 15-20% drugs were under price control.\[13\] We found in our study, price variation with antiplatelet drugs even though the price is high than the ceiling price quoted by DPCO is low. Hence, it is desired that the Government should bring all lifesaving drugs and combinations under price control.

The limitations of this study was only oral preparations are taken into account for our study. Antiplatelet combinations with Statins are also available in Indian market, but they have not been considered in our study.

CONCLUSION

The average percentage price variation of different brands of the same oral Antiplatelet drug manufactured in India is very wide. The appraisal and management of marketing drugs should be directed toward maximizing the benefits of therapy and minimizing negative personal and economic consequences.

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REFERENCES

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