RESEARCH ARTICLE

In vitro quantitative and qualitative analysis of anti-hypertensive tablets and comparison between their generic versus branded formulations

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ABSTRACT

Background: While generic drugs and branded drugs are supposed to be bioequivalent, generic drugs have the additional benefit of being available at a lower cost which can be important in patients with chronic diseases such as hypertension. However, there are some concerns among clinicians that generic drugs may not be as effective as the branded counterparts. Hence, there is a need to generate comparative data between the branded and the generic drugs.

Aims and Objectives: The objective of the study was to compare the pharmaceutical parameters and costs of four generic antihypertensive drugs with their branded counterparts.

Materials and Methods: Four antihypertensive drugs, namely, ramipril, atenolol, enalapril, and amlodipine were considered for evaluation for which their generic and branded samples were taken. All the drugs were in tablet form. The costs of these drugs were recorded, and various in vitro tests were conducted to assess and compare their characteristics, including disintegration, dissolution, hardness, weight variation, friability, thickness, diameter, and quantitative analysis using high-performance liquid chromatography and ultraviolet spectrophotometry. These tests were done in accordance with the specifications outlined in the Indian Pharmacopoeia 2018.

Results: All the branded drugs were more expensive than the generic counterparts. Quantitative assay of the generic sample of ramipril tablets showed a lower amount of the active ingredient than the stated value. Apart from the hardness values of the tablets, all the generic and branded samples fell within the specified normal range for most of the other important parameters.

Conclusion: Generic antihypertensive tablets, were less costly than their branded counterparts and generally met the specified standards in in vitro testing. However, there were instances of subpar hardness results and a deficiency in the stated drug amount in the generic (less ramipril content in sample). These findings suggest the importance of rigorous quality control measures for generic medications particularly for those formulations liable for degradation.

KEY WORDS: Quantitative Assay; Disintegration Test; Dissolution Test; Generic Drugs; Branded Drugs

INTRODUCTION

In the clinical management of patients, medicines can be prescribed by their brand names or by their generic names. A branded drug is one where the discovery and development of a drug is carried out by a pharmaceutical company, while generic drugs are launched after the expiry of the
patent period of the concerned drug.\[1\] It is expected that the pharmacological properties of the generic drugs such as dosage, route of administration, effects, side effects would be the same as the branded drug. While the color, shape, taste, inactive ingredients, packaging, etc., may differ, the Food and Drugs Administration requires them to be equivalent in safety and efficacy.\[2,3\]

However, since generic drugs are in many cases substantially cheaper than their branded counterparts, it has often raised a concern amongst people whether the decrease in the costs is a result of compromised quality.\[4\] The low cost is a major reason why health authorities support the substitution of branded drugs with generic ones which can be beneficial to patients, especially for chronic conditions like hypertension. However, this can prove to be problematic if the bioequivalence is not optimal, especially pertaining to drugs with narrow therapeutic index.\[5\]

Hypertension is a major risk factor that adds to the disease burden in India, accounting for 57% of stroke deaths and 24% of coronary heart disease.\[6,7\] One in four adults suffer from hypertension; however, only 12% have their blood pressure under control.\[7\] One of the major reasons behind this is non-compliance for the use of antihypertensives. The cost of long-term treatment is one of the important causes of this non-compliance especially relevant for developing countries. Promoting the usage of generic drugs may be useful to reduce the economic burden in such a scenario. For this reason, it is important that the generic drugs are equivalent with the branded drugs\[8\] so that clinicians can prescribe these drugs extensively.

Various \textit{in vitro} and \textit{in vivo} tests are available to test the bioequivalence of pharmaceutical agents. Two pharmaceutical products are said to be bioequivalent if they are pharmaceutically equivalent and their bioavailabilities after administering the same molar dose are similar to such a degree that their effects with respect to safety and efficacy can be expected to be the same.\[9\] Tablets and other such solid dosage forms are the most widely used mode for delivering an active pharmaceutical ingredient to a patient.\[10\] Various tests such as disintegration and dissolution tests, hardness, friability have been defined in Pharmacopeia for tablets.\[11\]

Dissolution and disintegration time of a drug are important factors that indicate the bioavailability of the drug and standardised testing procedures are available to measure the extent and rate of these parameters for a particular dosage.\[10,12\] The importance of dissolution time testing has increased over the period of time. In fact many articles have promoted the dissolution time testing as a replacement of high cost and time-consuming bioequivalence clinical studies for many of the drugs.\[3\]

Qualitative and quantitative analysis of a drug is done by high-performance liquid chromatography (HPLC) which has now replaced numerous other spectroscopic methods.\[13\] Guidelines for product development and the specifications for quality control for an oral dosage form should be followed to ensure that the tablets are made with proper features of hardness, friability, weight, thickness, etc.\[14\]

Low cost of any drugs should not be compromise to the quality of medicines given for the patients. Hence, it is important to evaluate the differences between generic and branded medications. However, very few similar studies have been conducted in India and there is a growing need to perform them to improve access to cheaper medicines.

Thus, the objective of this study was to evaluate the differences in quality of generic drugs with their branded counterparts available, using various \textit{in vitro} tests on four anti-hypertensive drugs, namely, ramipril, atenolol, enalapril, and amlodipine.

**MATERIALS AND METHODS**

The study was initiated by the department of Pharmacology of our institute, and the tests were done in a reputed pharmacy college in Mumbai. The study was initiated after getting approval from the Institutional Ethics Committee of the tertiary care center.

In this study, four different antihypertensive drugs were chosen, namely, ramipril, atenolol, enalapril, and amlodipine. The strips of the required drugs were procured from the private medical stores to represent the generic and branded drugs. The prices of the samples and other details were recorded. To ensure blinding, the strips were covered with opaque paper before being handed over for evaluation. The drugs were then subjected to the following tests as per Indian Pharmacopoeia (IP) 2018.

**Disintegration Test**

Disintegration time was recorded in minutes and seconds. Electrolab/ED 2L apparatus was used to measure the disintegration time. Six tablets of each sample were randomly selected. One tablet was introduced in each tube and a disc was added. The assembly was suspended in 37±2°C distilled water in the disintegration apparatus, and the machine was set to 30 rpm.

**Dissolution Test**

It was performed as per IP 2018.

**Quantitative Assay**

An assay test was done for each of the drugs on HPLC as per IP 2018.
Hardness
The Monsanto hardness tester was used to determine the crushing strength of the tablets. Ten sample tablets of each type were taken. Each tablet was placed between the moving jaw and the fixed jaw. With the help of the moving jaw, pressure was applied on the tablet by means of a screw. The point where the tablet got broken down was recorded by means of a scale and recorded in kg/m².

Weight Variation
Twenty tablets of each sample were selected and weighed individually. After calculating the average weight, individual weights were compared to the average and the percentage deviation was calculated as follows:

\[
\text{Percentage variation} = \frac{\text{Individual weight} - \text{Average weight} \times 100}{\text{Average weight}}
\]

Friability
Twenty tablets from each sample were dedusted, weighed, and placed in the drum of the friabilator and subjected to 100 revolutions (25 rpm × 4 min). The tablets were then again dedusted and weighed and percentage (%) loss was determined using the formula given below.

\[
\text{Percentage friability} = \frac{W_0 - W_1 \times 100}{W_0}
\]

where \(W_0\) and \(W_1\) are the initial and final weights, respectively.

Thickness and Diameter
A digital vernier caliper was used to measure the thickness and diameter of five tablets from each sample and the average was taken, and calculation of standard deviation was done.

RESULTS
Tables 1-4 and Figure 1 depict the observation after all the tests.

The cost of the generic sample of ramipril 5 mg was Rs. 15 for a strip of 10 tablets, while that of the branded drug was Rs. 131.21 for a strip of 15 tablets, which shows that the branded drug was almost 5.8 times more expensive than the generic drug. On performing the in vitro tests, it was found that the disintegration time, percentage of dissolution, and friability were found to be within the permissible range as specified by IP. The generic drug had a higher disintegration time than the branded drug by 1 min 23 s. The dissolution of the generic drug was 71.08–79.80% which was lesser than that of the branded drug ranging from 95.82% to 101.84%. On performing a quantitative assay by HPLC, the generic drug was found to be non-compliant since it had having drug concentration of 3.773 mg/tab (74.66%), which was less than the specified minimum value of 4.500 mg/tab (90% of specified drug concentration). Compared to this, the branded drug contained 4.826 mg/tablet of ramipril, which was within the acceptable range. The friability of both drugs was <1% as per specifications. Both the drugs were found to be non-compliant in terms of hardness test (i.e., <4 kg/m²) as the pressure required for breaking the tablet was 1.04 kg/cm² and 2.0 kg/cm² for the generic and branded drug, respectively. While the mean thickness of the tablets from generic samples was 3.564 mm, that of the branded drug was 2.999 mm, the diameter of the generic drug was almost twice that of the branded drug as that of the generic drug was 8.201 mm and the diameter of branded drug was 4.114 mm [Table 1].

The cost of the generic sample of atenolol 50 mg was Rs. 15 for a strip of 15 tablets, while that of the branded drug was Rs. 27.90 for a strip of 15 tablets, which shows that the cost of the branded drug was 1.87 times that of the generic drug. Both the generic and branded drugs were found to be within the specified range of 46.25–53.75 mg/tab. Here too both the drugs were found to be non-compliant in terms of hardness test (i.e., <4 kg/m²) as the pressure required for breaking both, the generic and branded drug was 3 kg/cm². The rest of the parameters were within the specified range as given in the IP [Table 2].

The cost of the generic sample of enalapril 2.5 mg was Rs. 7 for a strip of 10 tablets while that of the branded drug was Rs. 32.31 for a strip of 15 tablets, which shows that the branded drug was almost 3.07 times more expensive than the generic drug. However, the overall cost can be considered low. While the generic drug had a disintegration time of 2 min 30 s, that of the branded drug was 2.24 s. On performing a quantitative assay by HPLC, both, the generic and branded drugs were within the specified range of 2.250–2.750 mg/tab. Except for hardness, other parameters like disintegration time, quantitative tests, friability, etc. were found to be within the permissible range as specified by IP [Table 3].

The cost of the generic sample of amlodipine 5 mg was Rs. 8 for a strip of 10 tablets while that of the branded drug was Rs. 82.54 for a strip of 30 tablets, which shows that the branded drug was almost 3.4 times more expensive than the generic drug. On performing a quantitative assay by HPLC, both drugs were found to be within the specified range of 4.50–5.50 mg/tab. Other parameters including hardness were within the permissible range as specified by IP [Table 4].

DISCUSSION
This study was conducted to evaluate and compare the pharmaceutical parameters and cost of generic drugs with
Table 1: Comparison of qualitative and quantitative values of generic versus branded ramipril tablet. Standard tests were performed as per the Indian Pharmacopoeia 2018.[15]

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Generic drug</th>
<th>Brand drug</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed price on generic and branded drug strips</td>
<td>Rs. 15 (0.18 $) for 10 tablets</td>
<td>Rs. 131.21 (1.59 $) for 15 tablets</td>
<td>-</td>
</tr>
<tr>
<td>Disintegration test</td>
<td>3 min 48 s</td>
<td>2 min 25 s</td>
<td>NMT 15 min</td>
</tr>
<tr>
<td>Dissolution test</td>
<td>71.08–79.80%</td>
<td>95.82–101.84%</td>
<td>No t&lt;70% of the stated amount of C₂₀H₃₂N₂O₅</td>
</tr>
<tr>
<td>Assay: Tablet strength=5.0 mg (100%)</td>
<td>75.46% 3.773 mg/tab</td>
<td>96.52% 4.826 mg/tab</td>
<td>Ramipril tablets contain not &lt;90.0% and not more than 110% of the stated amount of ramipril, C₂₀H₃₂N₂O₅ (4.50–5.50 mg/tab)</td>
</tr>
<tr>
<td>Friability test</td>
<td>0.56%</td>
<td>0.72%</td>
<td>It must be less than or equal to 1%</td>
</tr>
<tr>
<td>Hardness test</td>
<td>1.04 kg/cm</td>
<td>2.0 kg/cm</td>
<td>4–10 kg/cm</td>
</tr>
<tr>
<td>Weight variation (% deviation)</td>
<td>1.04</td>
<td>0.71</td>
<td>±7.5%</td>
</tr>
<tr>
<td>Thickness</td>
<td>3.564 mm</td>
<td>2.997 mm</td>
<td>±5% variation of standard value</td>
</tr>
<tr>
<td>Diameter of the tablets</td>
<td>8.201 mm</td>
<td>4.114 mm</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Comparison of qualitative and quantitative values of generic versus branded atenolol tablet. Standard tests were performed as per the Indian Pharmacopoeia 2018.[16]

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Generic drug</th>
<th>Brand drug</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed price on generic and branded drug strips</td>
<td>Rs. 15 (0.18 $) for 15 tablets</td>
<td>Rs. 27.90 (0.34 $) for 14 tablets</td>
<td>-</td>
</tr>
<tr>
<td>Disintegration test</td>
<td>12 s</td>
<td>1 min 45 s</td>
<td>NMT 15 min</td>
</tr>
<tr>
<td>Dissolution test (USP 39)</td>
<td>85.56–89.41%</td>
<td>86.21–89.92%</td>
<td>Q. Not&lt;80% of the stated amount of C₁₄H₂₀N₂O₃</td>
</tr>
<tr>
<td>Assay: Tablet strength=50 mg (100%)</td>
<td>100.58% (50.35 mg/tab)</td>
<td>100.70% (50.35 mg/tab)</td>
<td>Atenolol tablets contain not &lt;92.5% and not more than 107.5% of the stated amount of atenolol, C₁₄H₂₀N₂O₃ (46.25 mg/tab to 53.75 mg/tab)</td>
</tr>
<tr>
<td>Friability test</td>
<td>0.63%</td>
<td>% 0.44</td>
<td>It must be less than or equal to 1%</td>
</tr>
<tr>
<td>Hardness test</td>
<td>3 kg/cm</td>
<td>3 kg/cm</td>
<td>4–10 kg/cm</td>
</tr>
<tr>
<td>Weight variation (% deviation)</td>
<td>0.855</td>
<td>0.77</td>
<td>±7.5%</td>
</tr>
<tr>
<td>Thickness</td>
<td>3.80 mm</td>
<td>3.1 mm</td>
<td>±5% variation of standard value</td>
</tr>
<tr>
<td>Diameter of the tablets</td>
<td>8.20 mm</td>
<td>8.23 mm</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Comparison of qualitative and quantitative values of generic versus branded enalapril tablet. Standard tests were performed as per the Indian Pharmacopoeia 2018.[17]

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Generic drug</th>
<th>Brand drug</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed price on generic and branded drug strips</td>
<td>Rs. 7 (0.085 $) for 10 tablets</td>
<td>Rs. 32.31 (0.39 $) for 15 tablets</td>
<td>-</td>
</tr>
<tr>
<td>Disintegration test</td>
<td>2 min 30 s</td>
<td>2.24 s</td>
<td>NMT 15 min</td>
</tr>
<tr>
<td>Dissolution test</td>
<td>92.8%–100.64%</td>
<td>97.28–107.36%</td>
<td>Not &lt;80% of the stated amount of C₉H₁₆N₂O₅ , C₇H₈O₄</td>
</tr>
<tr>
<td>Assay: Tablet strength=2.5 mg (100%)</td>
<td>96.66% 2.417 mg/tab</td>
<td>102.68% 2.567 mg/tab</td>
<td>Enalapril maleate tablets contain not &lt;90.0% and not more than 110% of the stated amount of enalapril maleate, C₉H₁₆N₂O₅ , C₇H₈O₄ (2.250 mg/tab to 2.750 mg/tab)</td>
</tr>
<tr>
<td>Friability test</td>
<td>0.17%</td>
<td>0.40%</td>
<td>It must be less than or equal to 1%</td>
</tr>
<tr>
<td>Hardness test</td>
<td>2.18 kg/cm</td>
<td>1.04 kg/cm</td>
<td>4–10 kg/cm</td>
</tr>
<tr>
<td>Weight variation (% deviation)</td>
<td>1.966</td>
<td>1.073</td>
<td>±7.5%</td>
</tr>
<tr>
<td>Thickness</td>
<td>2.484 mm</td>
<td>2.528 mm</td>
<td>±5% variation of standard value</td>
</tr>
<tr>
<td>Diameter of the tablets</td>
<td>8.167 mm</td>
<td>5.714 mm</td>
<td></td>
</tr>
</tbody>
</table>
Pawar et al. In vitro quantitative and qualitative analysis of anti-hypertensive tablets

The cost of all the brand-name drugs was more than that of the generic drugs. Various in vitro tests performed showed that the disintegration time, percentage of dissolution, friability, weight variation, and thickness were within the permissible range as specified by IP. The dissolution test of atenolol could not be performed as the method was not mentioned in IP. The quantitative assay test by HPLC on the generic and branded samples of atenolol, enalapril, and amlodipine was also within the specified range. However, the generic drug of ramipril was found to be non-compliant, with the drug concentration of 3.773 mg/tab (74.66%), which was less than the specified minimum value of 4.500 mg/tab (90%) as compared to the branded drug which was 4.826 mg/tab (96.52%). Although the exact reason may be unknown, according to a study by Regulska et al. ramipril has been found to be an unstable molecule and known to undergo a high degree of hydrolytic degradation due to the presence of an ester bond, mainly due to thermal degradation which may be accelerated by relative humidity. Immediate packing of the drug has been emphasized as the tableting process is known to reduce the stability of the drug. The above result for ramipril indicates additional measures should be taken to maintain the storage conditions of such drugs. Non-compliance was also seen in terms of hardness as only the generic and brand-name drug of amlodipine was found to be within the range of 4–10 kg/m² with regard to hardness, while the rest of the drugs were found to be below the specified range. The IP has specified that the hardness of the tablet should be between 4 and 10 kg/m². While excessive hardness hampers disintegration, a softer tablet not only undergoes premature disintegration but also tends to undergo damage during packaging and transportation.

Few studies have been published comparing generic and branded drugs. A study conducted by the Department of Pharmacy, university of Peradeniya, Sri Lanka, evaluated generic and branded versions of metformin and paracetamol using various in vitro tests. They examined the organoleptic properties, weight, disintegration, dissolution, assay, hardness, and friability of the above drugs. Their results showed that while the branded drugs were more expensive than the generic ones, all the tested tablets were within the ideal ranges of the in vitro tests conducted as per the Pharmacopoeia. Another study was carried out in India, where generic and brand versions of ranitidine and metformin were evaluated by carrying out similar in vitro tests. It was found that weight variation, hardness, friability, thickness, disintegration and quantitative assay showed better values in brand name drugs than generic, but all showed values within the specified limits. Another study comparing the generic and brand name counterparts of propranolol showed comparable values in various parameters such as weight variation, friability, hardness, percentage purity, and drug release profile, except the cost which was more for the branded drug.

Hypertension, being a chronic disease is known to require lifelong medications which can be a financial burden for many. In India, there is a National Pharmaceutical Pricing Authority which is a government regulatory agency

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**Table 4: Comparison of qualitative and quantitative values of generic versus branded tablet amlodipine. Standard tests were performed as per the Indian Pharmacopoeia 2018.**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Generic drug</th>
<th>Brand drug</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed price on generic and branded drug strips</td>
<td>Rs. 8 (0.097 $) for 10 tablets</td>
<td>Rs. 82.54 (1.0 $) for 30 tablets</td>
<td>——</td>
</tr>
<tr>
<td>Disintegration test</td>
<td>10 s</td>
<td>13 s</td>
<td>NMT 15 min</td>
</tr>
<tr>
<td>Dissolution test</td>
<td>98.23–103.68%</td>
<td>114–117%</td>
<td>Not &lt;75% of the stated amount of C₂₀H₂₅ClN₂O₅</td>
</tr>
<tr>
<td>Assay: Tablet strength=5.0 mg (100%)</td>
<td>99.64%</td>
<td>98.34%</td>
<td>Amlodipine tablets contain not &lt;90.0% and not more than 110% of the stated amount of amlodipine, C₂₀H₂₅ClN₂O₅ (4.500–5.500 mg/tab)</td>
</tr>
<tr>
<td>Friability test</td>
<td>0.6052%</td>
<td>0.672%</td>
<td>It must be less than or equal to 1%</td>
</tr>
<tr>
<td>Hardness test</td>
<td>6 kg/cm</td>
<td>4 kg/cm</td>
<td>4–10 kg/cm</td>
</tr>
<tr>
<td>Weight variation (% deviation)</td>
<td>0.921</td>
<td>0.654</td>
<td>±7.5%</td>
</tr>
<tr>
<td>Thickness</td>
<td>2.44 mm</td>
<td>2.61 mm</td>
<td>±5% variation of standard value</td>
</tr>
<tr>
<td>Diameter of the tablets</td>
<td>6.55 mm</td>
<td>8.57 mm</td>
<td>——</td>
</tr>
</tbody>
</table>

**Figure 1:** Cost comparison of generic versus branded

their branded counterparts in selected antihypertensive drugs. The cost of all the brand-name drugs was more than that of the generic drugs. Various in vitro tests performed showed that the disintegration time, percentage of dissolution, friability, weight variation, and thickness were within the permissible range as specified by IP. The above studies have demonstrated that the use of generic drugs can provide significant cost savings for patients, while maintaining the therapeutic efficacy of the branded drugs. The results of these studies highlight the importance of ensuring the quality and safety of generic drugs to ensure patient compliance and adherence to treatment regimens.
entrenched to implement the drug prices control order to control the selling price of essential medicines sold.[24] Hence, the cost of the essential drugs is fairly controlled. Despite this, a cross-sectional study in a slum in Mumbai noted that 34.2% of the households found the expenditure on the treatment of hypertension to be catastrophic and impoverishing.[25] This impacts the compliance and can lead to inadequate management of patients. Generic drugs are known to be around 10–80% cheaper than the branded versions.[26] This is mainly because research, development, marketing, promotion, etc., has already been done by the company that has the patent while bringing the new drug in the market and the manufacturers of generic drugs do not have to bear expenses of development and marketing of the drug.[27]

A more reliable assessment and comparison of generic and branded medications can be made by carrying out clinical trials and evaluating the differences between the clinical responses of these drugs. However, there seems to be a mixed response on clinical evaluation. A review by Cooper et al. stated that branded and generic anti-hypertensive drugs in the United States showed similar efficacy but did not show significantly improved adherence and outcome, despite the low cost.[28] According to a study by Zhang et al., it was found that there was no significant difference in terms of blood pressure lowering efficacy, blood pressure control rate, and cardiovascular outcomes between generic and brand-name anti-hypertensive. Whereas, in patients of age more than 60 years, brand-name drugs had a higher blood pressure control rate and a greater effect in lowering systolic blood pressure as compared to generic drugs. Furthermore, the blood pressure control rate was higher in male patients using branded drugs compared with those using generic ones.[29] Hence, there is a need for a long-term more comprehensive clinical study. We would like to conduct clinical studies in Indian patients with the Indian version of generic drugs to evaluate cost, acceptability, adherence, and efficacy to the generic medications. We would also like to conduct a similar study with other important drugs such as anti-diabetics and on drugs with narrow therapeutic index such as anti-epileptic agents.

**CONCLUSION**

The analysis suggests that drugs with stable chemical structures may exhibit minimal differences between branded and generic versions. However, special attention should be given to drugs like ramipril, which are susceptible to degradation and for tablet formulations where hardness affects dissolution. It is crucial to emphasize that quality assurance for generic drugs should encompass drug quality measurement, not just dissolution and disintegration tests. For drugs with comparable parameters, considering the cost-effectiveness of generic drugs can significantly support patient compliance and reduce the overall health-care cost burden on patients, families, and governments. Particularly in chronic lifelong conditions hypertension and diabetes, medication costs should not impose a lifelong financial burden. There is ample opportunity for further studies to assess the health and cost benefits of generic drugs in various medical contexts.

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