Study on the effectiveness of branded and generic antacid suspension forms

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ABSTRACT

The efficacy of the antacid suspension formulations and the price of the products are two important factors influencing the selection of an antacid preparation. The present work was aimed at comparing different branded and generic antacid suspensions for their effectiveness. Various tests like acid neutralizing capacity (ANC), viscosity, particle size and specific gravity were conducted for selected commercial antacid suspensions. The reported ANC values for all the suspensions were found to be higher than the recommended values i.e. 5 mEq. C1 and C2 were found to show highest ANC values whereas C2 and C3 were showing lowest effectiveness among the selected commercial suspensions. Low cost C1 and C3 suspensions were found to be equally effective with that of the C1, C3 and C4, costly branded suspensions. Though all the suspensions contain aluminum hydroxide as active ingredient, its strength is not reflecting the ANC of the corresponding suspension. It is not possible for the physician to select antacid suspension of required strength without ANC value. ANC value must be made as mandatory information on the label of the antacid products.

Key words: Antacid suspensions, ANC, physicochemical properties.

INTRODUCTION

Antacids are drug products which on oral administration neutralize excess gastric acid and lower the acidity of gastric contents. Antacids are used widely for the relief of heart burn and dyspepsia, and other non specific gastrointestinal symptoms. For the most part they are safe, but in the patients with compromised renal function indiscriminate use can lead to alkalosis and other complications1. In spite of their limitations antacids are popularly considered as first line of treatment. The potency of an antacid is generally expressed in terms of its Acid neutralizing capacity (ANC). ANC is defined as the number of milli equivalents (mEq) of 1N HCl that is brought to a pH of 3.5 in 15 minutes by a unit dose of an antacid preparation2. Chemical composition, nature of drug particles and rheology of suspension influences the ANC. Adriana Sales et al3 analyzed the ANC and the sodium contents of some commercial antacids. Another study4 also emphasized the need of ANC testing for antacids. The ANC and price of the product are two important attributes for an ideal antacid product in addition to the safety and palatability5.

The present work was aimed at comparing ANC and other physicochemical properties for different branded and generic antacid suspensions selected from the market. All the selected suspensions contained aluminum hydroxide and magnesium hydroxide as main active ingredients.

MATERIALS AND METHODS

Reagents used

Hydrochloric acid (HCl) obtained from Thermo Fisher Scientific India Pvt. Ltd, Mumbai. Sodium hydroxide (NaOH) obtained from Qualigens Fine Chemicals, Mumbai.

Acid Neutralizing Capacity7

The containers of the antacid suspensions were shaken, an accurate quantity of the suspension, equivalent to the minimum labeled dose, was transferred to a 250ml beaker.

To this water was added to make the total volume to 70ml and mixed for 1 minute on a magnetic stirrer. 30ml of 1.0N Hydrochloric acid was pipetted out and poured into the test preparation and continued to stir on the magnetic stirrer for 15 minutes. Then the excess hydrochloric acid was immediately titrated with 0.5N sodium hydroxide solution to attain a stable pH of 3.5 (for 10 to 15 seconds). The temperature was maintained at 37±3°C throughout the test. Then, the number of mEq of acid consumed was calculated by the formula:

$$\text{Total mEq} = (30 \times N_{\text{HCl}}) - (V_{\text{NaOH}} \times N_{\text{NaOH}})$$

Where $N_{\text{HCl}}$ and $N_{\text{NaOH}}$ were the normalities of the hydrochloric acid and the sodium hydroxide respectively; and $V_{\text{NaOH}}$ was the volume of sodium hydroxide used for titration.

ANC values were reported (n=3) as mEq of acid consumed by 5ml of suspension.

Viscosity

100ml of the antacid was taken in a beaker and the viscosity determination in triplicate was carried out by Brookfield viscometer LVDV-1 Prime fitted with spindle 62 and at an angular velocity of 6 rpm at room temperature (28°C). The average results were given in Table 2.

Table 1: Composition of Antacid Suspensions

<table>
<thead>
<tr>
<th>Code of Suspension</th>
<th>Al(OH)3 (mg)</th>
<th>Mg(OH)2 (mg)</th>
<th>Others (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>250</td>
<td>250</td>
<td>Activated Dimethicone 50</td>
</tr>
<tr>
<td>C2</td>
<td>6000</td>
<td>80</td>
<td>Activated Dimethicone 100</td>
</tr>
<tr>
<td>C3</td>
<td>415</td>
<td>92.5</td>
<td>Simethicone 50</td>
</tr>
<tr>
<td>C4</td>
<td>380</td>
<td>98</td>
<td>Omeprazol 10</td>
</tr>
<tr>
<td>C5</td>
<td>125</td>
<td>250</td>
<td>Simethicone 50</td>
</tr>
<tr>
<td>C6</td>
<td>300</td>
<td>100</td>
<td>MgO3H2O, 150, Omeprazol 10</td>
</tr>
<tr>
<td>C7</td>
<td>100</td>
<td>100</td>
<td>C4CO3, 125, NaHCO3, 125</td>
</tr>
</tbody>
</table>

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ANC values were found to be 19.00 and 16.00 respectively. Two preparations namely C5 and C2 priced at Rs 28.00 and 34.00 were showing ANC values 17.15 and 20.55 respectively. Neelam et al also reported the quality of generic drugs was at par with the branded products for cetirizine HCl tablets. They also revealed that the price tag did not have any bearing on the quality of the product. Thus, the myth of an inferior quality with respect to low cost generic drugs did not sound true in case of antacid suspensions. In addition to the ANC values, the results of other physiochemical properties like viscosity, particle size and specific gravity were shown in Table 2. There was a large variation in the consistency values among the suspensions selected. High viscosity might have also contributed to the high ANC of C2 preparation. Although the viscosity is higher and particle size was less for C7, it showed very low ANC comparatively. The specific gravity values were almost equal for all the suspensions.

CONCLUSION
The common perception i.e. higher cost implies better quality and lower cost implies inferior quality was found to be a wrong notion in the quality testing of antacid suspensions. No positive correlation was found between cost and effectiveness of antacid suspensions. Generic antacids of lower cost were found to be equally effective compared with the costly branded preparations. The strengths of aluminum hydroxide and magnesium hydroxide did not reflect the effectiveness (ANC) of the suspensions making it difficult for the physician to select preparation of suitable strength. Hence drug regulatory authorities should take appropriate measures to display information about ANC values on the label of the antacid preparations. It is concluded that, generic antacid suspensions are a good alternate to branded antacid suspension medications.

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REFERENCES

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