INTRODUCTION

Gastro-oesophageal reflux disease (GERD) is a common problem in the urban population of Pakistan.1 Number of liquid antacids are available for the treatment of GERD, peptic ulcer disease and other ill defined causes of dyspepsia.2 Several studies have revealed the efficacy of antacids for the management of heartburn and GERD. Although prescription medications are available to treat such disorders, liquid antacids continue to be in high demand due to ease of self-treatment.3 Additionally patients may be more likely to choose an antacid effective in low volume of doses, palatable, and being cost effective. Therefore, comparative analytical data is needed prior to recommending a
particular product. Few studies have been carried out to determine the compliance of patients when given a small volume of antacid vs. a larger, equally effective volume.

Previous work showed that palatability (taste, texture, smell and aftertaste) affects the choice of medication and compliance in patients. Patients taking antacids which are least palatable were compliant with the recommended dosing regimen only 50% of the time; moreover the cost of antacid may also affect the patient choice. Newer brands of antacids frequently arrive in the market and comparative data of new and previously available antacids is not available in Pakistan. The present study was designed to compare the palatability, efficacy and cost effectiveness of 07 frequently used brand name antacids available in the local market of Karachi, Pakistan.

METHODOLOGY

The study was conducted at Mid City Hospital, Karachi from June to November, 2008. In this double-blind, randomized study, 07 over the counter available antacids were assigned with single letter codes from A-G. The compositions of the antacids was as under:

- A, C & D: Aluminum Hydroxide and Magnesium Hydroxide;
- B: Sodium Bicarbonate and Sodium Alginate;
- E & G: Aluminum Hydroxide, Magnesium Hydroxide and Simethicone.

Each brand of antacids was evaluated for palatability using a method similar to wine tasting accredited previously. A total of 50 healthy subjects (20-59 years) were enrolled after signing the informed consent form. Volunteers were excluded if they were receiving any medication known to interact with the antacids or interfere with taste perception. Additionally, subjects with a history of upper respiratory illness within a week prior to and during the study period, pregnancy or individuals with chronic illnesses were excluded from the study. The individuals greater than 60 years of age were also not included due to the past reports of changes in taste perception in the elderly.

The study volunteers were asked to refrain from eating or drinking for one hour prior to the test. Before starting the rating of antacids, subjects received instructions regarding the definition of taste, texture, smell, and aftertaste. The antacids were dispensed at room temperature into 5ml medicine cups in a double blinded fashion. Subjects were asked to sip, smell and savor each brand of antacid and provided with water for gargling after evaluation of each antacid to remove any remaining residues and after taste effects. The subjects were asked to evaluate each antacid for smell, taste, texture, and aftertaste. Each palatability characteristic was based on a 9-point scale (ranging from 1. extremely poor, 2. Poor, 3. somewhat satisfactory, 4. Satisfactory, 5. Very satisfactory, 6. Somewhat good, 7. Good, 8. Very good to 9. excellent) similar to earlier work by Temple and Nahata, 2000.

Analysis of variance (ANOVA) and least significant difference tests were used to evaluate palatability scores. Physical parameters of antacids such as specific gravity, pH and chemical assays of Aluminum Hydroxide, Magnesium Hydroxide, Simethicone, Aluminum Phosphate, Sodium Bicarbonate, Sodium Alginate and Acid consuming Capacity were determined according to British Pharmacopeia (BP), 2007.

RESULTS

Seven antacid preparations were studied in this double-blind trial to assess the criteria which determine patient’s acceptance of liquid antacid therapy (Fig.1). There was a substantial range of finding
among palatability scores (Table-I) and comparative ranking on the basis of the scores secured by each antacid (Fig.2). Descriptive statistical analysis of the rank scores was performed using statistical software “MiniTab®” and presented in Table-I.

Moreover Siam suspension showed the minimum standard deviation of 3.6 in palatability scores compared with other brands of antacid. While, the Table II is used to present physical and chemical analysis of the seven antacid brands. Antacid brands A & C can be the antacids of choice offering comparatively less cost per ml of acid neutralized and good palatability scores. Antacid E and F are relatively expensive offering higher costs per ml of acid neutralized, while antacid-B exhibits lowest cost effectiveness and least palatability.

**DISCUSSION**

The clinical efficacy of antacids is well documented and they are popular for the treatment of GERD. Today, proton pump inhibitors are the treatment of choice for acid-associated diseases. Nevertheless, antacids are still very popular as self-medication of heartburn and dyspepsia. Several studies have been undertaken to determine palatability and in-vivo efficacy of the over the counter antacid brands. In this study seven antacid preparations have been studied in a double-blind trial to assess the criteria which determine patient’s acceptance of liquid antacid therapy (Fig.1). The Data revealed that there was a substantial range of finding among palatability scores (Table-I) and comparative ranking on the basis of the scores secured by each antacid (Fig.2). The variations in the palatability scores were also reported by Bahal-O’Mara N. Similarly, the comparative palatability scores (Table-I) of this study also showed variable scores and revealed that the A, D and G suspensions were most palatable having a maximum palatability score of 36 followed by

<table>
<thead>
<tr>
<th>Tests</th>
<th>D</th>
<th>E</th>
<th>C</th>
<th>A</th>
<th>B</th>
<th>F</th>
<th>G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shelf life</td>
<td>2 years 2 years</td>
<td>2 years 2 years</td>
<td>2 years 2 years</td>
<td>2 years 2 years</td>
<td>2 years 2 years</td>
<td>3 years</td>
<td></td>
</tr>
<tr>
<td>Appearance/Flavor</td>
<td>Pink, Viscous</td>
<td>White, Viscous</td>
<td>White, Viscous</td>
<td>White, Viscous</td>
<td>White, Viscous</td>
<td>Pink, Viscous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>suspension with peppermint</td>
<td>suspension with peppermint</td>
<td>suspension with peppermint</td>
<td>suspension with peppermint</td>
<td>suspension with peppermint</td>
<td>suspension with peppermint</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>7.65</td>
<td>7.55</td>
<td>7.96</td>
<td>8.35</td>
<td>7.97</td>
<td>6.45</td>
<td>8.45</td>
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<tr>
<td>Specific gravity</td>
<td>1.063</td>
<td>1.063</td>
<td>1.150</td>
<td>1.238</td>
<td>1.056</td>
<td>1.074</td>
<td>1.078</td>
</tr>
</tbody>
</table>

**Assay of the contents**

<table>
<thead>
<tr>
<th></th>
<th>D</th>
<th>E</th>
<th>C</th>
<th>A</th>
<th>B</th>
<th>F</th>
<th>G</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminium Hydroxide Gel</td>
<td>5.19 gm/ 5ml</td>
<td>215 mg/ 5ml</td>
<td>200 mg/ 5ml</td>
<td>200 mg/ 5ml</td>
<td>200 mg/ 5ml</td>
<td>200 mg/ 5ml</td>
<td>215 mg/ 5ml</td>
</tr>
<tr>
<td>Magnesium Hydroxide</td>
<td>85 mg/ 5ml</td>
<td>80 mg/ 5ml</td>
<td>200 mg/ 5ml</td>
<td>200 mg/ 5ml</td>
<td>200 mg/ 5ml</td>
<td>200 mg/ 5ml</td>
<td>80 mg/ 5ml</td>
</tr>
<tr>
<td>Simethicone</td>
<td>**</td>
<td>25 mg/ 5ml</td>
<td>**</td>
<td>**</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Sodium bicarbonate</td>
<td>**</td>
<td>**</td>
<td>**</td>
<td>**</td>
<td>**</td>
<td>267 mg/ 10ml</td>
<td>**</td>
</tr>
<tr>
<td>Sodium alginate</td>
<td>**</td>
<td>**</td>
<td>**</td>
<td>**</td>
<td>500 mg/ 10ml</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Aluminium</td>
<td>**</td>
<td>**</td>
<td>**</td>
<td>**</td>
<td>4.5%</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Phosphate Gel Acid</td>
<td>153.64 ml</td>
<td>80.57 ml</td>
<td>92.12 ml</td>
<td>98.75 ml</td>
<td>43.22 ml</td>
<td>30.20 ml</td>
<td>100 ml</td>
</tr>
<tr>
<td>Capacity/ 5ml</td>
<td>19.16</td>
<td>29.17</td>
<td>18.30</td>
<td>44.62</td>
<td>26.00</td>
<td>17.08</td>
<td></td>
</tr>
<tr>
<td>Cost (Rs)/ml acid</td>
<td>0.145</td>
<td>0.237</td>
<td>0.316</td>
<td>0.185</td>
<td>1.032</td>
<td>0.860</td>
<td>0.170</td>
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</table>

Antacids: Palatability & cost effectiveness

Table-I: Relative palatability scores ranked by different antacid brands.

<table>
<thead>
<tr>
<th>Antacids</th>
<th>N</th>
<th>Minimum score</th>
<th>Maximum score</th>
<th>Mean</th>
<th>St.Dev</th>
<th>SE Mean</th>
<th>P-Value</th>
<th>95% CI for Mu</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>50</td>
<td>13.5</td>
<td>36</td>
<td>24.5</td>
<td>4.9</td>
<td>0.703</td>
<td>0.039</td>
<td>23.1-25.9</td>
</tr>
<tr>
<td>B</td>
<td>50</td>
<td>0</td>
<td>27.6</td>
<td>15.71</td>
<td>8.2</td>
<td>1.17</td>
<td>0.003</td>
<td>13.3-18.05</td>
</tr>
<tr>
<td>C</td>
<td>50</td>
<td>2.25</td>
<td>33.5</td>
<td>22.5</td>
<td>6.6</td>
<td>0.937</td>
<td>0.01</td>
<td>20.6-24.4</td>
</tr>
<tr>
<td>D</td>
<td>50</td>
<td>0</td>
<td>36</td>
<td>18.4</td>
<td>6.5</td>
<td>0.93</td>
<td>0.08</td>
<td>16.5-20.3</td>
</tr>
<tr>
<td>E</td>
<td>50</td>
<td>1.2</td>
<td>28.1</td>
<td>16.3</td>
<td>6.2</td>
<td>0.883</td>
<td>0.001</td>
<td>14.6-18.1</td>
</tr>
<tr>
<td>F</td>
<td>50</td>
<td>2.3</td>
<td>32</td>
<td>16.4</td>
<td>7.8</td>
<td>1.11</td>
<td>0.001</td>
<td>14.2-18.6</td>
</tr>
<tr>
<td>G</td>
<td>50</td>
<td>22</td>
<td>36</td>
<td>32.7</td>
<td>3.6</td>
<td>0.511</td>
<td>0.001</td>
<td>31.6-33.7</td>
</tr>
</tbody>
</table>
antacids C, E, and F, while the antacid B showed least palatability score of 15.71. Moreover G suspension showed the minimum standard deviation (3.6) in palatability scores compared with other brands of antacid. The physical and chemical analysis of the antacid brands is presented in Table-II. The table shows that the antacid brand-D and Siam Suspension were most cost effective in terms of their acid neutralizing capacity / ml; however antacid-D showed relatively less palatability.

The acid neutralizing capacity of the antacid is related to the efficacy in heartburn due to direct reduction of intraluminal esophageal acid. Therefore, the extra strength antacids required in small dosage which concomitantly maximize the patient compliance.19 Antacid brands A & C can be the antacids of choice offering comparatively less cost per ml of acid neutralized and good palatability scores. Antacid E and F are relatively expensive offering higher costs per ml of acid neutralized, while antacid-B exhibits lowest cost effectiveness and least palatability.

CONCLUSION

The antacid preparations differed considerably in acid-neutralizing capacity, although the cost / 120 ml of the antacids do not differ significantly except for antacid brand-B which reveals lowest cost effectiveness and least palatability. While, based on the findings of this study G suspension can be one of the suitable antacid for the treatment of gastrointestinal disorders since it showed highest palatability scores and cost effectiveness.

REFERENCES