Convenience sampling was done. The study was conducted over a period of 3 years in community pharmacy settings in Tamil Nadu, India. The Consumer Medical Information Leaflets (CMILs) were randomly collected from different community pharmacies. Total of 19 CMILs which are commonly used by the consumers were collected and CMILs were assessed using BALD assessment tool.

Results: According to BALD assessment (46.28%) leaflets were rated as ‘above standard’ and (53.72) leaflets were rated as ‘standard or poor’ in layout and design since their scores were less than 25. This shows that this issue may be important from the patient’s perspective, which may discourage patient from actually reading the CMILs.

Conclusion: In India, generally CMILs are continued to be prepared in English and with higher proportion of consumers with English illiteracy. CMILs, which are prepared without taking consideration of reading level of consumers and proper layout and design, may not achieve the intended purpose. This is an important aspect that any company has to reckon while preparing leaflets and at least in some major local languages in which CMILs have to be prepared.

INTRODUCTION

Baker Able Leaflet Design (BALD) method is used to assess the layout and design of the leaflets. The scores are based on the length of the line, distance between the line, letter font size, graphics used, percent of white space, paper quality. A document scores 25 or more considered as the document with good layout and design. The presentation is of great importance from the point of view of readability and comprehensibility [1]. The text should be of sufficiently large type and easily readable. Different colours and text sizes may be used for distinguishing purposes. Clear listing of adverse effects; for example, improve the ease of understanding of the message [2].

Consumers must be given sufficient information; in a way they can understand, to enable them to exercise the right to make informed decisions about their care [3]. The provision of information requires effective communication primarily by discussion. Verbal information is useful if it is provided in manner intelligible to the hearer and at a pace at which the recipient can digest it. Leaflets allow consumers to digest information at their own speed and are a point of reference. Patient information leaflets could therefore provide a valuable contribution to informed consent [4].

Printed education materials are often used to augment healthcare professional's verbal information to consumers so it serves as an important component of symptom management. They also enhance the teaching process and can be used by consumers as a home reference. Information that is communicated in a readable and understandable manner helps people to become more knowledgeable about their diagnosis and to be more involved in their treatment plans [6]. They are also more likely to initiate self-care strategies for treatment related symptom relief. Yet none of these outcomes can occur unless consumers are able to read and understand the printed materials given to them [7].

OBJECTIVE

This study was aimed to interpret consumers’ perception on Consumer Medical Information Leaflets (CMILs) on obesity and lipid lowering drugs, on design and layout using the standard method such as Baker Able Leaflet Design (BALD).

METHODOLOGY

Sampling

Convenience sampling was done. The study was conducted over a period of 3 years in community pharmacy settings in Tamil Nadu, India. Name and identity card number of study participants were not taken to assure the confidentiality and anonymity of the participants. Study information sheet were shown and verbal consent were obtained from each individual prior to interview who agreed to participate in the study. People who are not interested to give consent for any reason were excluded from this study. Total of 1800 consumers who are using anti-obesity or lipid lowering drugs were interviewed. Among them 1500 consumers agreed to participate in the study while 300 consumers were not interested.

Study Design

The Consumer Medical Information Leaflets (CMILs) were randomly collected from different community pharmacies. Total of 19 CMILs which are commonly used by the consumers were collected and CMILs were assessed using BALD assessment tool [Table/Fig-1]. The leaflets’ total score 25 or more are considered
as ‘above standard’ leaflets while the leaflets total score from 22 to 25 are considered as standard. But leaflets score 21 and below are considered as poor.

**Baker Able Leaflet Design (BALD) Method [8]**

This method is used to assess the layout and design of the leaflets. The scores are based on the length of the line, distance between the line, letter font size, graphics used, percent of white space, paper quality. A document scores 25 or more considered as the document with good layout and design [2]. The presentation is of great importance from the point of view of readability and comprehensibility. The text should be of sufficiently large type and easily readable. Different colours and text sizes may be used for distinguishing purposes. Clear listing of adverse effects; for example, improve the ease of understanding of the message. The following is a list of some general observations associated with readability:

- It is recommended that the headings be emphasized with different colours.
- Numbering of the main headings will help the reader to follow the text of the CMIL; this is particularly important when the CMIL is double-sided or folded several times.
- The main headings should be placed on the left, not centered.
- The text size of the main headings should be minimum of 13 point.
- The less important information (the marketing authorization holder and manufacturer, addresses) may be written by using a smaller font.

Types of text should be indicated rather than the texts themselves [8].

**Assessment of consumers’ perception on design and layout**

The leaflets which were classified by their quality of design and layout according to the BALD [Table/Fig-2] score were Grouped together and given to the consumers. For this, the consumers were allotted into three different Groups with 500 consumers in each. Consumers who can read English were enrolled into the study. Consumers in Group 1 got any one of the CMILs rated as ‘above standard’ according to BALD Score. Consumers in Group 2 got any one of the CMILs rated as ‘standard’ according to BALD score. Consumers in Group 3 got any one of the CMILs rated as ‘poor’ according to BALD score.

Consumers were asked to rate the leaflets according to their perception as ‘very good’ ‘good’ ‘bad’ and ‘very bad’ for design and layout.

**RESULTS**

The following [Table/Fig-2] shows the design and layout of CMIL according to BALD method.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Leaflets</th>
<th>Scores</th>
<th>Design and layout</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lipid management (Unichem)</td>
<td>27</td>
<td>Above standard</td>
</tr>
<tr>
<td>2</td>
<td>Crestor (Astra Zeneca)</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Colestid (Pharmacia)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Ezetrol (MSD)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Lipantil (Solvay)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Lescol (Novartis)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Questran (Bristol)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Benzalk (Roche)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Modalm (Sanofi)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Reductil (Abbott)</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Supralip (Solvay)</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Lopid (Pfizer)</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Lipitor (Pfizer)</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Xenical (Roche)</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Antacids (Pfizer)</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Lipostat (Squibb)</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Zocor (MSD)</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Inegy (MSD)</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Olbetam (Pharmacia)</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

**DISCUSSION**

According to BALD assessment (46.28%) leaflets were rated as ‘above standard’ and (26.31%) leaflets were rated as ‘standard’ whereas (27.41%) leaflets were rated ‘poor’ in layout and design since their scores were less than 21. This shows that this issue may be important from the patient’s perspective, which may discourage patient from actually reading the CMILs [Table/Fig-2].

**Interpretation of consumers’ perception on design and layout**

When ‘poor’ leaflets were given to 500 consumers (Group 1), 93 consumers felt it was ‘very good’, 107 consumers rated as ‘acceptable’, 89 consumers rated as ‘bad’ and 211 consumers rated as ‘very bad’. In this Group 129 consumers were post-graduates, 155 consumers were graduates and 216 consumers completed High school education [Table/Fig-3].

When ‘standard’ leaflets were given to 500 consumers (Group 2), 142 consumers felt it was ‘very good’, 123 consumers rated as ‘good’, 178 consumers rated as ‘bad’ and 57 consumers rated as ‘very bad’. In this Group 164 consumers were post-graduates, 193 consumers were graduates and 143 consumers completed High school education [Table/Fig-4].

When ‘above standard’ leaflets were given to 500 consumers (Group 3), 52 patient felt it was ‘very good’, 204 consumers rated as ‘good’, 48 consumers rated as ‘bad’ and 196 consumers rated as ‘very bad’. In this Group 188 consumers were post-graduates, 212 consumers were graduates and 100 consumers completed High school education [Table/Fig-5].

From the results, it was found that most of the consumers were graduates or having higher qualification. However, most of them could rate the leaflets as ‘very good’ though the leaflet is of ‘poor’ layout and design [Table/Fig-3]. Whereas the leaflets which were rate ‘above standard’ were rated as ‘very bad’ by most of the
consumers [Table/Fig-5]. But again it depends on the qualification of the consumers who have rated it.

Though the consumers who are having post graduate degree were able to rate the leaflets promptly, the consumers who are having graduate degree or higher school education were unable to rate the leaflets correctly which clearly indicates these leaflets are not suitable for this Tamil Nadu state, India. This is because; the populations here are mostly either having high school education or graduate level [9].

In Indian pharmaceutical market, generally CMIILs are continued to be prepared in English and with higher proportion of consumers with English illiteracy. CMIILs, which are prepared without taking consideration of reading level of consumers and proper layout and design, may not achieve the intended purpose. This is an important aspect that any company has to reckon while preparing leaflets and at least in some major local languages in which CMIILs have to be prepared.

It can be observed that consumers with High school education level found it difficult to understand at the level of 7th standard [8]. It is expected that CMIILs need to be written at the level of fifth or sixth standard level to help the consumers with limited reading skill. This observation shows that there is a lack of awareness among the providers regarding the readability issues. This highlights the need for development of scales for which will match Indian education levels.

Future scope of this study
This study was conducted only in the state of Tamil Nadu, India and hence these results do not represent the whole India. In near future, more studies should be carried out throughout India which may produce a prompt information regarding CMIILs.

CONCLUSION
Design and layout scores showed by the BALD method did not match the perception of the consumers studied. This is because the consumers were either highly qualified like graduates or with high school level education who cannot read English properly. Consumers with college level education only can understand the CMIILs provided by pharmaceutical companies.

This study concludes that many of the pharmaceutical companies (leaflets providers) are not taking the reading level of consumer into consideration which may not achieve the intended purpose. There is a need for developing CMIILs having good readability score according to Indian set up. CMIILs can be designed with more pictograms and colorful pictures, which may result in better understanding. The companies should also look for the possible ways to produce leaflets in national language of the country.

REFERENCES